FULL/LONG TITLE OF THE STUDY	Evaluating Mental Health Decision Units in acute care pathways (DECISION): A quasi-experimental and health economic evaluation
SHORT STUDY TITLE / ACRONYM	Evaluating Mental Health Decision Units (DECISION)
PROTOCOL VERSION NUMBER AND DATE	Version 4.0 16.12.2019
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This protocol has regard for the HRA guidance and order of content	

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 publically 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:

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Date:
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Name (please print):

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Position:

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Chief Investigator:

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

Name: (please print):

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Committees	The independent Project Steering Committee will comprise a chair (a clinical academic work in an appropriate field), statistician and two patient and public members. Full contact details of the Project Steering Committee will be made public on the project webpage – www.sgul.ac.uk/decision – as soon as available. A Lived Experience Advisory Panel comprising mental health service users, carers and members of the public with appropriate experience related to Mental Health Decision Units and mental health services more generally will provide advice and oversight of the project from a lived experience perspective (see below).

STUDY SUMMARY	
Study Title	Evaluating Mental Health Decision Units in acute care pathways (DECISION): A quasi-experimental and health economic evaluation
Internal ref. no. (or short title)	DECISION
Study Design	Mixed methods observational (non-interventional) study in six work packages (WPs) comprising: WP 1 – systematic review and mapping; WP 2 – quasi-experimental interrupted time series analysis; WP 3 – synthetic control (ITS) study; WP 4 – cohort study; WP 5 – qualitative study; WP 6 – economic analysis using data from WPs 1-5

Study Participants	WP2/WP3: Four NHS Mental Health Trusts with MHDUs and related NHS Acute Trusts (A&E Departments), strategic managers with oversight of MDHUs and acute care pathway, selected (control) Trust sites without a MHDU; WP4/WP5: Service users referred to a MHDU over a 9-month period; WP5: Staff on the referral and assessment pathway to MHDU, MHDU staff 5)
Planned Size of Sample (if applicable)	20 (Work Package 2); 1151 (Work Package 4); 96 (Work Package 5)
Follow up duration (if applicable)	WP4/WP5; service user participants followed up for 9 months
Planned Study Period	24 months; 01/03/2019 to 28/02/2021
Research Question/Aim(s)	To ascertain the structure and activities of operational MHDUs in England, and to provide an evidence base for their effectiveness, cost benefit and optimal configuration in order to inform potential national scale up

FUNDING AND SUPPORT	
FUNDER(S)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
National Institute for Health Research (NIHR) Health Services and Delivery Research (HS&DR) Programme	The study is financed in full by grant HS&DR 17/49/70 awarded by the National Institute for Health Research Health Services & Delivery Research research funding programme.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Role of the Project Steering Committee: The Committee will be responsible for overseeing the conduct of the study, or more specifically, to monitor and supervise the progress of the study towards its interim and overall objectives and to provide advice, through its Chair, to the Sponsor, the Chief Investigator and Host Institution on all appropriate aspects of the project. It will be independent of the Principal Investigator and Co-applicants. There will be lived experience represented on the study steering committee by two people independent of the research team with expertise in service user involvement and leadership in research. Details of the Project Steering Committee membership and roles will be made public on the study website – www.sgul.ac.uk/decision - as soon as available.

Role of the Project Management Group: The Project Management Group is responsible for all aspects of day to day management of the study and is based at St George's, University of London; organising study meetings and training meetings; provision of study materials; data collection, checking and data entering; study data analysis; co-ordinating the production of trial reports and publications. The group will comprise the CI (SG), statistician (JS), post-doctoral researcher (LG), and research assistant (JT, KA). Other members of the larger project team (e.g., GC, DM, SJ) will be invited to participate when appropriate.

Role of the PPI Group: A Lived Experience Advisory Panel (LEAP) will be convened comprising representatives of our Peer Expertise in Education and Research (PEER) group, people who have had personal experience of the MHDUs and carers of people who have experienced mental health crisis. The

LEAP will six times during the study lifespan. The LEAP will help to ensure that service user and carer perspectives are incorporated into the realization of the protocol, conduct of the study, and analysis of the results. The LEAP and service user researchers will play a key role in developing interview schedules to ensure that these are informed by experiences of attending an MHDU or mental health services more generally.

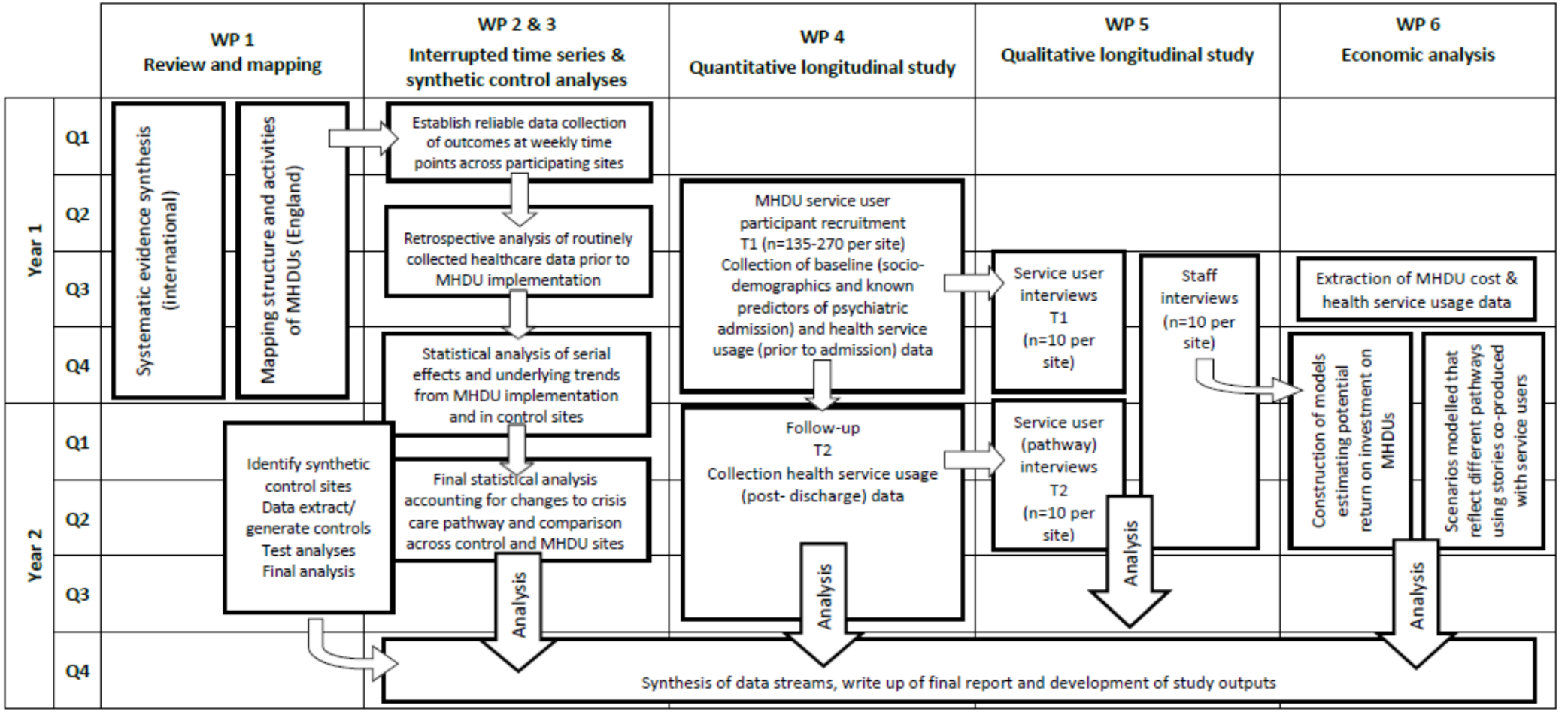
PROTOCOL CONTRIBUTORS

Steve Gillard (SG; St George's, University of London) conceived the study; SG and Jared G Smith (JS) initiated the study design and Sonia Johnson (SJ), Kati Turner (KT) and David McDaid (DMcD) helped with implementation. SG (Chief Investigator), JS, SJ, KT and DMcD are all applicants on the project grant. JS and Geraldine Clarke (GC) provided statistical expertise in study design and JS is conducting primary statistical analysis. All authors contributed to refinement of the study protocol and approved the final version.

Study funders have had/ will have no role in study design, collection, management, analysis and interpretation of data, writing of any report, or decision to submit a report, or any influence over any of these activities. The study Sponsor has the final decision about these aspects of the research.

Proposal development: Public and patient involvement has been integral to the development of the DECISION research project. St George's Peer Expertise in Education & Research (PEER) service user reference group have helped to inform the development of the research proposal, with particular attention paid to how being involved in the study may feel for service users. A panel of service users was convened to discuss the types of questions to ask in qualitative interviews, and again to refine and develop the recruitment and informed consent processes. Experienced service user researchers (including co-applicant Kati Turner (KT)) have also been involved in writing the research proposal, in particular PPI components, ensuring that their lived experiences were applied to issues such as recruitment of participants and support of service user researchers and around developing the process of interpreting qualitative datasets.

STUDY Schematic



ABBREVIATIONS	
AE	Adverse Event
AR	Adverse Reaction
A&E	Accident and Emergency
CI	Chief Investigator
CMHT	Community Mental Health Team
CRF	Case Report Form
CRHT	Crisis Resolution and Home Treatment
CRIS	Clinical Record Interactive Search
CSO	Clinical Studies Officer
EPR	Electronic Patient Record
GCP	Good Clinical Practice
GP	General Practitioner
HRA	Health Research Authority
HS&DR	Health Services and Delivery Research
ICF	Informed Consent Form
ISF	Investigator Site File
IM&T	Information Management & Technology
ITS	Interrupted Time Series
JRES	(St Georges) Joint Research and Enterprise Services
LEAP	Lived Experience Advisory Panel
LoS	Length of Stay
MHDU	Mental Health Decision Unit
NHS	National Health Service
NHS R&D	National Health Service Research & Development
NIHR	National Institute for Health Research
PEER	Peer Expertise in Education and Research
PI	Principal Investigator
PIS	Participant Information Sheet
QA	Quality Assurance

QC	Quality Control
RCT	Randomised Control Trial
REC	Research Ethics Committee
ROI	Return on Investment
SAE	Serious Adverse Event
SDV	Source Document Verification
SGUL	St Georges, University of London
SGHFT	St Georges, University Hospitals NHS Foundation Trust
SOP	Standard Operating Procedure
SSA	Site Specific Assessment
SWLSTG	South West London and St George's Mental Health NHS Trust
WP	Work Package

STUDY PROTOCOL

Evaluating Mental Health Decision Units in acute care pathways (DECISION): A quasi-experimental and health economic evaluation

1 BACKGROUND

With bed occupancy high, staff under pressure and resources constrained, the UK Accident and Emergency (A&E) system has been described as near breaking point.[1] Two-thirds of people attending A&E multiple times for any reason will have had previous contact with specialist mental health services or have previously been admitted to an acute hospital for a mental health condition,[2] with frequent attenders at greater risk of psychiatric inpatient admissions.[3] In 2012/13 alone, over 4,000 people with a mental health condition had attended A&E on multiple occasions (over 60 times) in the five years before the admission.[4] Bed occupancy in inpatient psychiatric facilities is well above recommended levels with 91% of wards operating above the recommended occupancy rate.[5] A recent study found that people presenting with a mental health issue were over 6 times more likely than people presenting with a physical concern to breach the four hour A&E wait time.[2] In response, a number of mental health decision units (MHDUs) have recently been developed across England.[6-8] MHDUs provide dedicated 24-hour facilities for an enhanced mental health assessment and offer short-term support targeting people experiencing acute and complex mental health crises, for whom inpatient admission is being considered (differing in function from the triage wards found in some Mental Health Trusts that admit all people requiring inpatient care for purposes of assessment for ongoing care).[9] The intention of MDHUs is to reduce the reliance on admissions to acute inpatient care, divert mental health service users from A&E and ensure parity of esteem for service users receiving expert and detailed assessments (see detailed specification in *Setting* below).[7, 10] While recent single site studies in the USA and Australia, and preliminary local evaluations in the UK suggest that MHDUs have potential to reduce demand on A&E services and psychiatric inpatient care,[6, 8, 11, 12] a rigorous, comprehensive study is needed to ascertain the structure and activities of operational MHDUs in England and provide an evidence base for their effectiveness and value for money.

2 RATIONALE

Mental disorders are estimated to account for around 5% of A&E attendances in the UK and almost 30% of acute inpatient bed occupancy and acute readmissions.[2, 4, 5] The experience of people attending A&E for a mental health problem remains less than satisfactory, with frequent delays in receiving appropriate care (breaches), a lack of provision of recommended interventions and poor continuity of care.[4, 13, 14] There is consistent evidence that particular black and minority ethnic communities are over-represented in the coercive and custodial aspects of mental health crisis care, particularly those who experience high levels of poverty.[15] Although the emergence of liaison psychiatry services has enabled organisations to provide responsive mental health advice and assessment within emergency care settings, there remain wide variations in service provision[16] and ongoing challenges to sustainability[17] with little ability to undertake in-depth assessments in a more settled environment outside of statutory waiting time standards. The introduction of crisis resolution

and home treatment (CRHT) teams and triage wards has offered little benefit in reducing contact with acute services, inpatient admissions or costs across the wider in-patient system compared with standard models of care,[18-20] with ongoing staff concerns over the negative impact on the accuracy of triage decisions for mental health presentations,[21, 22] while inpatient care remains unpopular, expensive and sometimes detrimental for individuals and their families.[2, 7, 23, 24]

The recent emergence of a number of dedicated MHDUs across Mental Health NHS Trusts, which allow relevant teams (e.g. Liaison Psychiatry, Street Triage, CRHT), following an initial (gatekeeping) assessment, to refer service users who would otherwise have been admitted to an inpatient ward to a safe and supportive environment where an enhanced assessment can take place to better determine ongoing care, is an important development.[6, 7, 25] The proposed work will be the first formal evaluation of MHDU services in England and the only project to date that includes comparison of different MHDUs. It is possible MHDUs introduce further fragmentation to the system, and, if not effective, may waste critical resources. As such, a formal evaluation of these services is urgently required to describe the model of care and generate much needed knowledge about the impacts, quality, and cost benefits of a new assessment-based service for people experiencing mental health crises and accessing emergency services.

There is a dearth of information regarding dedicated decision units for mental health crises in the UK. The last systematic review concerning residential alternatives to standard acute psychiatric wards was completed almost 10 years ago[30] and pre-dates the implementation of MHDUs in England. Recent reviews have focused on critical components of CRHTs[31] and indicators of quality for liaison psychiatry services,[32, 33] while studies of triage wards indicate little benefit in terms of reduce inpatient admission or cost[20] and an historical review of planned short hospital stays has become outdated.[34] Although formal evaluations of recently developed (single site) MHDUs in the US and Australia have suggested these type of units can reduce Length of Stay (LoS) in emergency departments and inpatient psychiatric admissions among patients with mental health presentations accessing emergency care,[11, 12] evidence regarding the characteristics of effective and acceptable MHDUs in England is restricted to informal local evaluations.[6, 25] While these reports suggest the service model has potential to reduce demand on A&E, key data have not been reported (e.g. A&E mental health breaches) and no follow-up of individual service users has been carried out. More generally, the prevalence, organisation, accessibility, effectiveness and economic benefits of this model of care across England remains unclear.

The emergence of wide-ranging reports concerning the need for better mental health crisis care, including the Schizophrenia Commission report in 2012,[26] the Chief Medical Officer's report in 2013[27] and the 2015 interim Crisp report for the Commission on Acute Adult Psychiatric Care,[28] indicate that this work will be highly relevant and important to the needs of the NHS. The Crisis Care Concordat in 2014 has emphasised the need to prioritise assessment of the level of, and reasons behind, frequent A&E attendances, and to consider the provision of alternative options for people identified as being at high-risk of attending frequently.[2, 29] Responsive mental health care at point of an individual experiencing mental health crisis remains an essential component of a broader health service agenda as outlined by The Crisis Care Concordat.[2, 28] This will remain a key objective for the NHS as increasing pressure is placed on urgent and psychiatric inpatient care systems as services respond to public finance constraints.

The proposed work will be the first formal evaluation of MHDU services in England and the only project to date that includes comparison of different MHDUs.

3 THEORETICAL FRAMEWORK

The underlining framework for the study is a multilevel organisational research approach that holds that findings at an individual level cannot be assumed to apply at a higher (e.g. population) level, or vice versa, because the 'nested complexity of organisational life' at multiple levels impacts on the phenomena we are trying to understand or measure.[26] Drawing on Goffman's multilevel frame analysis,[27] it is necessary to 'frame' our enquiry at macro, meso and micro levels in order 'to understand the pace, direction and impact of organizational innovation and change[28] as well as the interconnection between levels. This involves specifying, at each level, the construct we wish to test, how we will measure that construct, what our sample or data source will be, and what analytical approaches we will use. Best available data is used from a range of sources at each level – micro (individual service user and staff member), meso (service and pathway) and macro (policy) - in order to produce utilisable knowledge,[35] informing the further development and implementation of Mental Health Decision Units nationally. At the meso level, for example, MHDUs sit within crisis care pathways which differ between sites, with variation in referral routes that impact on population and therefore potentially outcomes. At the macro level, it is important to consider how policy changes nationally relating to crisis care services, or trends in A&E activity driven by wider population pressures for example, might impact on outcomes we are interested in. This study is designed to identify and determine the impact of those contextual factors on our evaluation of MHDUs. In our study we conceptualise our levels of enquiry as:

- Macro – national
  How do policy, clinical guidance and other trends at a national level (including the introduction of new policy) impact on the effectiveness and cost benefits of MDHUs?

- Meso – organisational
  How does the configuration of crisis care pathways (including the provision of other crisis care services) and the structure of MDHUs at a site, organisational level impact on the effectiveness and cost benefits of MDHUs?

- Mirco – individual
  How do individual service user experiences of crisis care (including the MDHU) and individual clinical staff decision-making processes along the pathway impact on the effectiveness and cost benefits of MDHUs?

The specific way in which we frame research questions and identify data sources and research methods at each level is detailed in the table in Appendix 2.

4 RESEARCH QUESTION/AIM(S)

This is a mixed methods study in six work packages (WPs) addressing the following questions:

Work Package 1: Review and mapping

1) What is the range of hospital-based, short stay interventions internationally designed to reduce standard admissions to acute psychiatric inpatient care and what is their effectiveness?

2) What is the scope and prevalence of MHDUs nationally and how are they configured?

Work Packages 2/3: Quasi-experimental interrupted time series analysis / synthetic control study

3a) How has the introduction of MHDUs impacted on psychiatric inpatient admissions and A&E psychiatric episodes/breaches?

3b) What is the impact of policy changes at national level?

Work Package 4: Quantitative longitudinal study using electronic patient record

4) What are the care pathways before and following an admission to the MHDU?

5) What is the impact of the introduction of MHDUs on inequalities of access to acute mental health services?

Work Package 5: Qualitative longitudinal study

6) How do service users and carers experience MHDUs, as well as crisis care pathways before and after admission to MHDU?

7) How are decisions made about referral and admission to MHDU, and assessment and onward signposting & referral?

Work Package 6: Economic analysis

8) How do the economic costs and impacts of MHDUs compare with areas without MHDUs?

9) How do the costs for individual service users post MHDU implementation compare with their costs prior to the introduction of MHDUs to crisis care pathways, as well as in areas without MHDUs?

10) What are the potential cost impacts of a) alternative configuration of MHDU pathways or access by specific populations, and b) roll out and scale up of MHDUs nationally?

4.1 Objectives

The aim of the study is to ascertain the structure and activities of operational MHDUs in England and to provide an evidence base for their effectiveness, costs and benefits, and optimal configuration.

The study objectives are as follows:

Work Package 1: Review and mapping

- Systematically review the scientific literature describing and evaluating short hospital-based interventions to prevent/reduce admissions to psychiatric inpatient care.
- Describe the model of MHDUs in the UK, including prevalence and scope.

Work Packages 2/3: Quasi-experimental interrupted time series analysis / synthetic control study

- Administer an interrupted time series analysis, including a synthetically controlled analysis, using routinely collected mental health Trust and Emergency Department data to assess whether the introduction of MHDUs in four sites effects psychiatric inpatient admissions and A&E psychiatric episodes.

Work Package 4: Quantitative longitudinal study using electronic patient record

- Examine the referral pathways into MHDUs and the care pathways followed by people before and following an admission to the participating MHDUs, and the extent to which these are influenced by organisational pressures and service users' socio-demographic characteristics and psychiatric history, using electronic patient record (EPR).

Work Package 5: Qualitative longitudinal study

- To examine qualitative interview data to understand experiences before, during, and after referral to MHDU from the perspective of service users, and the decision-making process of A&E, crisis services and MHDU staff along the crisis care pathway. Additionally to also explore the experience of carers of people who have accessed MHDUs using qualitative interviews and focus groups.

Work Package 6: Economic analysis

- Carry out an economic analysis of MHDUs in three sites to assess whether the introduction of mental health assessment units provides value for money compared with current service provision, and to consider the cost impact of roll out of optimally configured MHDUs nationally.

4.2 Outcomes

The study outcomes are as follows:

Work Package 1: Review and mapping

- A detailed summary of the evidence for the effectiveness of short hospital-based interventions intended to prevent/reduce admissions to psychiatric inpatient care.
- Identification of relevant covariates and predictor variables for risk adjustment in MHDU (WP3 synthetic control study) and outcomes for consideration in the quantitative longitudinal study (WP4), respectively.
- A model of MHDUs in operation mapped across the UK.

- Identification of comparison sites without MDHU for the synthetic control study (WP3).
- Recommendations for roll-out of MHDU provision that specifies optimal configuration.

Work Packages 2/3: Quasi-experimental interrupted time series analysis / synthetic control study

- An estimate of the extent to which change in key service parameters (e.g., informal psychiatric admissions and mental health presentations at ED) in the pre- and post-interruption period are explained by the introduction of MHDUs.

Work Package 4: Quantitative longitudinal study using electronic patient record

- A comprehensive profile of those individuals visiting the MHDU which includes descriptions of the care pathways before and following an admission to the MHDU.
- A model of individual-based factors most relevant to change in key MHDU service user outcomes (e.g., decrease in number of A&E presentations from the period pre-MHDU admission to the period post-MHDU discharge).

Work Package 5: Qualitative longitudinal study

- A detailed understanding of MHDU service user experience including pathways before and after MHDU admission.
- A detailed understanding of staff experience of MHDU implementation, particularly that concerning decisions made about MHDU referral/admissions, assessments and onward signposting.
- A detailed understanding of the experiences of carers of service users who have accessed MHDUs including comparisons to other forms of crisis care and experiences of supporting the person they care for when they are in crisis.

Work Package 6: Economic analysis

- An estimate of the cost-effectiveness of MHDU implementation, including consideration of alternative configuration of MHDU pathways or access by specific populations and roll out and scale up of MHDUs nationally.

5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

This study is not a trial and no additional interventions will be performed. This will be a mixed methods study in six work packages comprising: WP1 – systematic review and mapping; WP2 – quasi-experimental interrupted time series analysis; WP3 – synthetic control (interrupted time series) study; WP4 – cohort study; WP5 – qualitative study; WP6 – economic analysis using data from WPs1-5.

<u>WP1: Review and mapping (months 1-12)</u>

Objectives

- Systematically review the scientific literature describing and evaluating short hospital-based interventions to prevent/reduce admissions to psychiatric inpatient care.
- Describe the model of MHDUs in the UK, including prevalence and scope.

Outcomes

- A detailed summary of the evidence for the effectiveness of short hospital-based interventions intended to prevent/reduce admissions to psychiatric inpatient care.
- Identification of relevant covariates and predictor variables for risk adjustment in MHDU (WP3 synthetic control study) and outcomes for consideration in the quantitative longitudinal study (WP4), respectively.
- A model of MHDUs in operation mapped across the UK.
- Identification of comparison sites without MDHU for the synthetic control study (WP3).
- Recommendations for roll-out of MHDU provision that specifies optimal configuration.

Design and Methods

WP1 comprises a systematic review of (international) scientific literature investigating the effectiveness of MHDU-type services and a service mapping of MHDU operations within mental health Trusts across England.

Systematic Review

We, the central research team (St George's, University of London team and protocol contributors), will conduct a systematic review of scientific literature describing short hospital-based assessment interventions for people in mental health crisis intended to prevent (unnecessary) standard acute admissions to psychiatric inpatient care. This review will focus down and build on findings from the review of alternatives to inpatient admission conducted by co-applicant SJ.[29] The objective of the review is to identify and summarise both descriptive and efficacy literature on mental health triage, assessment and decision units and their equivalents internationally in order that we can situate the knowledge gained in this study within that wider evidence base.

The review will also allow the identification and selection of relevant covariates for risk adjustment in MHDU (synthetic control) ITS studies and predictor variables of outcomes for consideration in the quantitative longitudinal study.

Eligibility criteria

The intervention will be any mental health assessment service that meets all of the following criteria a) is hospital based (i.e. assessment in community or other residential settings will not be included),b) includes the option of overnight stay; c) there is a specified maximum length of stay (usually less than one week); and d) where the primary aim of the intervention is assessment with the purposes of reducing

the need for standard acute care admission (i.e. interventions where the primary aim is treatment will not be included).Studies included will be restricted to Randomised Controlled Trials (including cluster randomised trials).

Information sources and search strategy

Medline, PsycINFO, Embase, CINHAL and Cochrane Central Register of Controlled Trials databases will be searched. Reference lists of identified papers will be inspected for further relevant literature and a forward citation search performed using ISI Web of Science. There will be no date restriction to the search.

Search terms (MeSH/ thesaurus terms appropriate to each database and keywords for searching titles and abstracts) will be tested and refined as necessary. The PICO framework will be used to define terms. Population terms will encompass adults and a range of general and condition specific mental health terms (e.g. mental* or psychiatr* or psychotherap* or schizo* or psychosis or psychotic or depression or bipolar). Intervention terms will include sets of terms relating to assessment or triage or decision, and inpatient or hospital joined by AND arguments. Comparison terms for controlled studies will include variations on treatment/ care as usual. Outcomes terms will include variations on acute/ inpatient/ emergency/ psychiatric admission.

Study selection

Citations will be returned to an Endnote library. Detailed citations (title and abstract) will be independently screened by two researchers and marked as certain, uncertain or exclude. Full text of papers will be retrieved where there is disagreement or where both researchers are uncertain. Disagreements will be discussed by researchers using the full text until consensus is reached or a third researcher (the PI) brought in to make a final decision.

Data extraction

Details of research design and method, country, population (number, socio-demographics, diagnoses etc), setting, description of intervention, outcomes, implementation variables (e.g. length of stay [LoS]), mean scores and standard deviations for each time point and, statistical tests of significance will be extracted from all studies by one researcher of the central research team. A second researcher will check for accuracy of extraction and coding for 50% of studies. Where any issues arise discussion will be held with the PI to resolve issues. Study authors will be contacted to request missing data where necessary.

Assessment of quality

At time of data extraction methodological quality will be assessed using the Cochrane Collaboration Risk of Bias Tool[30]. Quality will be assessed by two researchers, with discrepancies resolved through

discussed with the PI. Studies at high risk of bias in one or more domains will be reported as such and findings considered with those qualifications in mind.

Meta-analysis

Where a sufficient number of moderate-high quality studies (according to criteria specified in the Cochrane Collaboration Risk of Bias Tool[30]) are identified for statistical pooling, meta-analyses will be performed. We will consider standard acute admissions to psychiatric inpatient care and, where data allow, other relevant outcomes (e.g. average LoS). For meta-analysis, we will initially compute relative risk (RR) to estimate the effect (i.e., risk reduction in standard psychiatric inpatient admissions) of the hospital-based interventions. We will employ random-effects estimation and 95% CI to calculate the overall effect for interventions.[31] Analyses will adjust for outliers (e.g. patients with multiple admissions),[32] for cluster trials, effect of clustering,[33] and between-study variation in effect sizes[34] and sample size.[35] Where data are available, we will administer sensitivity analyses to explore associations between outcome and intervention characteristics.

Service mapping

We will map the structure and activities of MHDUs in England to describe the prevalence and scope of MHDUs, the provision of care offered and variation in unit configuration. We will do this by direct approach to Acute Care Pathway leads (or equivalents), Medical Directors and Chief Operating Officers in all 54 Mental Health NHS Trusts in England (including other Healthcare Trusts holding responsibility for acute mental health services). We will use Trust websites to generate an initial contact list and verify names and contact details through Trust administrative services. At each Trust, we will address a short set of structured questions, by telephone or email, to one of the above roles, or other role, being the first individual we identify who is in a position to answer our questions. Questions will establish whether the Trust has an MHDU as well as whether the Trust has alternative assessment provision such as a triage ward or non-hospital based assessment service.

We will use Freedom of Information requests to minimize non-responses in the WP1 mapping exercise. We will make common sense assumptions about non-responses that remain providing at least 50% of Mental Health Trusts respond. That is, if we find that a third of responding Trusts have MHDUs we will assume this for Trusts as a whole. Data from the mapping are not used in statistical analyses other than modelling costs and benefits of scale up of MHDUs in WP5, for which a range of scenarios will be modelled. If a response rate of less than 50% of Trusts is achieved, we will repeat a basic mapping exercise in year 2 to inform WP5.

The mapping exercise will enable us to contextualise our findings when establishing the current cost and clinical benefits of MHDUs in England (WP2, WP3, WP4, WP5 and WP6) as well as modelling the cost and impact of widespread roll out of MHDU provision (see WP6 below). Analysis of variation of MHDU structure in study cases will enable us to make recommendations for optimal configuration of MHDUs (e.g. referral pathways, maximum LoS etc.). Finally, mapping will enable us to identify comparison sites without MDHU for the interrupted time series study (WP2).

WP2: Interrupted time series analysis (months 1-18)

Objective

- Administer an interrupted time series analysis using routinely collected mental health Trust and Emergency Department data to assess whether the introduction of MHDUs in four sites effects psychiatric inpatient admissions and A&E psychiatric episodes.

Outcome

- An estimate of the extent to which change in key service parameters (i.e., informal psychiatric admissions and mental health presentations at ED) in the pre- and post-interruption period are explained by the introduction of MHDUs.

Design and Methods

An interrupted time series (ITS) design, using routinely collected healthcare data, will explore change in acute and psychiatric hospital activity after the introduction of MHDUs in our four partner sites. Semi-structured interviews with strategic managers in each site will also be administered with a view to identify and consider the impact of other initiatives and changes, at both national (macro) and site (meso) level, on the time series and its analysis.

Quasi-experimental methods, such as an ITS design, are appropriate when the randomisation and/or the 'trialability' of the intervention is limited. They are particularly well suited to evaluations of organisational interventions or changes to health care at a delivery level that target population-level health outcomes and when a time series is available, as in this instance.[36, 37]

In ITS studies, data are collected at multiple time points before and after the introduction of a change or intervention enabling detection of whether or not the change has a significantly greater effect on outcomes of interest than any underlying secular trend.[38] ITS findings primarily concern whether the level or slope of the outcome measurement is altered once change has been implemented. The method is advantageous in so much as it allows control for baseline variation, periodicity, cyclical trend and/or autocorrelation in the time series design, prior to examination of change effects. The number of observations is important; examining a long series of outcome measurements more readily allows analyses to track both immediate and delayed effects.[39]

Site selection

Study sites will be Mental Health NHS Trusts with MHDU, defined broadly as a hospital-based unit that receives targeted referrals of people in acute mental health crisis, prior to a decision about admission being made, for purposes of assessment, therapeutic input, and either subsequent admission, discharge or forward signposting to appropriate recovery and preventative services. To maximize generalisability, MHDUs in four contrasting Mental Health NHS Trusts will be evaluated in depth; South West London & St George's, Lincolnshire, Sheffield and Birmingham.

Sites have been chosen for reasons of a) feasibility; we have the support of host NHS Trusts to access participants and data, and b) there is an appropriate level of variation (as identified in the WP1 mapping exercise) in configuration of the MHDU model across the four sites to allow comparison and ascertain models of MHDU which are likely to be optimal with respect to service productivity, quality of care as experienced by service users and cost-benefit.

Primary and secondary outcome measures

ITS will be used to identify any effects observed across the four participating MHDUs on a range of outcome measures focussed on the activities of the relevant acute and mental health Trusts. The primary outcome measures (for mental health Trust and A&E department – acute Trust – respectively) are changes in the number and pattern of:

- informal admissions to mental health Trust adult inpatient wards
- A&E psychiatric presentations

The secondary outcomes are changes in:

Mental health Trust

- total inpatient admissions
- number of 0-5 day inpatient admissions
- average length of inpatient stay (bed days)
- compulsory admissions
- occupied bed days (daily mean for the week)
- out of area admissions (from the site MH Trust to other MH Trust or private provider)
- number of psychiatric liaison episodes in A&E
- transfer to MDHU by ambulance and police

Acute Trust (collected for each hospital which refers to the site MDHU)

- number of 4 hour psychiatric A&E breaches
- average length of psychiatric A&E wait
- number of 12 hour trolley waits
- number of admissions to an acute bed
- arrival at A&E by ambulance and police

Data collection for ITS

Outcome data will be collated as weekly series for 24 months pre- and 24 months post-implementation of MHDUs, totalling 208 (weekly) time points. This is more than the 40 data points (20 pre- and 20 post-

change) typically considered as adequate for valid ITS model analysis,[40] and provides sufficient power to detect medium effects where they exist. For example, to detect a time x slope interaction with medium effect size on an outcome, a sample of 208 time points has > 99% power (assuming one parameter tested and no more than five factors entered in model; calculated using G-Power, 'linear multiple regression: fixed model, r^2 increase' module).

The metrics used as dependent measures within the ITS modelling will include key parameters associated with acute and psychiatric hospital activity. Waiting time in Accident and Emergency departments (A&E), especially performance against the UK's 4-hour waiting time target has recently been reiterated a key metric used to assess mental health care in acute care hospitals.[41] Similarly, psychiatric inpatient admission (and emergency re-admission) and length of stay (LoS) remain a key driver of NHS hospital costs, especially when care is staff-intensive as is the case in mental health.[42]

Aggregated service use data over the relevant 208 weeks will be sourced locally from mental health Trusts and A&E departments (acute hospital Trusts) of participating MHDU sites, as detailed above, through contact with Information Management & Technology (IM&T) departments at each Trust. Contact will be made with IM&T departments in advance of the study beginning and test data downloads requested and fields validated. Where there is more than one A&E department referring to the MDHU in any one site we will aim to collect A&E data from each acute hospital Trust, and at least from the main general hospital in that area.

Analytical strategy for ITS

We will provide both visual representations of the results in the form of graphical representations of outcome data over time and tables of the parameter estimates from the regression analyses for statistical inference. Graphical analysis will help to identify any stepwise change in outcome measures as a result of the introduction of MHDUs as well as detect changes in activity patterns before and after the introduction of MHDUs.

Formal statistical analysis will include a time series regression analysis, used to estimate the effectiveness of introducing MHDUs on outcome variables. We will adopt an autoregressive integrated moving average (ARIMA) modelling approach,[43] as it allows for accurate analysis of outcomes, taking into account any serial correlation, background variation and underlying trends independent of the intervention over time. ARIMA modelling has previously demonstrated successful prediction emergency department (ED) presentations and hospital admission,[44] including psychiatric visits.[45]

Initially, for each outcome, to check for serial auto-correlation due to repeated measures, we will examine the plot of residuals from regression analyses and use the Durbin-Watson test. Where no significant autocorrelation is detected, we will use a simple time series regression model. If significant autocorrelation exists, then adjustment for autocorrelation will be made using the ARIMA method.

For each outcome, we will calculate regression coefficients corresponding to both change in level (outcome) and trend (slope) after the introduction of MHDUs. In this model, the estimated parameters of interest are as follows: 1 the underlying trend prior to MHDU introduction (b1); 2 the level change immediately following MHDU introduction (b2); 3 the slope change from pre- to post-MHDU introduction

(using the interaction between time and change; b3); 4 the trend (slope change) following MHDU introduction (b1_b3).

Secondary analyses will include separate time series analyses of informal admissions to mental health Trust adult inpatient wards administered considering only people with discharge from psychiatric inpatient services in the last 24 months. In a similar manner, separate analyses of A&E psychiatric presentations will be administered considering only people with a previous A&E visit in the last 24 months. This is to ensure that we can estimate the effect of introducing MDHU on those populations most likely to be repeat users of mental health inpatient care and A&E respectively. External validity will be explored by examination of primary outcomes in subgroups, including but not limited to gender and ethnicity.

Semi-structured interviews; Data collection and interpretation of time series analysis

Semi-structured interviews (n=5 per site) will be held with strategic managers in each site, including MHDU manager, Acute Care Pathway lead, mental health lead commissioner (or their equivalent locally) and the A&E manager and A&E clinical director at the main general hospital at each site. Interviews will seek to identify any changes to the crisis care pathway within the duration of the time series, including the introduction or withdrawal of services or new initiatives, either as a result of national policy changes or reflecting local commissioning or clinical decision making priorities, including provision of services outside of the NHS Mental Health Trust (e.g. by third sector agencies) and changes in policy or protocol relating to the assessment and managing of psychiatric presentation to A&E. These interviews will be conducted by the Post-Doctoral Researcher to reflect the strategic level of interviews.

Alongside documented acute and crisis care pathway maps, interviews will seek to identify all aspects of the crisis care pathway, both directly provided by the mental health Trust and by other agencies, their referral routes (to acute admission and to the MHDU), and the assumed impact of these services on outcomes of interest to the study (including seasonal impacts). Where possible, internal reports and evaluations will be used to triangulate interviews, with quality of evaluation methods taken into consideration when interpreting findings. Changes in pathway or withdrawal of services or introduction of new initiatives that coincide with the time series – both prior to and following the interruption point – will be of particular interest and will be carefully dated in relation to the time series. This might include reconfiguration of services not directly related to crisis care – e.g. community mental health teams – that might nonetheless impact on our outcomes of interest.

Interviews will be used to build a comprehensive, descriptive model of the crisis care pathway (including changes to the pathway) – rather than subject to a phenomenological analysis – and the known and assumed impact on our outcomes at all points along the 48 month time series in each site carefully mapped. To account for potential confounding of any identified service reconfiguration or changes to models of care, sensitivity analysis comparing the months following the introduction of MHDUs to the same period prior to the service change will be administered. These data will be used in interpreting time series curves for each of our outcomes (for example, where reconfiguration of community services was followed by a temporary spike in inpatient admissions, or where the introduction of a street triage service coincided with a sustained reduction in A&E presentation). Acute

care and crisis pathway maps will also be used to inform development of service user pathways developed in WP5.

WP3: Synthetic control study (months 1-18)

Objective

- Administer a synthetically controlled time series analysis, using routinely collected mental health Trust and Emergency Department data to assess whether the introduction of MHDUs in four sites effects psychiatric inpatient admissions and A&E psychiatric episodes.

Outcome

- An estimate of the extent to which change in key service parameters (i.e., informal psychiatric admissions and mental health presentations at ED) in the pre- and post-interruption period are explained by the introduction of MHDUs.

Design and Methods

The inclusion of comparative control sites or unit in interrupted time series, in which no change occurs, improves the specificity of the evaluation and better controls for secular trends over the baseline, change or intervention, and follow-up periods.[37] Advanced synthetic control methods will be used for controlled analysis to estimate a robust counterfactual against which to compare the impact of the introduction of each of the four participating MHDUs on primary outcome variables.

Site selection

As in WP2, MHDUs in four contrasting Mental Health NHS Trusts will be evaluated in depth; South West London & St George's, Lincolnshire, Birmingham and Sheffield. Sites have been chosen for reasons of a) feasibility; we have the support of host NHS Trusts to access participants and data, and b) there is an appropriate level of variation in configuration of the MHDU model across the four sites (see Table 1 above) to allow comparison and ascertain models of MHDU which are likely to be optimal with respect to service productivity, quality of care as experienced by service users and cost-benefit. The counterfactual (control) will be constructed from selected sites without a MHDU, as identified in WP1.

Outcome measures

The synthetic control approach will be used to compare effects observed across the four participating MHDUs against selected control sites (identified from the service mapping exercise; WP1) on outcome measures focussed on the activities of the relevant acute and mental health Trusts. The primary outcome measures (for mental health Trust and A&E department – acute Trust – respectively) are changes in the number and pattern of:

- Informal admissions to mental health Trust adult inpatient wards
- A&E psychiatric presentations

In addition, where data can be accessed using NHS Digital Hospital Episodes Statistics and the Mental Health Services Data Set (see below), secondary outcomes of interest will be changes in the numbers and patterns of:

Mental health Trust

- total inpatient admissions
- number of 0-5 day inpatient admissions
- average length of inpatient stay (bed days)
- compulsory admissions
- occupied bed days (daily mean for the week)
- out of area admissions (from the site MH Trust to other MH Trust or private provider)
- number of psychiatric liaison episodes in A&E
- transfer to MDHU by ambulance and police

Acute Trust (collected for each hospital which refers to the site MDHU)

- number of 4 hour psychiatric A&E breaches
- average length of psychiatric A&E wait
- number of 12 hour trolley waits
- number of admissions to an acute bed
- arrival at A&E by ambulance and police

Data collection for synthetic control study

Outcome data will be collated at treated and control unit sites as monthly series for 24 months pre- and 24 months post-implementation of MHDUs), totalling 49 time points. This provides us more than the 40 data points (20 pre- and 20 post-change) typically considered as adequate for valid ITS model analysis,[40] and provides sufficient power to detect medium effects where they exist.

As with ITS (WP2), the metrics used as dependent measures within the synthetic control study will include key parameters associated with acute and psychiatric hospital activity. Aggregated service use data over the relevant 48 months for treated and untreated units will be sourced from Hospital Episodes Statistics (HES) and the Mental Health Services Data Set (MHSDS). HES and MHSDS are databases recording all admissions, outpatient appointments and A&E attendances at NHS hospitals in England and Mental Health NHS Trust service use respectively (see http://content.digital.nhs.uk/ for details).

Where there is more than one A&E department referring to the MDHU or control (counterfactual) in any one site, we will aim to collect A&E data from each acute hospital Trust, and at least from the main general hospital in that area. Research costs are included in the proposed funding to enable timely access to HES and MHSDS.

Analytical strategy

Difference-in-Difference (DID) is often used to estimate the impact of an intervention when data exists before and after a policy change. DID relies on the assumption that, in the absence of the intervention, the expected outcomes for the treated and control units would have followed parallel trends. However, this assumption is often implausible, particularly in a health policy setting where unobserved covariates may differ over time between the comparison groups. When the parallel trends assumption fails, DID may provide biased estimates.[46, 47] The original Synthetic Control (OSC) method introduced by Abadie et al.[48, 49] offers an alternative to DID, which avoids the parallel trends assumption and allow for the effects of unobserved covariates to vary over time. The central idea of OSC is to construct a weighted combination of untreated units to represent a counterfactual treatment free outcome for the treated region. Weights are chosen so that the treated region and the synthetic control region have similar values of the outcome and covariates over the pre-intervention period. However, the OSC approach has been shown to provide biased estimates under certain circumstances: when the treated units lie outside the convex hull of the controls;[50] when there are too few pre-intervention time periods[51] or when there are endogenous treatment effects.[52] Further, the OSC estimator is not designed for high dimensional data or multiple treated units, does not allow for heterogenous effects and offers uncertainty estimates that are cumbersome and not easily interpretable.[53]

Recent methodological advances include Micro Synthetic Control (MSC)[54], which allows for high dimensional data, and Generalised Synthetic Control (GSC)[53], which combines insights from interactive fixed effect modelling with insights from the OSC method. These methods overcome the limitations of DID and OSC, providing more reliable estimates in scenarios where there are no parallel trends or few pre-intervention periods. In general, GSC is favourable, however MSC offers more reliable estimates when there is strong serial dependence of the error terms.[55] If no strong serial correlation is detected in the outcome of interest, analysis will be performed using GSC, otherwise MSC.

WP4.Quantitative longitudinal study using electronic patient record (months 4-21)

Objective

- Examine the referral pathways into MHDUs and the care pathways followed by people before and following an admission to the participating MHDUs, and the extent to which these are influenced by organisational pressures and service users' socio-demographic characteristics and psychiatric history, using electronic patient record (EPR).

Outcomes

- A comprehensive profile of those individuals visiting the MHDU which includes descriptions of the care pathways before and following an admission to the MHDU.

- A model of individual-based factors most relevant to change in key MHDU service user outcomes (e.g., decrease in number of A&E presentations from the period pre-MHDU admission to the period post-MHDU discharge).

Design and Methods

ITS analyses will allow us to assess whether the introduction of MHDUs for people experiencing a mental health crisis accessing emergency care has affected service delivery outcome measures. Service re-design also needs to be examined from a broader context to better understand who is referred to MHDUs (including an equalities 'impact assessment') and what works for which groups of service users and why. A prospective, longitudinal study will address the following research questions:

1) How does attending an MHDU impact on psychiatric inpatient admissions and A&E psychiatric episodes/breaches for current MDHU users?
2) What are the care pathways before and following an admission to the MHDU for current MDHU users?
3) What is the impact of the introduction of MHDUs on inequalities of access to acute mental health services?

Participant selection criteria

All service users at south west London, Lincolnshire, Birmingham, and Sheffield MHDU sites referred for the first time to a MHDU over a 9-month period will be eligible to participate (there are no eligibility criteria other than first admission to MDHU and capacity to consent to participate in research). For sites where service use data cannot be extracted anonymously (e.g. Lincolnshire), only those service users who consent to participation will be included.

Data collection

Baseline data will be collected for all included participants on socio-demographics (e.g., age, gender, ethnicity, sexuality, postcode) and known predictors of psychiatric admission and health care utilisation by UK adults with mental illness (e.g. diagnosis, previous inpatient admissions, accommodation status, comorbidity, high previous health care utilisation).[56, 57] In line with previous research, discharge destination after MHDU assessment being admission to psychiatric hospital will be used as a 'proxy of severity' of presentation.[58] Fields will be specified in pseudonymised Clinical Record Interactive Search (CRIS) reports for those sites with the CRIS facility (SWLSTG and Birmingham), and as appropriate to local Electronic Patient Records system through working with Information Management teams at other sites. The quality and completeness of EPR data is critical to the study. Although data resources including EPR are not shaped by research priorities,[59] the positive predictive value of EPR has previously been reported as high.[60] We will test data requirements and identification of fields through repeat iterations as necessary at each site prior to WP3 commencing.

Individual mental health service use data (including those outcomes specified in WP2 in addition to total number of admissions and use of community mental health team (CMHT) and other mental health trust services), numbers of A&E presentations (measured as psychiatric liaison episodes in A&E as recorded in the EPR) and transfers by ambulance and police to MDHU will be collected for each participant for 9 months prior to MHDU admission and 9 months post-discharge. The primary outcome for Mental Health Trust will be the number of informal admissions, and for the acute Trust will be number of A&E presentations.

For those service users who provide consent, we will also collect health-related quality of life (HRQOL) data, following MHDU admission and at 9 months post-discharge (for the latter, this will be a postal questionnaire with stamped self-addressed envelope or an online questionnaire sent by email or SMS, as preferred by the participant) for use in the WP6 health economic evaluation (see below). Specifically, participants will be asked to complete the EQ-5D-5L, a brief, generic health status questionnaire that consists of five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Using a 5-point ordinal scale (0 = no problems; 1 = slight problems; 2 = moderate problems; 3 = severe problems; and 4 = extreme problems), participants are asked to select the level that best matched their health for each domain. For each participant, an overall health state valuation (EQ-Health) ranging from –0.285 for extreme problems in all domains to 1.000 for no problems in any domain will be calculated according to a value set recently developed for the population in England.[61] Participants will also be asked to indicate their self-rated health on a 20-cm vertical visual analogue scale (EQ-VAS) with worst (0) and best (100) health they could imagine as scale anchors.[62]

Sample size

Multivariate regression models will be constructed for primary and secondary outcome measures to explore the impact of each predictor variable. It has been proposed that for (multivariate) logistic regression, the minimum number of cases to include is n = 10 k / p, where p is the smallest of the proportions of negative or positive cases in the population and k the number of independent variables.[63] For example, if there are (up to) 5 explanatory variables to include in the model and the proportion of positive cases (for key outcomes) in the population is 0.20 (20%), the minimum number of cases required is N=10 x 5 / 0.20 = 250. Throughput for all MHDUs in the study is approximately 30-40 service users per month. We assume informed consent will be obtained for 50% of service users referred to MHDUs in Lincoln and Sheffield, yielding (Lincolnshire = 138; Sheffield = 75). We plan to obtain anonymised data for patients in Birmingham and SWLSTG, (SWLSTG = 270 Birmingham = 668). Participant consent is not required for collection of anonymised data. Including both types of data (collected anonymised data and from consented participants), the anticipated sample size is 1151. These sample sizes will be adjusted in discussion with study sites in relation to actual rates of admission.

Analytical strategy

Initially, the sample of MHDU service user participants will be described with respect to socio-demographics and relevant factors associated with psychiatric admission and health care utilisation (e.g. ethnicity, diagnosis, previous inpatient admissions, accommodation status, comorbidity, previous

health care utilisation).[56, 57] Where appropriate, individual mental health service use data will be compared between the pre- to post-MHDU discharge periods using paired sample t-tests or McNemar mid-*p* test for binary matched-pair data[64] depending on distributional properties. Where continuous variables do not meet requirements for univariate normality using skewness and kurtosis estimates, bootstrapping using 2000 replications[65] will be employed to calculate 95% confidence intervals of mean difference and associated p values.

We will use Generalized Linear Modelling (GLM) to develop Logistic and Poisson regression models which examine relationships between important service/service user characteristics and (individual) mental health service use data post discharge from the MHDU. For example, Poisson regression will be employed to estimate relative risks (RRs) and 95% confidence intervals (CIs) for the associations of independent variables (ethnicity, diagnosis, previous inpatient admissions, accommodation status, comorbidity, previous health care utilisation, time spent in MHDU, severity of presentation as indicated by discharge destination after MHDU assessment)[58] with those outcome measures that use count data (e.g., total number of admissions and numbers of A&E presentations in the 9 months after MHDU discharge). We will also develop regression models using GLM (e.g., Linear and/or Logistic, depending on data distribution) to explore which independent variables are most closely related to change in primary outcome variables (e.g., decrease in number of A&E presentations from the period pre-MHDU admission to the period post-MHDU discharge). For all categorical independent variables in models (e.g., diagnosis), the reference group will be selected on the basis of it being 1) the largest or 2) most interpretable.[56] To account for missing data on relevant variables (e.g., accommodation status), a multiple imputation approach will be adopted to create imputed datasets using chained equations.[66] We will check for the occurrence of multicollinearity and calculate Cook's distances[67] to identify influential outliers. We will use two-sided significance tests for all analyses with statistical significance set at a *p* value of 0.05.

WP5.Qualitative longitudinal study (months 7-21)

Objective

- To examine qualitative interview data to understand experiences before, during, and after referral to MHDU from the perspective of service users and carers, and the decision-making process of A&E, crisis services and MHDU staff along the crisis care pathway.

Outcomes

- A detailed understanding of MHDU service user and carer experience including pathways before and after MHDU admission.
- A detailed understanding of staff experience of MHDU implementation, particularly that concerning decisions made about MHDU referral/admissions, assessments and onward signposting.

Design and Methods

This WP will employ qualitative research methods, namely semi-structured interviews with MHDU service users and staff involved in MHDU referral and admission pathways. Carers will be invited to attend either a focus group or semi-structured interview. The analytical approach combines inductive and deductive theme development.

Participant selection criteria

A sub-sample of service user participants in WP4 (n=12 per site) will be invited for in-depth interviews post-discharge and 8-10 months later (while the target is 10 per site, we will oversample due to anticipated study attrition; where significant numbers of individuals are lost to follow up post-discharge, matched individuals – see variables below – as close as possible to nine months post-discharge will be identified through the MHDU record and invited to interview). A sampling framework will be used that ensures that participants are included that: a) have been referred from across the range of referral sources on the pathway locally; b) have a range of service use histories (e.g. previous admission to MHDU or not; previous acute inpatient admission or not); c) include socio-demographic variation that reflects the local community. Only those service users who consent to participate in interviews will be interviewed.

Staff (n=6-8 per site) on the referral and assessment pathway to MHDU (including a member of the general hospital based, Liaison Psychiatry team, A&E Nurse and A&E manager at the main general hospital at each site, one or more referring clinician from each of CRHT, street triage service and other agencies that directly refer to MHDU, and a paramedic and police officer involved in transferring people from A&E to MDHU) and MHDU staff (n=4 per site; unit manager, nurse, healthcare assistant and psychiatrist consulting to the unit) will be invited for an in-depth interview. Only those staff members who consent to participate in interviews will be interviewed.

Carers who care for someone who has accessed MHDU services will be invited to take part in the study. For interviews, (n=6-10 across all sites), and for focus groups, (n=1-2 across all sites). Per site, there will be (n= 0-1 focus groups), and (n=0-6 carer interviews). Interviews will take place in an NHS venue, suitable community setting, or over the telephone. Focus groups will take place in an NHS venue or suitable community setting. Each consenting carer will only take part in one interview or focus group. A sampling framework will be used that ensures, at a minimum, that the range of carers included represent the socio-demographic variation that reflects the local community.

Data collection

Service user participant interviews

All interviews will be face-to-face and semi-structured, exploring service users' experiences of referral to the MHDU, of assessment, unit environment and therapeutic input on the MHDU, and care pathway in the year pre- and post-stay on the unit. Interviews will be used to construct 'stories' of typical pathways into and out of MHDUs to inform WP6 pathway modeling. Two workshops with the PEER group (service user and carer research reference group at the lead site) identified a number of issues important to explore in interviews, including: different experiences of referral from different sources or teams; if and how the MHDU had therapeutic value other than avoiding an acute admission; if and how the MDHU was experienced differently from a ward (and was preferable or not);the experience of people frequently

referred (revolving door or preferred crisis care experience?); experience of signposting and fit with people's usual support network; impact of experience of MDHU on 'where you are now' compared with 'where you were', and so on. Final interview schedules will be coproduced by the team, including the service user researcher, and our Lived Experience Advisory Panel (LEAP).

Carer interviews and Focus Groups

All interviews will be semi-structured. Interview and focus groups will explore carers' experiences of supporting the person they care for, with a particular focus on their experience of the MHDU in the context of other experiences of caring for a loved one in crisis. This includes: if and how the MDHU was experienced differently from a ward (and was preferable or not); experience of signposting and fit with people's usual support network; impact of experience of MDHU on 'where you are now' (as a carer) compared with 'where you were', and so on. Final interview schedules will be coproduced to include the perspectives of people with lived experience.

Staff participant interviews

Semi-structured interviews with staff on the referral and assessment pathway to MHDU will ask about their experiences and understandings of acute mental health crisis (in A&E or other referring crisis service), how this is assessed within their services, decision-making process and reasons for referral to MHDU, who are the typical patients or groups of patient they refer to MHDU and why, plus their view on the impact that the introduction of the MHDU has made on their services (and on the crisis care pathway as a whole).

Semi-structured interviews with MHDU staff will explore staff views on appropriateness of referrals from other services (fit with service specification), how those referrals are assessed and the unit gate-kept, decision-making process and reasons for accepting/ refusing admission, experience of working on the unit (including appropriateness of people admitted for the unit, balance of assessment/ therapeutic intervention while on the ward), assessment process and decision making around discharge, acute admission, and onward referral and signposting to other services (within and outside of the NHS), who are typical patients or groups of patients received at the MHDU (including who are the frequently returning patients and why), plus their view on the impact that the introduction of the MHDU has made on their services and on the crisis care pathway as a whole). Staff interviews will also be coproduced with the service user researcher and LEAP to ensure that data responds to service user priorities for the crisis care pathway.

Analytical strategy

Interviews will be recorded and transcribed, with transcripts cross-checked against the original recordings to ensure accuracy. These data sets will be analysed thematically[68] using an approach that combines inductive and deductive theme development in order to integrate both 'theory-driven' codes (i.e. a sensitivity to those phenomena that we already expect to be taking place; e.g. clinical decision-making about who to refer/ admit to the MDHU and why), and data-driven codes that articulate the idiosyncratic and unexpected in our data (e.g. comparative experience of care in the MDHU and care in other components of the crisis care pathway).[69] Output from qualitative analyses will be, first, descriptive, providing a detailed account of the crisis care pathway – into and out of MDU – at each site (including differences between sites), both from the perspective of clinicians along the pathway (including MDHU

staff) and also service users, as they experience care in the MDHU and reflect on the quality of crisis care before and after first visit to the MDHU. Second, analysis will be explanatory, accounting for how and why different groups of service users might better access MDHU, from different referral sources, and then might differently benefit from MDHU care in subsequent months. As described below, analyses will be synthesised with our other datasets in order to offer insight into optimal configuration of MDHU and the crisis care pathway going forward.

The service user researcher and co-applicant working from a lived experience perspective (KT) will play a key role in the interpretive process. The service user researcher will produce preliminary thematic analyses of each qualitative data set. These will be taken to an interpretive workshop involving members of the research team and LEAP using an approach to coproducing analysis developed by the team at SGUL[70] to ensure that service users' priorities and concerns regarding crisis care are integrated into our findings. The analytical framework developed in the workshop will then be applied to the whole dataset by the service user researcher.

For the carer interviews and focus groups, the analytical strategy is similar: interviews and focus groups will be recorded and transcribed, with transcripts cross-checked against the original recordings to ensure accuracy. These data sets will be analysed thematically[68] using an approach that combines inductive and deductive theme development in order to integrate both 'theory-driven' codes (i.e. a sensitivity to those phenomena that we already expect to be taking place), and data-driven codes that articulate the idiosyncratic and unexpected in our data (e.g. comparative experience of care in the MDHU and care in other components of the crisis care pathway).[69] Output from qualitative analyses will be, first, descriptive, as carers reflect on their experiences of caring for a loved one in crisis. Second, analysis will be explanatory, accounting for how and why the carer experience differs when different parts of the crisis care pathway are used. This will include (as appropriate), caring for a loved one in crisis when services are not accessed (as driven by the data). Summaries from the carer interviews and focus groups will be incorporated into and woven into synthesis from the rest of the project.

WP6. Economic analysis (months 7-21)

Objective

- Carry out an economic analysis of MHDUs in three sites to assess whether the introduction of mental health assessment units provides value for money compared with current service provision, and to consider the cost impact of roll out of optimally configured MHDUs nationally.

Outcome

- An estimate of the cost-effectiveness of MHDU implementation, including consideration of alternative configuration of MHDU pathways or access by specific populations and roll out and scale up of MHDUs nationally.

Design and Methods

WP6 comprises an economic analysis of aggregate and individual level Mental Health Trust and A&E service use data with respect to MHDU implementation, including a potential return on investment of intervention analysis.

Data collection

To date there has been no economic analysis of the introduction of MHDUs. The economic analysis will consist of several linked elements. We will estimate economic impact from an NHS perspective of the introduction of MHDUs at mental health trust level. The results of the analysis in WP2/WP3 from the ITS/synthetic control study will provide data on sustained trend changes in primary outcomes (informal admissions to mental health trust adult inpatient wards and A&E psychiatric presentations), as well as in secondary outcomes such as changes in average length of stay, being mindful of differences in trends between the different MHDUs. This will allow us to estimate changes in costs between each MHDU and non-MHDU area following the introduction of MHDUs. Appropriate unit costs, e.g. from NHS Reference costs, will be attached to these changes in resource utilisation to estimate costs. These data, together with estimates of MHDU programme costs under different configurations, will subsequently be used in decision modelling work in WP6 to inform the potential return on investment (ROI) of scaling up different configurations of MHDUs across England.

The resources and costs to the NHS associated with the delivery of MHDU services will also be determined. This will involve liaison with the three mental health trusts and use of routine data to identify staff time, other resources and overheads allocated to MHDU delivery, recognising that MHDUs may share staff with other services and have flexible capacity depending on the changing levels of service demand over the study period. We have used similar approaches previously to estimate the costs of selected mental health services in A&E and crisis care related to self-harm.[71]

In addition to aggregate level data on differences in costs between sites, we will also look at individual longitudinal service user data to determine whether there are sustained significant differences in costs between different MHDU sites and in comparison to at least one control site. Data obtained as part of WP4 will provide information on changes in service utilisation in acute and mental health trusts for individual service users in the 9 months pre- and post-MHDU use or crisis contact (in the case of controls). Appropriate unit costs, such as NHS Reference costs, will then be attached to resources used to estimate incremental changes from an NHS perspective for each specific cost element, as well as total costs of individual service users over the 9 months pre- and post-intervention. Individuals from the control population cohort will be selected to match the characteristics of MHDU service users, allowing us to compare incremental costs between control and MHDU sites (we will select as control site a mental health Trust using the CRIS tool to facilitate generating a control cohort and have begun discussions with a partner Trust to that effect). Where we obtain follow-up data on health-related quality of life from participants we will use that data to model the impact of attending an MDHU on Quality Adjusted Life Years (QALYs). Selected service user sub-group analyses for costs will also be conducted reflecting different socio-demographic characteristics or factors associated with the use of mental health services.

Analytical strategy

Generalised Linear Models (GLMs) and parametric bootstrapping methods will be used to model costs and to determine significance of the differences in individual components of cost, e.g. inpatient length of stay, contacts with CMHTs, use of ambulance services as well as in total costs and, where possible, quality adjusted life years (QALYs).

Decision modelling is an approach that can synthesise existing data on costs and outcomes (in this case changes in the use of acute and mental health trust services) in order to look at potential return on investment of an intervention, such as the introduction of MHDUs. It can be used to deal with issues of uncertainty around effects, levels of uptake and variations in cost, as well as potentially look at the benefits of sustaining change over longer periods of time than can be used in trials and observational studies.

We will use decision modelling to look at the potential ROI for individuals in MHDUs under different scenarios, as well as the potential ROI if scaled up across England. Return on Investment analyses will compare the costs associated with MHDU investment with the costs of any potential resource use averted as a result. Models will be built using Excel so that potentially policy makers and others might in future have an opportunity to modify our assumptions, for instance on unit costs, number of individuals reached or impacts on primary outcomes and see what impact this has on overall ROI in their locality. Previously we have used this approach to estimate the potential return on investment of selected mental health promotion and early intervention actions in different locations in England.[72]

We will create ROI models at an individual service user level and then at an aggregate level to look at impact of scale up. For individual ROI analysis, three to four scenarios that reflect and have been developed using ‘stories’ co-produced with service users in WP5 will be created. These scenarios will describe individual journeys along service use pathways. Costs from an NHS perspective will then be attached to selected different pathways associated with MHDU use and non-MHDU use. For instance, models may take account of differing pathways linked to different personal characteristics and different levels of intensity of previous service use. These models can also take account of extent to which service user experience indicates that MHDUs rather than care as usual is appealing; this could affect the level of initial uptake as well as the subsequent reuse of MHDU services if required. Model pathways will also take into account insights from interviews with staff on the referral and assessment pathway to MHDU or other alternate service use. This could include potential impacts of changes in the configuration of the mental health workforce on costs associated with pathways.

Finally, informed by MHDU service mapping across England in **WP1,** as well as by results from **WP2, WP3, WP4 and WP5**, we will estimate the potential budgetary impact of scaling up MHDU service provision to all mental health Trusts in England. The ROI of scaling up different configurations of MHDU services will be estimated, drawing on data on the service configurations and relative impact of our three MHDU sites.

Data synthesis (months 22-24)

Synthesis of data from across all WPs and across sites will be conducted to provide insight into optimal configuration of MHDUs in relation to the wider crisis care pathway and to inform potential future upscale

and roll out of MHDUs nationally. Data synthesis will adopt a Critical Interpretive Synthesis approach, as has been widely applied to the synthesis of quantitative and qualitative evidence in systematic reviews[73] and the development of evidence based practice.[74, 75] In this approach 'constructs' are derived from the various analyses (i.e. from descriptive analysis or hypothesis testing of quantitative data, and thematic analysis of qualitative data) and mapped onto an integrative grid that explores how those analyses interface. This process enables the development of 'synthesising arguments' – analytical narrative - that offer explanatory insight into findings and inform applied learning from the research (here on MDHUs and optimal pathway configuration). A second interpretive workshop involving members of the research team and LEAP will be held to ensure that service user views and experiences inform this process.

The approach to using typical qualitative pathway stories from which to construct alterative economic models, as described in WP6 above, is one such data synthesis approach. A further set of constructs will be specified, derived from WP2, WP3 and WP4 quantitative analyses, and from analysis of our WP5 qualitative data (for examples, see Table 1). These constructs will reflect our levels of enquiry and will specifically explore issues around (but not be limited to):

1. the crisis care pathway, including policy changes (macro), pathway configuration (meso), and clinical decision-making and experience of barriers to/ facilitators of admission to MDHU (micro);
2. the MDHU environment, including accommodation and staff mix (meso), and experience of assessment and treatment (micro);
3. population and crisis care, including identification of frequent users and under-represented groups (meso), and experience of pathway and clinical decision-making (micro).

Table 1. Examples of hypothetical constructs that might be tested by data synthesis.

	Impact of MDHU on A&E	Unit environment	Frequent users of MHDU
WP2/WP3 Time series analysis/ Synthetic control study	No impact on 4 hour breach		Reduction in informal admissions for people with an acute admission in preceding 2 years
WP4 Cohort study analysis	Few referrals to MDHU from A&E (compared to other referral sources)	Extended LoS on MDHU (>24 hours) no impact on outcomes post-discharge	Fewer acute admissions and increased engagement with community services post admission to MDHU for subgroup with previous MDHU admission
WP5 Qualitative interviews	A&E staff report very few referrals to MDHU accepted MDHU staff report high numbers of 'high risk' referrals from CRHT	MDHU service users report high satisfaction with unit environment, including accommodation in units with recliners rather than beds, and positive therapeutic engagement with MDHU staff	Subsample of service users with previous MDHU admission report positive experience of assessment and signposting while on MDHU and increased access to community

			services post-discharge from MDHU

6 STUDY SETTING

This study takes place in Mental Health Decision Units (MHDUs; sometimes called Psychiatric Decision Units, or Crisis Assessment Units). There is no single service specification for MHDUs but rather a shared set of characteristics that distinguish units from other hospital based assessment services such as Triage Wards. Triage or Assessment wards are hospital wards 'to which all patients requiring admission will go for initial assessment and treatment. Length of stay is anticipated to be brief and patients will either be discharged or transferred to a treatment ward if requiring a longer period of admission'.[9] MHDUs, in contrast, receive targeted referrals of people in acute mental health crisis, prior to a decision about admission being made, for purposes of assessment, therapeutic input, and either subsequent admission, discharge or forward signposting to appropriate recovery and preventative services. MHDUs offer an alternative pathway – to acute admission - for people who experience excessive stays in emergency departments, frequent use of other services, such as the police and ambulance services, and who have complex and frequent crisis-related needs. Generally, all admissions to MHDUs are voluntary – whereas Triage Wards will admit people under assessment or treatment sections of the Mental Health Act – although some MHDUs make a limited number of specific exceptions to this (e.g. step-down from Section 136 Suite). MHDUs are configured as an integrated element of the crisis care pathway alongside CRHT teams and psychiatric liaison teams, and, where provided, street triage and crisis houses, and aim to reduce admission to standard acute care – especially avoidable short admissions and expensive out of area or private admissions – as well as subsequent crisis presentations at A&E. Furthermore, as admission to MDHU is not a formal inpatient admission, MDHU staff are not required to complete inpatient treatment plans or the clustering tool for admission as they would on a triage ward, the focus of assessment and planning in the MDHU being on community-based provision in the medium term rather than inpatient care.

Referrals to MHDU can be made from a range of services including liaison psychiatry teams (typically from A&E departments), Crisis Resolution & Home Treatment teams and street triage teams, with referrals triaged at a decision point prior to admission to the MHDU. MHDUs do not accept self- or family referrals, except, by implication, via A&E. Most MHDUs are co-located with a Section 136 Place of Safety, are able to share staff and in some cases, have variable capacity through using flexible partitioning between units. MDHUs have the option of overnight stay – although this often takes the form of reclining seating rather than beds – with maximum length of stay restricted to, typically, 48 or 72 hours (Table 2). Overnight accommodation is single sex, again with flexible partitioning to enable the unit to respond to different numbers of male and female service users. Units tend to be small (capacity of about 6) with staff: service user ratios of at least 1:2 to allow substantial time for detailed assessment, brief intervention and onward referral/ signposting. Brief intervention generally includes cognitive or psychosocial work around, for example, improving resilience, solution focussed approaches and so on. Onward referral can be to NHS or third sector services providing therapeutic, social or practical support around, for example, housing, welfare and benefits and so on. MHDUs are typically nurse-led units with

consulting input from psychiatry and other mental health professionals, usually from a co-located acute ward and/ or shared with a Section 136 suite.

Table 2: Key structural variation in MHDUs at site level

MHDU	Max LoS	Accommodation	Capacity	Referral route
South West London	48 hrs	Recliners	5(7 including Section 136 beds)	A&E (liaison), CRHT, Street Triage
Lincolnshire	24 hrs	Recliners	6	A&E (liaison), CRHT

7 SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

There will be no exceptions (waivers) to eligibility criteria prior to individual participant inclusion into the study (WP2, WP4, WP5). Any questions raised about eligibility should be addressed prior to entering the participant.

The eligibility criteria have been carefully considered and are standards used to ensure the study results can be appropriately used to make future treatment decisions for other people with similar disease or medical condition. It is therefore vital exceptions are not made to the selection criteria.

All participants that are screened for inclusion into the study must be entered onto the Sponsor screening log JREOLOG0001 and will be assigned a sequential number. Participants will be considered eligible for enrolment into this study if they fulfil the inclusion criteria (as stated in section 7.1.1 below).

Eligible participants will be entered onto the Sponsors Subject ID log JREOLOG0002 and assigned a study-specific Identification number in a pre-agreed format in accordance with Site identifier and next sequential numerical value (e.g. SG001).

7.1.1 Inclusion criteria

WP2: Strategic manager interviews

- Strategic managers and Mental Health and Acute NHS Trusts, and mental health commissioners with strategic oversight of MDHUs and the mental health acute care pathway

WP4, WP5: Cohort Study and qualitative interviews with service user participants

- First admission to MDHU
- Capacity to consent to participate in research (for all interviews and for clinical notes' data in sites where service use data cannot be extracted anonymously)

WP5: Staff interviews

- Staff on the referral and assessment pathway to MHDU (including a member of the general hospital based, Liaison Psychiatry team, A&E Nurse and A&E manager at the main general hospital at each site, one or more referring clinician from each of CRHT, street triage service and other agencies that directly refer to MHDU, and a paramedic and police officer involved in transferring people from A&E to MDHU).

- MHDU staff (unit manager, nurse, healthcare assistant and psychiatrist consulting to the unit).

WP5: Carer interviews

- Carer of a service user who has stayed in a mental health decision unit at a site in the DECISION Study.

7.1.2 Exclusion criteria

WP2: Strategic manager interviews

- Not working in a role relevant to the mental health crisis care pathway.

WP4, WP5: Cohort Study and qualitative interviews with service user participants

- Not first admission to an MDHU.

- Not having capacity to consent to participate in research.

WP5: Staff interviews

- Not working in a role relevant to the mental health crisis care pathway.

WP5: Carer interviews

- Not a carer of a service user who has stayed in a mental health decision unit at a site in the DECISION Study.

7.2 Sampling

Please see Site/Participant selection criteria for WPs as detailed above (in Methods).

7.2.1 Size of sample

Please see Data Collection for ITS/synthetic control study (WP2, WP3), Sample size (WP4) and Staff participant interviews (WP5) in Methods for sample size details and justification.

7.2.2 Sampling technique

Please see Site/Participant selection criteria for WPs as detailed above (in Methods).

7.3 Recruitment

Participant recruitment at a site (WP2, WP4, WP5) will only commence once evidence of the following approval/essential documents are in place:

DECISION

1. REC approval, including HRA approval
2. Final sponsorship
3. Host site permission/ Confirmation of Capacity and Capability

7.3.1 Participant identification

WP2: Strategic managers

Potential participants will be identified by role – see WP2 above – and invited by a member of the study team to participate in a semi-structured interview. Potential participants will be given study information and invited to give their Informed Consent to participate before being interviewed.

WP4: Service user participant recruitment

Where service use data can be extracted anonymously (e.g. in the South West London site where the Clinical Record Interactive Search (CRIS) tool is available[76]), all eligible service users who are referred to the MHDU during the recruitment period will be included in the study (subject to approval from the SWLSTG CRIS oversight committee). At sites with CRIS, participants will be identified using pseudonymised information only, as previously approved by NRES (following local application for approval for this research).

At other sites (e.g., Lincolnshire), the direct care team at each site (MDHU team) will identify eligible potential participants, give them a copy of the study PIS and ask them if they are happy to be approach by a Clinical Studies Officer about the study. The clinical team will be able to check eligibility using the individual's electronic patient record (i.e. to check whether this is their first admission to the unit. Potential service user participants will first be approached by a member of their direct care team (MDHU team) after the crisis for which they have been referred has abated and prior to their discharge or transfer from the unit. A member of the care team will ask them if potential participants would like to hear about a research study that they may be interested in and offer them copies of the study Participant Information Sheet (PIS) and the study leaflet. If the individual is then interested in finding out more, the member of the care team will ask if a Clinical Studies Officer can arrange to come and see them while they are on the unit or, arrange by telephone or other preferred means of contact to meet them at another location within two weeks of leaving the unit. We retain this option of contacting and meeting people after they have left the unit because MDHUs have a very short length of stay (typically from 24 to 72 hours maximum) and so people can be discharged from the unit at short notice without opportunity to participate in the research.

WP5: Service user participants

Service user participants in WP4 (n=12 per site) will be invited for in-depth interviews (within 1 month) post-discharge and 8-10 months later by (Trust) PIs. A sampling framework will be developed that ensures that participants are included that: a) have been referred from across the range of referral sources on the pathway locally; b) have a range of service use histories; and c) include socio-demographic variation that reflects the local community. Where an individual is lost to follow up post-

discharge a closely matched individual will be identified through the MHDU record and invited to interview 8-10 months post discharge.

WP5: Staff participants

(Trust) PIs will identify potential participants that meet our role requirements for staff interviews. PIs will usually be MDHU manager in Mental Health Trusts and A&E Dept manager in Acute Trusts. Staff in the MHDU and those on the referral and assessment pathway to MHDU will be invited to participate in interviews taking place at the conclusion of the final programme in the study period.

WP5: Carer participants

Carer participants in WP5 (n=6-10 across all sites for interviews; and n=1-2 across all sites for focus groups. This breaks down per site as n=0-6 for interviews and n=0-1 for focus groups) will be invited for in-depth interviews or focus groups. A sampling framework will be developed that ensures that participants are included that: a) care for people who have been referred from across the range of referral sources on the pathway locally; b) care for people who have a range of service use histories; and c) include socio-demographic variation that reflects the local community.

7.3.2 Consent

Informed consent from the strategic manager (WP2), service user (WP4, WP5) and staff (WP5) participants will be obtained following explanation of the aims and methods of the study and before any participant specific data is collected. All Clinical Studies Officers (CSOs) and research staff members undertaking the informed consent process have signed the Sponsor's Delegation of Responsibilities Log JREOLOG0004 to ensure that the person has been delegated the responsibility by the study CI. All personnel taking informed consent will be GCP trained or equivalent.

WP2 and WP3: ITS and synthetic control methods will be used to identify any effects observed across the participating MHDUs on a range of outcome measures focussed on the activities of the relevant acute and mental health Trusts. We will not seek informed consent from individual service users for this aggregate data, because we are interested in changes to service-based variables, including but not limited to, the number of informal admissions to mental health Trust adult inpatient wards, number of A&E psychiatric presentations, change in wait times, number of breaches in A&E, changes in average length of psychiatric inpatient stay, and changes in overall health economics cost. We do not require and will not analyse data on an individual (service user) basis. There is no need for the research team to have any access to any patient identifying information, and so individuals will not be identifiable in the data we will receive.

WP4 Cohort study: once a potential participant has indicated to a member of their direct care team that they are interested in being contacted to find out more about the research they will be contacted by a Clinical Studies Officer either in person on the unit, or by telephone or other preferred means of contact (as agreed with the member of the care team) within two weeks of leaving the unit in order to

arrange a meeting at a suitable NHS or community provider location. The potential participant will have been given a Participant Information Sheet (PIS) and leaflet about the research by the member of the care team. The Clinical Studies Officer will bring additional copies to the meeting in order to address any questions the potential participant might have and to check that they are fully informed about what the research involves in all respects. The Clinical Studies Officers (CSOs) and research staff members undertaking the informed consent process will explain that the patients are under no obligation to enter the study and that they can withdraw at any time during the trial, without having to give a reason and (for service users) without their care being affected in any way, and that they will not be named in any report or publication and that data will remain confidential. Part of the consent process (WP4) will detail exactly what data will be accessed from the clinical notes by the research team. Clinical Studies Officers have all been trained in informed consent processes. Clinical Studies Officers will meet potential participants on a second occasion if they are initially unsure about participating in the research. If people are willing to participate in the research, they will be invited to sign two copies of an Informed Consent Form, counter-signed by the Clinical Studies Officer, one of which they keep. For sites where service use data can be extracted anonymously, we will request that the Trusts supply us with anonymous data by electronic download (WP4). These will be sites that utilise the Clinical Record Interactive Search (CRIS) system only, as approved by the Health Research Authority and the Confidentiality Advisory Group, and where approval for this study to access anonymised data is given by the local CRIS Oversight Committee at each site.

WP5 Service user qualitative interviews: The PIs will explain that participants may also be contacted subsequently (using participants preferred contact details) and invited to participate in qualitative interviews by a member of the research team (we interview a subsample of cohort study participants only). This will be made clear to potential participants as part of the informed consent process. In sites using CRIS, potential participants in qualitative interviews will be approached exactly as described above but will be contacted by a member of the research team (rather than a CSO) and invited to consent to participate in a qualitative interview only. We have different PIS for sites with and without CRIS that makes this distinction clear. The research staff member will inform (potential) participants that semi-structured interviews might be digitally recorded, and that anonymised quotations might be used in reports/publications, and that any recording will be stored securely for the duration of the study and then destroyed.

WP2/WP5 Staff qualitative interviews: PIs will give potential staff participants a copy of the staff PIS, and ask if they are happy to be approached by a member of the research team by their preferred means of contact. A member of the research team will then contact staff directly to arrange to meet to answer any questions about the study and invite them to give informed consent. A copy of the signed Informed Consent Form (ICF) will be given to the study participants. If people are willing to participate in the research, they will be invited to sign two copies of an Informed Consent Form, counter-signed by the Clinical Studies Officer, one of which they keep. The research staff member will inform (potential) staff participants that semi-structured interviews might be digitally recorded, and that anonymised quotations might be used in reports/publications, and that any recording will be stored securely for the duration of the study and then destroyed. Staff participants will also be informed that while they will not be named

in any report or publication, because they are part of a small group of highly specialist staff working in this service, who are known to each other and to some members of the research team, it will not be possible to guarantee their contribution and participation will be anonymous.

WP5 Carer interviews: Participants will be contacted by a member of the research team or a CSO and invited to consent to participate in a qualitative interview or focus group. Prior to giving informed consent, the potential participant will be informed that semi-structured interviews and focus groups will be digitally recorded, and that anonymised quotations might be used in reports/publications, and that any recording will be stored securely for the duration of the study and then destroyed.

Consent provisions for collection and use of participant data and biological specimens

No biological specimens will be acquired, transferred and stored during the study.

Withdrawal from study

All consenting participants in WP2, WP4 and WP5 will be free to withdraw their participation from the study at any time during the recruitment and data collection process. When potential participants express an interest in joining the study, either clinical studies officers or a member of the study team will discuss with them all the relevant information about the study, including that they are free to withdraw at any time and that whether they join the study or not (or discontinue participation), there will be no impact on the care they receive.

Where (service user) participants indicate their withdrawal from the cohort study (WP4), their withdrawal will be recorded and only (EPR) data collected prior to withdrawal date will be used (unless participants request that no data is retained). A dated participant withdrawal form will be completed indicating whether data collected to date is to be retained in the study or not. No replacement for (withdrawing) individuals in the cohort study will be sought.

Where (service user, staff) participants indicate their intent to withdrawal from the qualitative study (WP5), the interview will be terminated and no data will be used in analyses. Participants for interviews will be replaced so long as this can occur with the study recruitment window and appropriately matched individuals can be recruited. Where a service user participant is lost to (9-month) follow up post-discharged, a matched individual will be identified through the MHDU record and invited to interview. Carer participants may also choose to withdraw. If a carer interview participant withdraws, the interview will be terminated and no data from the interview will be used in analyses. If a carer participating in a focus group chooses to withdraw, they are free to leave the focus group, but data from the focus group will be used in the analysis. This is because it would be unfair on the other focus group participants to not use the data from the focus group.

7.3.3 Data collection tool

Please see relevant sections above (WP1, WP2, WP3, WP4, WP5, WP6) for details of data collection in each work package.

DECISION

7.3.4 Biological Sample Handling

No biological specimens will be acquired, transferred and stored during the study.

8 ETHICAL AND REGULATORY CONSIDERATIONS

The project will be submitted for ethical approval from an NHS Research Ethics Committee. There are particular ethical issues around conducting qualitative interviews about sensitive topics such as mental health crisis, and around use of routinely collected data for research, that will be properly addressed by the team in the ethics application. Health Research Authority approval will also be sought in order that participating NHS Trusts can confirm capacity and capability to support the research.

The site will conduct the trial in compliance with the protocol as agreed by the Sponsor and as given favourable opinion by the Research Ethics Committee (REC).

Participant recruitment at a site (WP4, WP5) will only commence once evidence of the following approval/essential documents are in place:

1. REC approval, including HRA approval
2. Final sponsorship
3. Host site permission/ Confirmation of Capacity and Capability

8.1 Assessment and management of risk

If any inadvertent or incidental data came to light during the course of the study – from this or other studies – that are of potential relevance for participants or their families (e.g. are either indicative of risk to participants or impact on the way in which the study is conducted), participants will be informed of this information and, on the advice of the approving REC, invited to consent to their continued involvement in the study.

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

Before the start of the study, a favourable opinion will be sought from an appropriate REC for the study protocol, informed consent forms and other relevant documents e.g. advertisements.

For HRA- NHS REC reviewed research

- Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at site.
- It is the Chief Investigator's responsibility to produce the annual reports and submit the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended.

- The Chief Investigator will notify the REC of the end of the study within one year after the end of the study.
- If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination.

Regulatory Review & Compliance

Before any site can enrol patients into the study, the Chief Investigator/Principal 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.

Amendments

For any amendment to the study, the Chief Investigator or designee, in agreement with the sponsor will submit information to the appropriate body 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.

8.3 Peer review

The study has been subject to extensive double-blind peer review overseen by the funder, National Institute of Health Research, Health Services and Delivery Research (HS&DR) Programme.

8.4 Patient & Public Involvement

Patient & Public Involvement (PPI) is integral to this proposal in a number of ways:

Proposal development: Public and patient involvement has been integral to the development of the DECISION research project. St George's Peer Expertise in Education & Research (PEER) service user reference group have helped to inform the development of the research proposal, with particular attention paid to how being involved in the study may feel for service users. A panel of service users was convened to discuss the types of questions to ask in qualitative interviews, and again to refine and develop the recruitment and informed consent processes. Experienced service user researchers (including co-applicant Kati Turner (KT)) have also been involved in writing the research proposal, in particular PPI components, ensuring that their lived experiences were applied to issues such as recruitment of participants and support of service user researchers and around developing the process of interpreting qualitative datasets

Planned PPI within the study: Service user researchers and other team members working from lived experience perspectives will play an integral role in the research decision making process across the project as members of the research team. We will employ service user researchers to undertake and analyse qualitative interviews. Service user researchers will receive specially designed training on using

lived experience in their work, delivered by an experienced service user researcher co-investigator, who will also provide mentoring to service user researchers.

A Lived Experience Advisory Panel (LEAP) will be convened comprising representatives of our PEER group, people who have had personal experience of the MDHU at the lead site and carers of people who have experienced mental health crisis. Two places on the LEAP will be protected for people from Black Asian & Minority Ethnic (BAME) communities (although BAME places will not be limited to two). The service user researcher will also facilitate the LEAP with KT's support. The LEAP will six times during the study lifespan. Its members will work with the research team to provide input into (but not confined to): study design and methodology; ethics and associated concerns; research tools (interview schedule, participant information sheets, lay summaries and reports); interpretive workshops; planning and undertaking dissemination. Dissemination will be a standing item on the LEAP agenda and we will feed the LEAP's input on dissemination into the Project Management Group, including for publications, presentation and outputs for PPI audiences. We will bring proposals for presentations and publications to the LEAP for discussion and input.

There will be lived experience represented on the study steering committee by two people independent of the research team with expertise in service user involvement and leadership in research. The service user researcher, KT and research team will be able to consult with lived experience steering committee representative on all aspects of study design and ethics.

KT as co-applicant will oversee PPI within the project. She will liaise closely with the service user researcher and the LEAP and provide support, mentoring and any training as necessary. We see this as key to the success of PPI and have produced best practice guidance to support this.[77] We have over 12 years' experience of this approach as a research group and have an established support structure and culture within the department which supports and encourages research coproduction. KT will be responsible for ensuring that the research is informed by a lived experience throughout and that we successfully deliver on our commitment to best practice in. KT will also document PPI activity in order to be able to accurately assess where and how the lived experience perspective has been used throughout the study and the impact this has had, both on research process and research findings.

8.5 Protocol compliance

Protocol deviations, non-compliances, or breaches are departures from the approved protocol.

All protocol deviations must be adequately documented on the relevant forms and reported to the Chief Investigator and Sponsor immediately.

Deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach.

8.6 Data protection and patient confidentiality

All data should be handled in accordance with the Data Protection Act 2018 (UK implementation of the EU General Data Protection Regulation (GDPR)).

For WP2 and WP3, aggregated service use data over the relevant study period weeks will be sourced locally from mental health Trusts and A&E departments (acute hospital Trusts) of participating MHDU/non-MHDU sites through contact with Information Management & Technology (IMT) departments at each Trust and from Hospital Episodes Statistics (HES; bespoke extract from Data Access Request Service - see http://content.digital.nhs.uk/hes for details). Data from relevant IMT departments will be electronic transferred to the research team via password-protected data files.

Information Management Services personnel within the NHS Trusts from which participants are recruited will access participant's Electronic Patient Record in order to collate and pseudonymise the service use data required for study analyses (WP4). These are personnel who would normally have access to this data for routine information management purposes within the NHS provider organisation. Electronic transfer of the aggregate of this data between NHS Trusts and the lead university (St George's, University of London [SGUL]) will be by encrypted email transfer.

This data will be pseudonymised and will not be shared by SGUL with any third party or linked with other data that might render the information more identifiable. Participants will be asked for their consent for this to take place.

Personal addresses, 'phone numbers or email addresses, where given to members of the research team by participants as preferred contact details for the purposes of arranging follow-up and sending study findings, will be kept in a single Participant Identification Log at each study site only. This and the Informed Consent Form, being the only documents that cross references personal contact details to the participants' study identification numbers, are held securely and separately from any other data about the participant. Any publication of direct quotation of participants (as qualitative interview data) will not be identified, and every effort will be made to ensure that the quotation does not include any other information that might identify that individual (e.g. names, places or other contextual information). Participants will be asked to give their informed consent to this taking place.

In accordance with the Standard Operating Procedures of the study sponsor, all data will be pseudonymised at the point of data collection, identifiable only by the participant's study information number. Identifiable details will be kept in a single Participant Identification Log (and on the Informed Consent Form) at each study site only, these being the only documents that cross references personal contact details to the participant's study identification number. This log will be held securely and separately from any other data about the participant. Paper and electronic records of data will only be identified by the participant study identification number only.

All data in manual files will be securely held in locked filing cabinets in locked offices in NHS or University premises (in some study sites researchers will be based in a university, and in other in the NHS). All data held on NHS or university computers will be securely held on password protected servers and not on individual PCs.

Quantitative data relating will be analysed by researchers at the lead university (JS, assisted by LG), based at St George's, University of London. Health Economic analyses will be analysed by the Health Economist (at the London School of Economics and Political Science) using relevant software (e.g., SPSS, Stata). Qualitative analyses will be undertaken by the research team working collaboratively

(including research assistants based within each study site, the project manager and chief investigator) using relevant software (NVivo).

Quality Control will be applied at each stage of data handling to ensure that all data are reliable and have been processed correctly. A Data Protection Impact Assessment (DPIA) will be completed by the Sponsor for all aspects of the study and reviewed and approved by the Sponsor's Data Protection Officer and Information Governance Manager. The DPIA will specify datasets, the type of data that comprises each dataset and how each dataset will be processed, procedures for informing individuals about how and why personal data is being collected and processed, and data transfer and security arrangements. A schedule for robust audit of all data processing will be agreed as part of that assessment. Data transfer between study sites (NHS Trusts) and the Sponsor will be governed by a Data Sharing Agreement incorporated into the Capacity and Capability agreement between Sponsor and study sites. It is the Principle Investigator's responsibility to ensure the accuracy of all data entered and recorded in datasets. A Staff Delegation of Responsibilities Log JRESLOG0004 will identify all personnel responsible for data collection, entry, handling and managing the database.

8.7 Indemnity

St George's, University of London holds insurance to cover participants for injury caused by their participation in the study. Participants may be able to claim compensation if they can prove that St George's has been negligent. This includes negligence in the writing of the protocol, or selection of trial resources.

Where the Study is conducted in a hospital, the hospital has a duty of care to participants. St George's University of London will not accept liability for any breach in the hospital's duty of care, or any negligence on the part of hospital employees.

If a participant indicates that they wish to make a claim for compensation, this needs to be brought to the attention of St George's University of London immediately.

Failure to alert St George's University of London without delay and to comply with requests for information by the sponsor or any designated Agents may lead to a lack of insurance cover for the incident.

8.8 Access to the final study dataset

The chief investigator and the statistical experts will have access to the full datasets. Data analysis and appropriate sections of the datasets will be shared with coinvestigators.

9 DISSEMINIATION POLICY

9.1 Dissemination policy

Publication: "Any activity that discloses, outside of the circle of trial investigators, any final or interim data or results of the Trial, or any details of the Trial methodology that have not been made public by the Sponsor including, for example, presentations at symposia, national or regional professional meetings, publications in journals, theses or dissertations."

All scientific contributors to the Trial have a responsibility to ensure that results of scientific interest arising from Trial are appropriately published and disseminated. The Sponsor has a firm commitment to publish the results of the Trial in a transparent and unbiased manner without consideration for commercial objectives.

To maximise the impact and scientific validity of the Trial, data shall be consolidated over the duration of the trial, reviewed internally among all investigators and not be submitted for publication prematurely. Lead in any publications arising from the Trial shall lie with the Sponsor in the first instance.

Before the official completion of the Trial,

All publications during this period are subject to permission by the Sponsor. If an investigator wishes to publish a sub-set of data without permission by the Sponsor during this period, the **Steering Committee/the Funder** shall have the final say.

Exempt from this requirement are student theses that can be submitted for confidential evaluation but are subject to embargo for a period not shorter than the anticipated remaining duration of the trial.

Up to 180 days after the official completion of the Trial

During this period the Chief Investigator shall liaise with all investigators and strive to consolidate data and results and submit a manuscript for peer-review with a view to publication in a reputable academic journal or similar outlet as the Main Publication.

- The Chief Investigator shall be senior and corresponding author of the Main Publication.
- Insofar as compatible with the policies of the publication outlet and good academic practice, the other Investigators shall be listed in alphabetic order.
- Providers of analytical or technical services shall be acknowledged, but will only be listed as co-authors if their services were provided in a non-routine manner as part of a scientific collaboration.
- Members of the Steering Group shall only be acknowledged as co-authors if they contributed in other capacities as well.
- If there are disagreements about the substance, content, style, conclusions, or author list of the Main Publication, the Chief Investigator shall ask the Steering Group to arbitrate.

Beyond 180 days after the official completion of the Trial

After the Main Publication or after 180 days from Trial end date any Investigator or group of investigators may prepare further publications. In order to ensure that the Sponsor will be able to make comments and suggestions where pertinent, material for public dissemination will be submitted to the Sponsor for review at least sixty (60) days prior to submission for publication, public dissemination, or review by a publication committee. Sponsor's reasonable comments shall be reflected. All publications related to the Trial shall credit the Chief and Co-Investigators as co-authors where this would be in accordance with normal academic practice and shall acknowledge the Sponsor and the Funders.

9.2 Archiving Arrangements

Each site will be responsible for their onsite level study archiving. The trial essential TMF along with any central trial database will be archived in accordance with the sponsor SOP.

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11. APPENDICIES

11.1 Appendix 1 Research questions

Work Package (WP)	Question	Method	Level	Data source
WP 1 – Review & mapping	1) What is the range of hospital-based, short stay interventions internationally designed to reduce standard admissions to acute psychiatric inpatient care and what is their effectiveness?	Systematic review	Macro	Peer reviewed literature
	2) What is the scope and prevalence of MHDUs nationally and how are they configured?	Service mapping	Macro	Telephone interviews, Mental Health Trust strategic leads
WP2/WP3 – Interrupted time series / Synthetic control study	3a) How has the introduction of MHDUs impacted on psychiatric inpatient admissions and A&E psychiatric episodes/breaches?	Interrupted time series analysis Qualitative interview study	Meso	Routinely collected, aggregate data from Mental Health NHS Trusts and A&E Departments at Hospital NHS Trusts
	3b) What is the impact of policy changes at national level?		Macro	Comparison site time series data Semi-structured interviews with Mental Health Trust and A&E strategic leads and commissioners
WP4 – Cohort study	3) How has the introduction of MHDUs impacted on psychiatric inpatient admissions and A&E psychiatric episodes/breaches? 4) What are the care pathways before and following an admission to the MHDU? 5) What is the impact of the introduction of MHDUs on inequalities of access to acute mental health services?	Cohort study	Meso	Routinely collected, individual data of mental health and A&E service use (new admissions to MHDU) Participant characteristics (socio-demographic, psychiatric history etc)
WP5 – Qualitative study	6) How do service users/caters experience MHDUs, as well as crisis care pathways before and after admission to MHDU?	Qualitative interview study	Micro	Semi-structured interviews with service users admitted to MHDU
	7) How are decisions made about referral and admission to MHDU, and assessment and onward signposting & referral?			Semi-structured interviews with A&E, Mental Health Trust crisis services and MHDU staff
WP6. Economic analysis	8) How do the economic costs and impacts of MHDUs compare with areas without MHDUs? 9) How do the costs for individual service users post MHDU implementation compare with their	Interrupted time series Cohort study	Meso Macro	Economic analysis of aggregate and individual level Mental Health Trust and A&E service use data Appropriate unit cost data attached to services

	costs prior to the introduction of MHDUs to crisis care pathways, as well as in areas without MHDUs?			Liaison with MHDU service providers and use of administrative data to determine resources used to deliver MHDU services
	10) What are the potential cost impacts of a) alternative configuration of MHDU pathways or access by specific populations, and b) roll out and scale up of MHDUs nationally?	All	Macro	As above plus qualitative pathway stories, referral source and participant characteristics data

11.2 Appendix 2

Amendment Log				
Amendment No.	**Protocol version no.**	**Date issued**	**Author(s) of changes**	**Details of changes made**