# MINDS Study

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| Full title: | Coproducing improved mental health acute inpatient discharge using a Systems Approach: MINDS study |
| Version: | 3.0 |
| Date: | 24May2023 |
| NIHR | 133013 |
| Chief Investigators: | Dr Jon Wilson, Consultant Psychiatrist<br>Sarah Rae, Expert by Experience |

# Contents

# 1. Project overview

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| Funder | NIHR<br>This study is funded by the NIHR HSDR Programme (NIHR133013). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care. |
| Sponsor | Norfolk and Suffolk NHS Foundation Trust |
| Contact for Public Enquiries | minds.project@nsft.nhs.uk |
| Title | Coproducing an improved mental health acute inpatient discharge intervention using a Systems Approach: MINDS study Research Plan. Protocol for Work Package 1. |
| Committees | Project Management Group (PMG)<br>Study Steering Committee (SSC)<br>Lived Experience Advisory Group (LEAG) |
| Recruiting Countries | England |
| Sites | East London NHS Foundation Trust, Hertfordshire Foundation Trust, Norfolk and Suffolk Foundation Trust |
| Research Questions | 1. What are the requirements of service users being discharged from adult mental health wards?<br>2. How is personalised discharge planning understood by service users, carers and staff and what do they identify as key outcomes to determine this?<br>3. How do active components of discharge planning and their relationships to each other at individual, interpersonal, community, organisational and policy levels meet service user discharge requirements?<br>4. How does an understanding of the interaction between system and service user requirements inform an SDCA that supports discharge planning?<br>5. How can we implement an SDCA to improve SU outcomes? |
| Eligibility Criteria | *Clinical population:*<br>For interviews/focus groups: All service users (18 years and over), under the care of the Mental Health Trusts involved, with capacity to give informed consent, admitted within the previous 12 months to study wards will be |

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| | eligible for inclusion in the study. Participants for interviews and focus groups will be in the community, under a community mental health team, at time of participation.<br>For Ward based observations: All service users (18 years and over) currently admitted on one of the selected wards, with capacity to give verbal informed consent.<br>*Staff:*<br>All staff with roles in inpatient discharge, working in one of the three Mental Health Trust sites, at service user, administrative and management levels will be eligible.<br>*Carers/supporters:*<br>All carers/supporters of people who have experienced inpatient discharge in one of the participating Mental Health Trusts will be eligible. |
| Study Design | *Work Package 1:*<br>Realist Review and Evaluation: Case Design – Interviews and Focus Groups (with Service Users, Carers and staff) and Ward Observations<br>*Work Package 2:*<br>Engineering better care Approach, including exploratory design workshops, Coproduction of the SCDA, and stakeholder feedback focus groups<br>*Work Package 3:*<br>Mixed methods Service Evaluation |

## 2. Abbreviations

| | |
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| CMOCs | Context- Mechanism Outcome Configurations |
| CPD | Continuing Professional Development |
| CQC | Care Quality Commission |
| EBC | Engineering Better Care |
| GDPR | General Data Protection Regulations |
| LEAG | Lived Experience Advisory Group |
| NICE | National Institute for Clinical Excellence |
| NIHR | National Institute of Health Research |
| PI | Principal Investigator |
| PPI | Public and Patient Involvement |

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| PIS | Participant Information Sheet |
| PT | Programme Theory |
| SDCA | Systemic Discharge Care Approach |
| SSC | Study Steering Committee |
| SU | Service User |
| WP | Work Package |
| IRAS | Integrated Research Application System (ethics application) |
| RAMESES | Realist And Meta-narrative Evidence Syntheses: Evolving Standards |

# 3. Background

Around 50,000 people are discharged from acute mental health settings annually[1]. The transition period following discharge is high risk in terms of relapse, readmission, and suicide[2-5]. Prior to COVID-19, around 13% of service users in England were readmitted shorty after discharge[2] and 32% of suicides occurred within 2 weeks[4,5]. Research and our PPI work indicate that discharge is one of the highest risk areas of service provision and that a wide range of factors contribute to relapse following discharge e.g. feeling overwhelmed, managing mental health symptoms and the day-to-day pressures of paying bills, grocery shopping and caring for dependants[3,6,7]. COVID-19 has complicated this further with a significant increase in rapid discharge[8,9] exacerbation of mental health difficulty[7,10] and social distancing rules that impact social support and the management of day-to-day tasks. There is also a risk that pandemic could add systemic pressures that result in further neglect of service user need and practice that carries a greater risk of harm for service users.

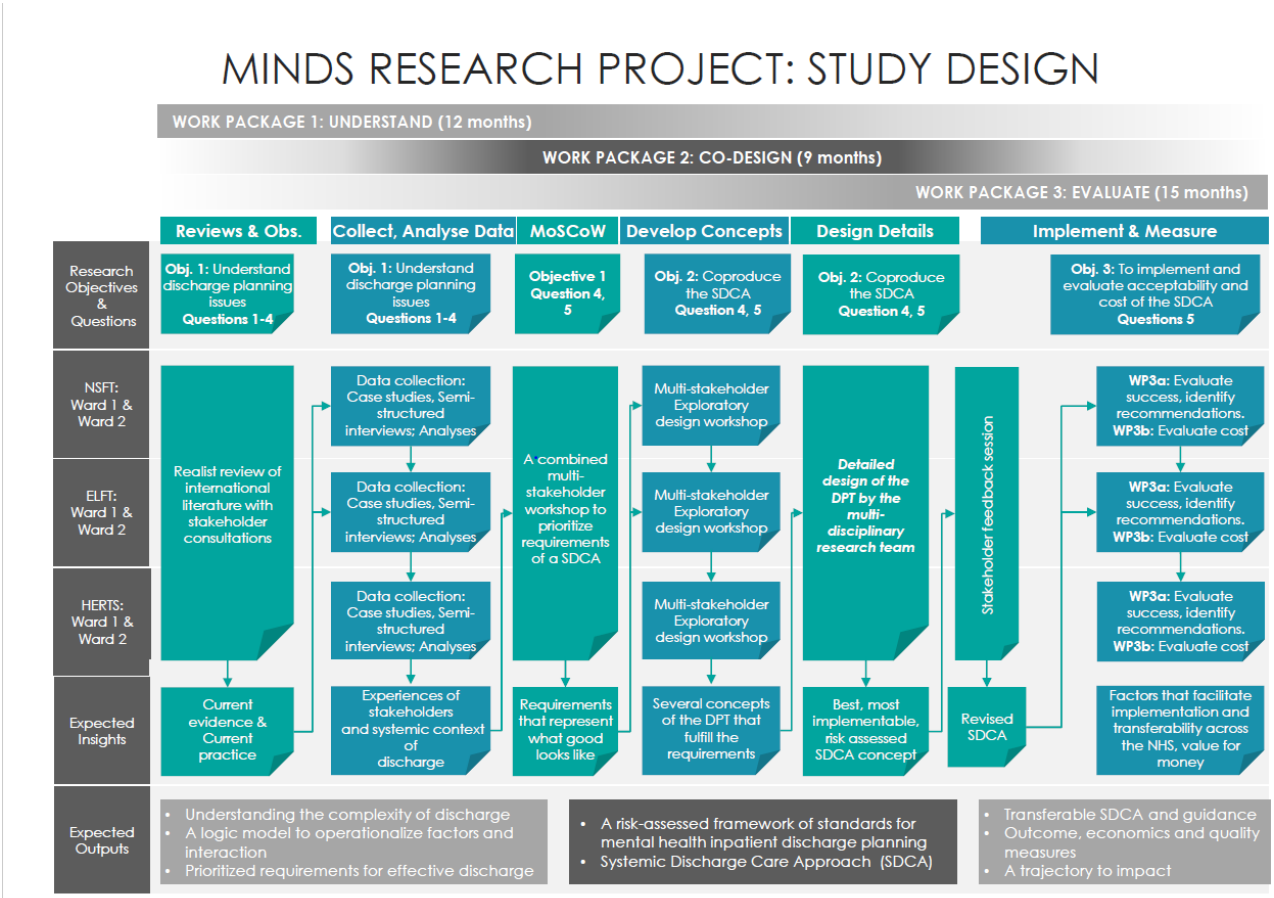
Discharge planning supports transition and reduces risk by identifying post-discharge needs and how service users could work with service providers to manage these[3,11]. National Institute of Health and Care Excellence (NICE) guidance and the Care Quality Commission (CQC) identify that discharge planning should be collaborative and led by individual need[12,13] but there is limited clarity regarding how this should be achieved. The intransigency of negative ward cultures has been identified as a barrier to the implementation of clinical guidance generally[14,15]. This study aims to directly address these barriers potentially devising new ways of working to eliminate them.

Research findings and our Patient and Public Involvement (PPI) work show that for service users discharge is often inadequately planned with little involvement from them, resulting in poor transition and increased risk[16-19]. A Mind survey of 1,221 people who had experienced discharge found that 33%

were given either no or insufficient notice of discharge and for 37% there was no plan post discharge[20]. To capture experience of discharge planning, we conducted a national survey of 120 people, finding that over half had no or little involvement in planning and just 17% felt very involved. Findings and our PPI work suggest these problems have been further exacerbated by COVID-19, which has put increased pressure on NHS services.

Service users in the PPI survey told us that lack of a discharge plan leaves people feeling overwhelmed, distressed and at risk of relapse. Through our ongoing engagement with staff we have learnt that they are unsure of how to best plan discharge. Additionally, previous interventions neglect complex systemic factors that either support or undermine discharge planning[21] including (but not limited to) policy and protocols, workforce arrangements, bed capacity, administrative burden and communication habits.

The MINDs study is separated into three Work packages (WP, Figure 1), with the aim to synthesise data via a Realist Review and Evaluation (WP1), to develop a discharge care approach (WP2), and to conduct a service evaluation to test and evaluate the tool in practice (WP3). The MINDS study is a co-produced study, bringing together expertise from people with lived experience, their supporters and staff working in this field, continuously and iteratively. The following sections outline each WP's aims, objectives, study design and output.




# 4. Work Package 1 – Realist Review and Evaluation

Work package one has Ethical Approval – IRAS 315309

## 4.1 Aims and objectives

The overarching project aim is thus to co-produce and evaluate an intervention to improve discharge from acute mental health wards.

The aim for work package 1 is to build, test and refine an evidence-based programme theory of what supports personalised discharge planning in adult acute mental health settings.

**WP1 objectives**

The primary objective for work package 1 is to understand discharge planning as a complex intervention within complex ward systems and the discharge preparation and planning requirements of people leaving the ward. Three associated objectives are:

1) Conduct a realist review using the Engineering Better Care systems approach to map and explain the relationship between key factors involved in discharge planning.
2) Test programme theories in a realist evaluation involving case studies with three Mental Health Trusts in the East of England and London.
3) Refine programme theories to inform co-design work in WP2.

## 4.2 Study design

This work package consists of two phases:

1) a realist (literature) review
2) a realist evaluation using a case study design in three Mental Health Trusts.

## 4.3 Realist review

The evidence base for discharge planning is heterogeneous[21] and therefore requires an approach to synthesis that can incorporate this. Realist review can draw together evidence across diverse sources and interventions described in the literature to develop theories that explains the inconsistences and variations in outcomes. By exploring contextual factors and their relationships to outcomes through causal mechanisms, the review will set out what works, for whom, in what circumstances.

The realist review will synthesise international evidence on service user, carer and staff experiences of discharge preparation and planning and on interventions for discharge planning. The review will result in evidence-based theories (initial programme theory) of discharge planning that include factors across all system levels to explain post-discharge outcomes.

The review will consist of three iterative stages over 12 months:

Stage 1: Defining review scope: concept mining and theory development

Stage 2: Theory testing and refinement

Stage 3: Analysis and synthesis

The realist review protocol is registered on PROSPERO (CRD42021293255). As the realist review is a literature review, no ethical approval is required for this part of WP1.

## 4.4 Realist evaluation

The realist evaluation is the data collection part of Work Package 1. Collecting additional data will refine the programme theories to set out what needs to be in place across different system levels for personalised discharge preparation and planning that meets service user requirements and is deliverable by staff. We will conduct a realist evaluation using a case study design. Data collection methods in realist evaluations are selected for their potential to contribute to theory testing and refinement[22]. We will use an embedded case study design[33] with multiple data collection methods to investigate, in-depth, discharge planning in three mental health trusts. Cases will be defined as 1) the Trust, 2) the ward, 3) the service user. We will conduct Service User, carer and staff interviews and focus groups and ward observations, to generate data to refine our programme theory (see Figure 1).

This will support investigation of the programme theory across the system (e.g., organisation level, service level, individual level) and allows us to test programme theory components that are common to and differ within and across sites.

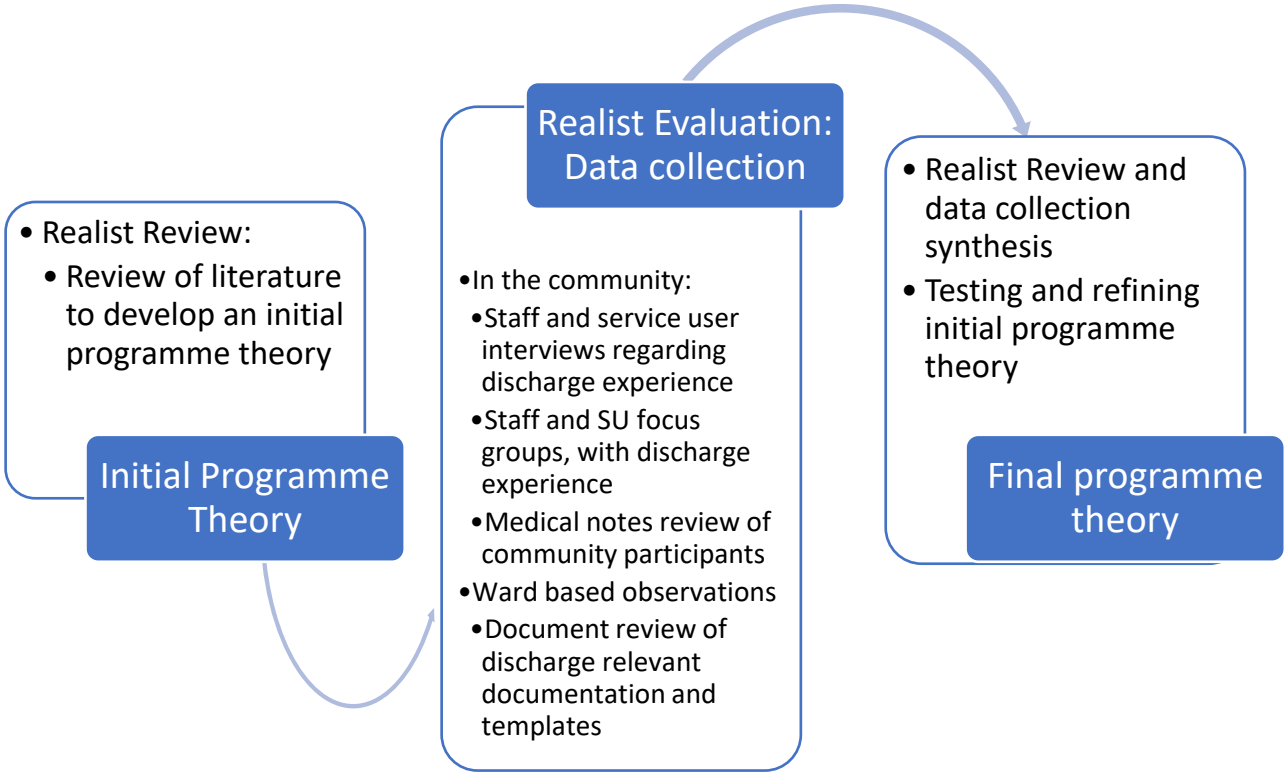



*Figure 1 Work Package 1 Project Work Flow*

### 4.2.1 Recruitment

*Sites*

Three Mental Health Trusts have agreed to participate in the study (East London Foundation Trust, Hertfordshire Foundation Trust and Norfolk and Suffolk Foundation Trust). These Trusts were purposively sampled as they represent mental health trusts with different local demographic profiles of the populations, are geographically distinct and have mixed CQC ratings. Population statistics[23] shows the percentage of people who identify as from a non-white British background for Norfolk (9.37%), Suffolk (11.09%), Hertfordshire (18.44%) and East London (45%). Ethnic minorities service users have been reported to be disproportionately detained under the Mental Health Act, 1983[24-26] and ethnic minority groups are overrepresented among psychiatric inpatients in the NHS[27] Providing better mental health services for people from ethnic minorities is a national priority[28,29].

*Recruitment for interviews and focus groups:*

The study will be promoted in community mental health teams in the 3 sites. People who have seen or heard promotional materials and are interested in participating in the research will either be directed to make contact with the research team or will consent to their mental health care professional, or the local participation team (that is people who are employed by the mental health trust to support participation in service development, interviews and research) to be contacted by the research team to discuss participation. We will also ask the Community Mental Health Team, associated admin, or Business Support Officers in participating mental health Trusts to screen their caseload and identify any participants who may meet the study's inclusion criteria, in line with trust policy. Potentially eligible participants will be contact by their clinical team to enquire if they are interested in the MINDS project and if so, will be referred to the research team.

Once contact is made, the research team member will introduce themselves and the study. The study's aim and implications of participation will be described. There will be the opportunity to ask questions about the study or implications for participation at this point. If the individual is interested in participation, arrangements will be made for them to receive a Participant Information Sheet (PIS) either electronically via email, a hard copy in the post, or both (depending on individual preference).

Sixty participants (n = 20 participants from each of the 3 sites), will be recruited for in-depth interviews and focus groups. This will include members of staff, and service users who have been discharged from an adult acute mental health unit from the recruited Trusts in the past 12 months and their carers/supporters. Staff will include, but are not limited to allied health professionals, medics, nurses, support workers, peer workers, bed managers, ward managers and discharge coordinators. Staff, service user and carer selection will be informed by their potential to contribute to the development of the programme theories. We aim to conduct up to 10 focus groups and up to 40 interviews with service users and staff. The number of focus groups and interviews will be determined by the quality of data available, as well as the progress of the programme theory testing.

The sample sizes are considered adequate to ensure enough data is collected to test and refine the programme theories[31,32].

*Recruitment for ward based observations:*

Two adult general acute inpatient mental health wards will be recruited from each of three study sites (n=6 mental health wards). The findings from the realist review, in combination with guidance from the Lived Experience Advisory Group (LEAG), will determine the final selection of the 6 wards. Wards will be selected to maximise heterogeneity in terms of rural/urban location, and social demographics of patient populations. Wards will be eligible that:

- Have managers who are supportive of the study and can identify at least one member of staff to support researchers access and navigation of the ward for the duration of the study
- Are considered to have inherent characteristics that will be important for testing programme theories, (e.g., access to staff with explicit responsibilities for discharge planning)

### 4.2.2. Eligibility

*Clinical population:*

For interviews/focus groups: All service users (18 years and over), under the care of the Mental Health Trusts involved, with capacity to give informed consent, admitted within the previous 12 months to study wards will be eligible for inclusion in the study. Participants for interviews and focus groups will be in the community, under a community mental health team, at time of participation.

For Ward based observations: All service users (18 years and over) currently admitted on one of the selected wards, with capacity to give verbal informed consent.

*Staff:*

All staff who have roles that impact on inpatient discharge (both directly and indirectly including management), working in one of the three Mental Health Trust sites, at service user, administrative and management levels will be eligible.

*Carers/supporters:*

All carers/supporters of people who have experienced inpatient discharge in one of the participating Mental Health Trusts will be eligible

### 4.2.3 Consent

There are three studies within WP1 which require consent:

1) Staff and service user & carer interviews
2) Staff and service user focus groups
3) Ward-based observations

We are thus consenting two groups of service users, carers/supporters, and staff:

1) Service users who are currently admitted to on one of the selected wards for ward-based observations,
2) Service users in the community who have had experience of discharge from a mental health ward within the last 12 months for interviews and focus groups
3) Carers/supporters for interviews and focus groups
4) Staff who have roles that impact on inpatient discharge.

For those service users in the community, we will also request access to their medical records, to retrospectively collect discharge relevant data (as outlined in 4.2.4 Data Collection).

The consent process differs for these groups. Participants will be made aware that their participation is voluntary and of their right to withdraw at any time without giving a reason and without their care or work being affected. Consent procedures and documentation and Participant Information Sheets have been co-produced with the LEAG.

Interviews and focus groups (Service users & carers)- written consent

Participants will be recruited as described above (4.2.1 Recruitment). Once contact has been made, the study's aim and implications of participation will be described. There will be the opportunity to ask questions about the study or implications for participation at this point. If the individual is interested in participation, arrangements will be made for them to receive a Participant Information Sheet (PIS) either electronically via email, a hard copy in the post, or both (depending on individual preference). The research team member will then arrange a consent meeting (to take place a minimum of 48 hours after receipt of the PIS). The consent meeting will either be in person or remotely over a secure platform (depending on the preference of the potential participant, issues of practicality

(e.g. distance to the participant), and status of the COVID-19 pandemic). During the consent meeting it will be established that the participant has read the PIS, understands the nature of the study and implications of participation and has any more questions answered. Capacity to consent will be assessed by the research team member. The consent form will be then be completed (if the consent meeting is remote the potential participant will be instructed to do this on a hard copy that has been sent in advance with a prepaid envelope to return a hard copy, or they will be emailed with an electronic consent form which they will return upon completion). The researcher will make it clear that consenting to the study is voluntary and people are free to withdraw at any time without giving a reason and this will not impact any aspect of their relationship with the participating mental health trust. We will retain data already collected to the point of withdrawal, unless requested otherwise.

Interviews and focus groups (staff) – written consent

The research team will provide staff with information about the study in appropriate team meetings and explore the possibility of arranging to meet with the ward managers so that they are offered the opportunity to ask relevant questions. Staff members of the recruited adult acute mental health wards will also be informed of the study by the ward managers. The research team will provide the staff members with the PIS form. After at least 48 hours, researchers will establish interest in participation and arrange a consent meeting. As with service user participants, the consent meeting will take place either in person or remotely depending on the person's preference and issues of practicality. The consent meeting will establish that the participant has read the PIS, understood the nature of the study, and potential implications around their participation, and answer any questions they have in relation to the study. Staff members met with face-to-face will be provided with a hard copy of the consent form, which they will be asked to return to the research team following completion. Staff members met with remotely and will either sign on-line or be sent the electronic consent form via email, which they will be asked to return it to the research team upon completion (as per trust policy).

Ward-based observations – verbal consent

We will be undertaking ward-based observations of contexts and activities relevant to discharge preparation and planning. These are listed below. The observations will be conducted by research assistant psychologists at each site and/or the study manager. All observers will require a contract from the the participating trusts and will have relevant DBS checks and understanding of relevant clinical policy and protocol. The 6 wards that are participating in the study will have a good understanding of the project from staff – including a prior awareness and managerial agreement of the ward-based observations. On the days of the observation, information posters will be displayed in areas where the observations are taking place. All staff and service users will be given verbal

information and a simplified PIS about the reason for the observations and be asked to verbally opt out of the observations if they do not consent to be observed. This simplified consent process has been selected to minimise burden and confusion for service users on the ward. This consent procedure is in line with other ward-based observation studies in mental health hospitals.[39] Observers will be wearing a lanyard that makes it clear who they are and that they are undertaking observations. If they are approached by a participant, they will answer any questions openly and transparently about the reasons for the observations. Service users will be informed that they can choose to opt out of the observations at any time (they will also of course be free to leave whatever space is being observed). Staff will also be asked to opt out verbally if they do not want to be observed (we are aware that this might limit the capacity for observation, but the service user and staff's comfort and wishes will be prioritised over any research activity). Staff will also be informed that if they are concerned about observations including a particular service user, or if they become concerned about anybody during the observation, they will ask for the observation to be moved or terminated.

### 4.2.4 Data collection methods

Realist evaluation data collection methods are theory driven. These methods have been chosen based on their ability to test and refine the initial programme theory (developed as part of the realist review). As outlined above, data will be collected to refine this theory:

1) Interviews and focus groups
2) Ward based Observations
3) Medical Notes Review
4) Documentary Review (does not require consent)

*Interviews and focus groups:*

As described above, data collection will serve two purposes:

1) Gather data on contexts, processes and experiences of discharge planning:

- Staff will be asked to explain their role in the trust, any processes, resources or strategies they use in discharge planning and their experiences of discharge planning with service users.

- Service users who have been discharged from one of the adult inpatient units from the participating mental health trusts in the last 12 months will be asked about their experiences pre-, during and post-admission that relate to discharge planning.
- This will establish the personal and professional context of participants and allow for potential, as yet undefined concepts to be identified.

2) Test the theory. This will take the form of a 'teacher-learner' cycle[31]. The initial programme theory (as identified in the realist review) will be set out to the participant, who will then be invited to comment or provide detail related to the theory. In this way they will be encouraged to confirm, refute or expand the ideas based on their experience.

An interview and focus group topic guide has been developed in collaboration with the LEAG that can be adapted to recognise each participant's potential to contribute to theory testing on areas familiar to them and include new concepts uncovered during data collection.

Interviews and focus groups will be recorded and transcribed. Participants will be given a personal identifier once they give written consent to participate in the interviews or focus groups. This unique identifier will be used throughout the data collection. All collected data will be anonymous by the researcher at the earliest opportunity, such as at the time of interview transcriptions.

*Ward-based Observation*:

In total, we plan to conduct ward-based observations 4 days per ward (total = 24 days). They will consist of:

a) Ward-based observations to understand local context of discharge planning including: physical and social environment, staff and service user mix and how interactions between staff and service users are conducted. This will inform an understanding of how different contextual factors within and across the sites might contribute to different discharge processes, experiences and outcomes.

b) Targeted ward-based observations of communal areas, discharge conversations, relevant meetings and ward rounds[35,36]. This will aid understanding of what factors are prioritised during discharge planning and to map the process from a service user's admission to discharge. This will include evidence of who talks to who about what, how they are involved and why.

A semi-structured topic guide for observations will be used. Ward observations will seek to understand how processes and practices for discharge planning takes place in wards that separately will be contextually different but are subject to national standards.

Observations will also provide opportunities for the researcher to clarify their understanding of situations, ask participants why they did something and understand their experience of an action in-the-moment. This method not only provides rich descriptions of context and outcomes, but also provides insights into the causal mechanisms[37]. Data will be collected in the format of field notes, using a trial specific template, which has been developed with LEAG input. This is paper based and will be stored as outlined in 5.6 Data protection. Data will be anonymised and transcribed at the earliest opportunity.

*Medical notes review*: Relevant sections of the medical notes of service users recruited to the interviews and focus groups (in the community) will be reviewed with their informed consent (as outlined in 4.2.3 Consent). Trial relevant data will be collected based on a trial specific template. Anonymised data will be collected to describe service user characteristics and evidence of discharge planning discussions. This information will be used to provide aggregated service user characteristics and, in conjunction with interview and ward observation data, to map the discharge planning process of service users that can be compared across sites and service user characteristics.

*Documentary review*: Pawson and Tilley (1997)[22] highlight that programme theories for interventions may be evident in policy and strategy documents. Documentary review will provide an account of stated organisational aims and priorities for discharge planning and demonstrate how discharge planning documents are structured to support the process. Documents will be identified with the support of staff working at the sites and are likely to include reports related to discharge processes and outcomes, organisational strategies related to discharge, discharge planning documents and templates and information leaflets given to service users.

### 4.2.5 Analysis

As with the realist review, analysis will commence with data collection, be iterative and take multiple forms to understand and interrogate the data. NVivo will support management and analysis of qualitative data across the different sources. Attribute values will be used to classify the data by ward and by data source to assist within and cross case comparison and triangulation of data[38]. At the start of analysis, parent nodes that represent CMOCs from the realist review and new programme theory areas will be created. Data from the realist evaluation will be mapped onto the CMOCs. Two researchers will code data and regular debates will take place with WP1 team, project team and LEAG. We will analyse data collected using the methods appropriate to each type of data) using a realist

logic[22] to interpret and judge data from each source. Data coding will be deductive (informed by our initial programme theory developed from WP1), inductive (derived from the collected data) and retroductive (making inferences about mechanisms based on interpretations of our data to infer underlying causal processes). Juxtaposing, reconciling, adjudicating and consolidating data will be used.

To ensure rigour during data analysis, extensive notes will be kept to map the analysis development. Analysis will be conducted across the embedded cases[33] allowing for a detailed understanding of discharge planning at Trust, ward and service user level. Evidence tables will be produced that relate to each CMOC to demonstrate theory refinement. The analysis will follow RAMESES quality standards[35]

Final CMOCs will be translated into a set of requirements to be used in the MoSCoW prioritisation exercise (see below) and inform creation of a **logic model** that specifies the steps for implementation of the CMOCs, key stakeholders, mechanisms of change, quality indicators and outcomes.

### 4.2.6 Logic model & MoSCoW prioritisation exercise

MoSCoW prioritisation exercise: complex systems with diverse stakeholders often produce large numbers of requirements. The requirements define how the SDCA will work. The requirements will be subjected to a MoSCoW ("Must haves", "Should haves", "Could haves" and "Won't haves") exercise; an SA technique for engaging stakeholders in prioritisation. This will involve a single workshop with multiple stakeholders (including the LEAG and the research team) to develop a reasonable set of requirements, achievable within time and resource constraints.

While the outputs from this innovative process cannot be predicted; the parameters could include staff training, updating patient record systems, discharge mapping and planning tools and guidelines to meet psychological needs.

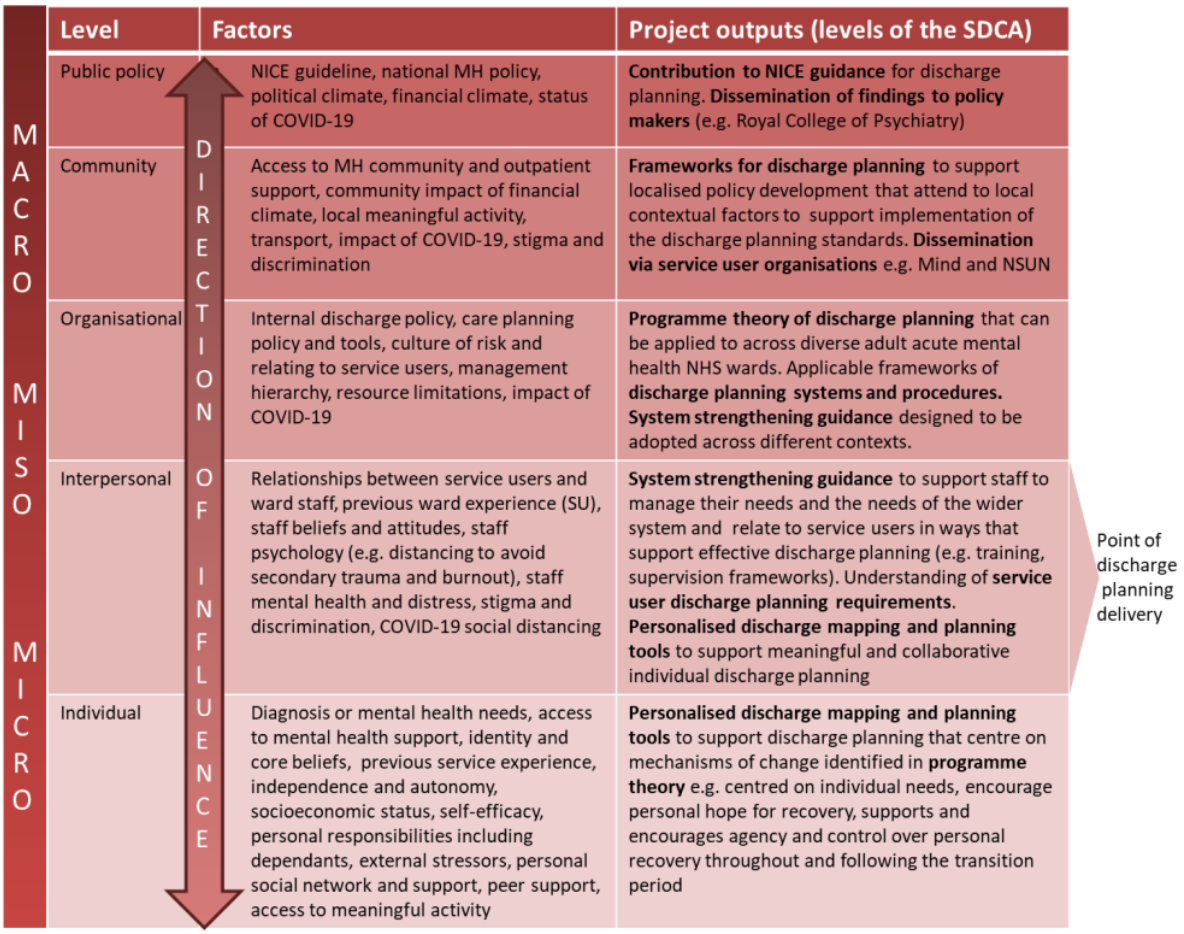
## 4.5 Work Package 1 – Outcomes

The outcome of Work Package 1 is a set of evidence-based programme theories of what personalised discharge planning is (including service user requirements for discharge planning), for whom, and key contextual influences and mechanisms of change. It also aims to understand service user discharge planning requirements and the ways these interact with systemic factors and to identify domains of outcome, relevant to the discharge process.

# 5. Work Package 2 – Develop the Systemic Discharge Care Approach Tool

Work Package 2 Ethical Approval has been granted – IRAS 324731.

MINDS aims to develop a Systemic Discharge Care Approach, which influences the discharge process at the macro, miso and micro level (Figure X). In order to develop the SDCA, the MINDS study will use the Engineering Better Care approach, as outlined in 5.3.




| Level | Factors | Project outputs (levels of the SDCA) |
|---|---|---|
| Public policy | NICE guideline, national MH policy, political climate, financial climate, status of COVID-19 | **Contribution to NICE guidance** for discharge planning. **Dissemination of findings to policy makers** (e.g. Royal College of Psychiatry) |
| Community | Access to MH community and outpatient support, community impact of financial climate, local meaningful activity, transport, impact of COVID-19, stigma and discrimination | **Frameworks for discharge planning** to support localised policy development that attend to local contextual factors to support implementation of the discharge planning standards. **Dissemination via service user organisations** e.g. Mind and NSUN |
| Organisational | Internal discharge policy, care planning policy and tools, culture of risk and relating to service users, management hierarchy, resource limitations, impact of COVID-19 | **Programme theory of discharge planning** that can be applied to across diverse adult acute mental health NHS wards. Applicable frameworks of **discharge planning systems and procedures. System strengthening guidance** designed to be adopted across different contexts. |
| Interpersonal | Relationships between service users and ward staff, previous ward experience (SU), staff beliefs and attitudes, staff psychology (e.g. distancing to avoid secondary trauma and burnout), staff mental health and distress, stigma and discrimination, COVID-19 social distancing | **System strengthening guidance** to support staff to manage their needs and the needs of the wider system and relate to service users in ways that support effective discharge planning (e.g. training, supervision frameworks). Understanding of **service user discharge planning requirements. Personalised discharge mapping and planning tools** to support meaningful and collaborative individual discharge planning |
| Individual | Diagnosis or mental health needs, access to mental health support, identity and core beliefs, previous service experience, independence and autonomy, socioeconomic status, self-efficacy, personal responsibilities including dependants, external stressors, personal social network and support, peer support, access to meaningful activity | **Personalised discharge mapping and planning tools** to support discharge planning that centre on mechanisms of change identified in **programme theory** e.g. centred on individual needs, encourage personal hope for recovery, supports and encourages agency and control over personal recovery throughout and following the transition period |

## 5.1 Aims and Objectives

### Objective

Coproduce a Systemic Discharge Care Approach (SDCA) involving discharge planning processes, personalised discharge planning tools and implementation guidance.

### Aim

Translate the Programme Theory and prioritised discharge planning requirements and logic model from WP1 into an innovative and sustainable system for discharge (SDCA) that meets SU needs, is compatible with how staff work and implementable. A systematic approach to design is required.

It will seek to

1. Understand characteristics of a personalised discharge planning process (what does 'good' look like?)

2. Agree a design goal and develop a solution-independent statement. Understanding the characteristics of a personalised design process is necessary but will not tell us what to design for. We will agree on the design goal based on knowledge of what 'good' looks like. We will then develop a solution-neutral statement of the design problem which the entire team can agree to.

3. Translate the characteristics of a personalised discharge planning process into a set of requirements to be fulfilled by the new SDCA.

4. Prioritise requirements and agree trade-offs using the MoSCoW prioritisation technique.

5. Develop measures of success for each 'Must Have', 'Should Have' and 'Could Have' requirement to be taken into the core activities in WP2

## 5.2 Study Design

### Method

WP2 uses a systems design component, the Engineering Better Care (EBC) framework and toolkit.

The choice of the EBC framework and toolkit provides several advantages, including 1) it provides a framework for thinking and the tools for action, 2) it is compatible with the realist research methods we are using, 3) it puts a strong emphasis on design and risk in the context of systems, 4) it was co-created with a broad range of stakeholder from across the NHS and is underpinned by a rigorous systems-engineering model.

The EBC approach aligns with complex intervention and development as the process of development is non-linear dynamic, iterative, creative, open to change and forward looking to future evaluation.

### Setting

The setting is the same as WP1, please see 4.2.

### Participants

We aim to involve the same participants throughout the MINDS trial; Participants in WP2 will be a purposive sample of 60 service users, carers and staff recruited during WP1. WP1 community participants were asked to give written consent to be contacted about participating in WP2. Those participants will be contact again for WP2. Depending on attrition rates, more staff and SU may need

to be recruited. Should more participants need to be recruited, this will follow the same pathway as outlined in WP1 (please see 4.2.1). For work package 2, only service users who are currently under a community team in the three sites will be recruited, as well as staff and carers. The eligibility criteria remains the same as WP and is outlined in 4.2.2 – interviews and focus groups.

All WP2 participants will be provided with a WP2 specific Participant Information Sheet and should they wish to take part, give informed written consent using the WP2 consent form.

Participants will be recruited for a two part study for WP2:

1) Exploratory design workshops
2) Feedback session

8-10 service users and carers as well as 8-10 staff per hospital site will be asked to firstly take part in a one off, exploratory design workshops (5.3.), which will be used to inform the design of the SDCA. Participants will then be invited back to a one-off feedback session, to ensure that their ideas have been understood and executed correctly (as outlined in 5.5).

## 5.3 Exploratory design workshops (WP2 Objectives 1 and 2)

For WP2, participants will take part in one of three 3-hour Exploratory design workshops (WP2 Objectives 1 and 2). We will conduct one workshop in each study site with 16-20 participants.

The research team will use the EBC Improving Improvement toolkit (IItoolkit© ) to work with key stakeholders to use the priority requirements (from the MoSCoW exercise WP1) together with the logic model (coproduced in WP1) to coproduce the SCDA. The toolkit supports the EBC approach; containing tools and activities to guide creativity and innovation in understanding problems and searching for solutions. It encourages divergent thinking to identify potential concepts and guides the selection of the most feasible concepts within constraints and limits of implementation.

This will be an iterative process, the three workshops will be conducted sequentially with the aim of designing the SDCA, and with the outputs of each workshop informing our approach to the next. Each workshop will start with a summary of the findings from WP1 or the previous workshop. Workshops will include a systems mapping exercise of the “System of Interest” including the service user, staff and systemic requirements for discharge planning, the barriers and facilitators and solutions. This will be aided by the programme theory and logic model outputs from WP1. The systemic discharge requirements will be reviewed and any contextual issues identified. Various techniques from the

IItoolkit will be used to develop the SCDA, guiding the development of ideas for addressing each of the requirements. This is where the solution-neutral statement of the problem is essential to allow participants to be as creative as possible in developing ideas and solutions. The ideas that emerge will be captured and assessed using a morphological chart and assembled into several competing design concepts. A morphological chart is a visual technique for capturing alternative solutions for specific system functions. If facilitates decision-making between competing alternatives. Researchers will keep detailed notes and iterative versions of the morphological map throughout, as part of the data collection and analysis process.

When all three workshops are completed, the resulting SDCA concepts will be compiled for the next activity.

## 5.4 Coproduction of the SCDA (WP 2 Objective 2)

Design sessions: Exploratory design workshop outputs will be considered at two 3-hour sessions with the research team and LE Advisory Group to undertake the detailed design, evaluate, risk assess and finalise. Key research team members will combine and finalise the outputs from the design workshops into the SDCA involving discharge planning processes, personalised discharge planning tools, and system strengthening and implementation guidance. Team members involved in this work contribute skills in systems engineering and design, psychological, nursing and psychiatric input and experts by experience. This will lead to a detailed design specification for the full development of SDCA. The team will work closely with the professional designers in the University of Cambridge on the full development process.

## 5.5 Feedback sessions for the face validity and implementability of the SDCA:

The key question will be “have we designed the right thing?”. The SDCA will be subjected to three 2-hour feedback sessions. Participants from the exploratory design workshops will be invited back to feedback on the developed SDCA. This should include 8-10 service users and supporters and 8-10 clinical staff per study site. Assessment will be based on the requirements that informed the SDCA design, together with success measures identified in WP1. A key assessment element will be implementability; thus, WP3 leads will play an important role. These sessions will triangulate WP1 findings and will focus on face validity of the proposed SDCA Any resulting revision to the design of the SDCA at this stage will be undertaken by the WP leads drawing on appropriate members on the team and other available resources.

### 5.6 WP 2 outputs:

The risk assessed SDCA; containing discharge planning processes, high specification personalised discharge planning tools, and system strengthening and implementation guidance

## 6. Work Package 3

Work package 3 does not have ethical approval currently. Ethical approval will be sought following completion of WP2.

### 6.1 Aims and Objectives

#### WP3 aims

WP3 will comprise WP3a and WP3b running in parallel:

1) WP3a evaluates implementation of the SDCA and assesses risk in practice,

2) WP3b explores resource implications and estimates cost implications of the SDCA and determines feasibility of collecting data for a future economic evaluation.

Together these WPs will produce a final specification for the SDCA which can be tested in a future Hybrid Type II trial that will determine effectiveness of the SDCA for improving service user outcomes; and the effects of the intervention on implementation processes and outcomes.

#### WP3a objectives

(1) Identify how delivery and fidelity of the SDCA is shaped by the wider context of mental healthcare;

(2) Measure reach, adoption and maintenance of the intervention (4-6week follow up);

(3) Understand acceptability, barriers and facilitators of implementation to staff and service-users;

(4) Identify feasibility of collecting service user outcome measures pre- and post-discharge; and

(5) Risk assess the use of the SDCA in practice and

(6) Identify recommendations for optimisation and wider implementation of the SDCA.

Using an observational approach developed in our previous health systems research, we will investigate the interaction between the implementation of the SDCA within specific wards and the wider health system context of delivery, drawing on MRC process evaluation guidance that

understanding adaptation to the local context is more appropriate than a strict assessment of fidelity. This requires a focus on how implementation of the intervention 'disrupts' the complex system into which it is being introduced, exposing wider social forces structuring implementation at the point of delivery, relations which are otherwise hidden from view. Such insights provide the basis for theoretical generalisations and clear directions for how the wider health system context can be strengthened to optimise SDCA implementation.

## 6.2 Study Design

### Method

Using the outputs from WP1 and WP2, a parallel, mixed methods process evaluation will test and refine the programme theory of 'personalised' discharge planning and assess the feasibility of implementing the SDCA and system strengthening components in mental health inpatient wards. Design of the process evaluation will be flexible in order to adapt to the design of the SDCA and health system strengthening components developed in the formative research of WP1 and WP2. The logic model will be key for structuring evaluation, specifying the steps for implementation, key stakeholders, mechanisms of change, quality indicators and outcomes.

Qualitative methods will include semi-structured interviews, focus groups and direct observations of intervention delivery.

Quantitative methods will include questionnaire and routinely available data to obtain measures of reach, adoption and maintenance as well an assessment of the feasibility of collecting service user outcome data.

### Setting

The process evaluation will be conducted in the six mental health wards that participated in WP1. This will maximise research resources and maintain focus on whether or not the intervention is feasible.

### Participants, sampling and recruitment

*Participants:*

The clinical population is the same as WP1 and WP2. Staff will need to have a role in either delivering discharge planning directly with service users or have a role in organising wards to implement the SDCA, including mental health nurses, psychiatrists, peer support workers, assistant practitioners, allied health professionals and ward managers.

The recruitment and consent process will be the same as outlined in WP1 (4.2.1-4.2.3). A WP3 specific participant information sheet and consent form will be used.

*Sampling:*

Observations, interviews and participants will be theoretically sampled. We will use the programme theory and prioritised discharge planning requirements from WP1 and WP2 as a starting point to determine which discharge planning activities to observe, and which service users and staff will extend our understanding of how the SDCA 'works' to meet service user needs. Analysis will commence as soon as data is collected which will then inform further theoretical sampling of participants and data types as analytical interpretations develop. As is practically feasible, staff and service users will be sampled on a sequential basis to facilitate ongoing iteration between data analysis and further purposive sampling. For each participant we will consider which sampling characteristics may disconfirm rather than confirm hypotheses.

*Qualitative data collection*

Ethnographic ward-based observations:

We will conduct ethnographic ward-based observations (4 days per ward – 24 days in total) to investigate how implementation of SDCA interacts with the wider context of mental healthcare, using the findings from WP1 to guide the selection of observations. We will observe SDCA consultations between staff and service users to understand how different components of the SDCA are created between staff and service users (e.g. understanding service user needs, goal-setting and action planning). We will also observe ward-based processes that impact on the delivery of the SDCA, likely to include risk management or discharge planning meetings, or informal discussions of discharge planning for specific service users. Depending on the health system strengthening components developed in WP2 we will also observe relevant encounters and activities that enact these components (e.g. training sessions). The ethnographic observations will be conducted across the first 8 months post implementation (at 2 months, 4 months, 6 months and 8 months.

Semi-structured interviews with service users:

Five per ward at three months post discharge (30 in total). Interviews will aim to obtain service user perspectives on the acceptability of the SDCA, with a specific focus on how the resulting discharge plan supported; a) their transition from the ward to home, b) the quality of collaboration between themselves and ward staff, and c) whether service users felt their discharge plans were supportive of a safe and effective transition from the ward to home and were supportive of personal recovery goals. This will be informed by the programme theory from WP1 of what a personalised, safe and effective discharge could look like for individual service users. Five semi-structured interviews per ward will be

carried out with staff six months after commencing use of the SDCA (30 in total) to allow time for the intervention to be embedded into routine practice, thereby obtaining diverse perspectives of acceptability, barriers and facilitators to implementation, impact on access and quality of care over time, and recommendations for wide-scale implementation.

### *Quantitative data collection*

#### Document review:

We will collect data from completed discharge planning tools and routine medical records to measure reach, adoption and maintenance of SDCA in all six wards. We will carry out monthly cross-sectional assessments of data throughout the six-month period to measure trends in adoption and implementation. Process and quality indicators will be identified in the logic model developed in WP1. These may include: - Numbers and different case-mix of service-users (e.g. different diagnoses/symptoms) - Frequency of SDCA use - Number and form of discharge actions (e.g. ways to increase social support, plans for engagement in personally meaningful activity, referral for psychological therapy)

Service user outcome data: We will assess the feasibility of collecting service user outcome data based on user-reported outcome measures identified by service users in WP1 and informed by a four-item core outcome set developed for interventions to improve discharge from mental health inpatient services, 95 including: readmission, suicidality and suicide completed (from medical records), mental health symptoms and quality of life. The data will be collected from routine medical records and questionnaires and would support recommendations for a future scaling-up evaluation.

#### Routine medical records:

We will collect data from routine medical records for all participants 6 months after discharge to assess the feasibility of collecting data on readmission and suicide completed.

Service user questionnaires: We will also administer service-user questionnaires to assess the feasibility of collecting data on service user-reported psychological distress and quality of life and depending on WP1 findings, outcomes such as social connectedness, suicidality, quality of life (e.g. ReQoL)96 , personal recovery (e.g. HAO), ,97 mental health status (e.g. CORE-OM), 98 readmission to acute services and additional service use (see WP3b).

### *Data Analysis*

#### Qualitative Data analysis

To analyse how intervention implementation ‘disrupts’ the system of inpatient wards we will use the programme theory and logic model form WP1 as a framework supported by purposive sampling of observations and participants. To do this work we will:

1) Analyse how different intervention components interact with relevant macro (e.g. national policy on mental health discharge); meso (e.g. in-patient ward protocols, staff arrangements); and micro (e.g. talk and behaviour within discharge planning encounters) contextual features relevant to implementation.

2) Target where likely tensions in implementation are likely to occur at each contextual level (e.g. difficulties allocating dedicated staff resource; need to complete additional administration or protocols alongside SDCA delivery).

3) Analyse tensions within targeted activities involved in intervention delivery.

4) Consider the consequences of these tensions for how the intervention was implemented and the implications of these for scaled up implementation.

We will initially analyse observational fieldnotes to describe the sequence and structure of different discharge planning processes and activities (e.g. staff meetings, identifying service user requirements within individual discharge planning encounters). As the analysis develops, we will aim to identify points of tension in discharge planning processes using data from service user and staff interview transcripts and fieldnotes to 'test out' and extend analytical interpretations.

Service user and staff interviews will be transcribed verbatim and thematically analysed with the aid of NVivo software. We will evaluate how the process and content of the SDCA as delivered by staff 'worked' from the participants' perspective, aiming to understand the quality of collaboration and identify barriers and facilitators to implementation. A constant comparison approach will be adopted, working iteratively between data obtained from different interviewees within and between wards and mental health trusts.

### Quantitative data analysis:

Statistical analysis will include descriptive analyses of changes over time (such as numbers and proportions of different discharge action plans), and graphical plotting of changes, comparing trends between wards, both descriptively and potentially with regression. Additional analyses prompted by qualitative findings – for example concerning effects of SDCA on specific groups or diagnoses – will be explored.

### *Data Synthesis*

We will triangulate quantitative and qualitative findings from each ward to refine the programme theory and logic model from WP1 and WP2, focusing on how the SDCA functions within varying health system contexts, using interpretations generated from qualitative analysis to explain trends in quantitative findings and inform further analyses. By analysing implementation within a contextual

framework, we will be able to refine our theoretical understanding of how different contextual features and intervention components shape moments of delivery, which then impact on specific outcomes. Such insights will provide a breadth and depth of evidence for making concrete recommendations for optimising implementation of SDCA on a wider scale. However, given the complexity of factors that may influence individual discharge plans such insights are unlikely to be achieved by aiming to identify 'typical cases' that are said to be representative of all service users. Instead we will focus on identifying 'telling cases,' 99 which 'follow a thread'100 between wider contextual forces, the components and mechanisms of SDCA, service user requirements and service user outcomes. The refined programme theory and the relationship of the data to the conceptual literature underpinning the intervention will be discussed and refined at team meetings throughout the research.

### WP3a outputs

This work will: 1) refine the programme theory of how the intervention works, 2) evaluate the feasibility and acceptability of delivering the SDCA 3) assess the feasibility of collecting service user outcome measures; and 4) make specific recommendations for refining the SDCA and health system implementation strategies to optimise delivery.

## Work Package 3b: Evaluate the cost of the SDCA

### WP3b aims & Objectives

Working closely with WP3a, WP3b's focus is to explore the resources used, and estimate cost implications, of using the developed SDCA. Additionally, we will explore the feasibility of collecting data (costs and benefits) necessary for a future economic evaluation. The former helps inform and refine implementation and adoption, while the latter informs next steps for evaluation. Specific objectives include:

1. Estimating resource impact of implementing the SDC on: inpatient ward resources; wider NHS & personal social services (PSS); and service users and carers

2. Costing these resources

3. Exploring feasibility of collecting data required for an economic evaluation

## Setting, participants, sampling and recruitment

Conducted at the same sites as WP3. We will recruit from participants recruited to WP3a (potentially stratifying if particular sub-groups/factors emerge). Participants will consent separately to: 1)

permission to consult their medical notes; and 2) to complete a questionnaire(s). Aiming to recruit 30 service users willing to complete questionnaires; more may be willing to provide access to notes.

Resource use data

We will collect resource use information from:

• Discharge planning tools

• Routine medical records

• Participant self-completed resource use questionnaires (adapting either the Client Service Receipt Inventory101 or other suitable measure from DIRUM102 , in consultation with the LE Advisory Group and research team).

Methods and precise information to be collected will tailored to reflect the final form of the intervention, in consultation with the LE Advisory Group. This WPs context precludes having a comparator, but we will work with wards, wider team and service users to identify which resource use is likely driven by the developed intervention. Alongside the resource use questionnaire, participants will also be asked to complete a small number of quality of life (QoL) instruments (e.g. the EuroQol EQ-5D-5L103 and the ICECAPA, 104 which could be used in a future economic evaluation.

## Costing and analysis

Recorded resource use will be multiplied by standard unit costs105 to determine costs (using the latest costing year for which costing resources are available). A key costing perspective will be that of the NHS and PSS, but we will also disaggregate costs to consider those incurred by 1) the inpatient wards; 2) other NHS and PSS providers (e.g. primary care); and 3) patients themselves (e.g. out of pocket costs). Within ward costings, we consider which costs are oneoff (e.g. training) and recurring, and which are ward level (e.g. training) versus individual patient. Return rates and levels/patterns of missing data on the questionnaires (both resource use & QoL) will be descriptively analysed to inform: 1) the feasibility of a future economic evaluation; and 2) refinements to the questionnaires to improve completion rates. WP3b Outputs This work package will: 1) help identify the resources impacted by the developed intervention (importantly at the level of the inpatient ward); 2) estimate the cost of these resource commitments; 3) consider the feasibility of a future economic evaluation. Outputs 1 & 2 inform implementation planning and 3 informs next steps for evaluation.

## Combined output from WP3 (a&b)

*Optimising the SDCA – Stakeholder focus groups:*

Two stakeholder focus groups (6-8 participants per group, 12-16 in total) will be carried out at the end of WP3a&b to identify how to optimise the SDCA intervention for wide-scale implementation and to determine priorities for a future evaluation. The key stakeholders will include a mixture of those who participated in the research but also service users, mental health staff, directors of mental health services and policymakers who can provide critical insight on wider implementation. We will share findings from WP3 and ask stakeholders to make recommendations for finalising the design and content of the SDCA and required system strengthening components to optimise intervention implementation. We will then map components against the implementation strategies identified by the Expert Recommendations for Implementing Change106 to finalise the SDCA.

## 7. Study Steering Committee

The MINDS Study benefits from an overarching study steering committee (SSC). It consists of experts by experience, as well as research experts in Qualitative, ethnographic and realist methodologies and healthcare engineering experts. Their input ensures oversight of the project, and will ensure that the project stays on time and target, and help maintain the scientific integrity of the trial.

## 8. Lived Experience Advisory Group involvement

The MINDS study recognises the immense value of lived-experience. It is co-led by an experts-by-experience; who conceived the idea from lived-experience. The research team includes 3 members with inpatient experience in addition to wider research skills including ethnographic and qualitative expertise. MINDS will include a diverse Lived Experience Advisory Group (LEAG) to offer governance and embed coproduction throughout.

The LEAG will meet before each MINDS research team meeting and to support high standards of coproduction, considering accessibility, diversity and representation in all key decisions and developments (e.g., reviewing service-user materials, coproducing localised recruitment strategies, coproducing interview topic guides, supporting analyses and reviewing design output).

# 9. Ethical considerations

Ethical approval for the study will be gained through the Health Research Authority using IRAS.

The LEAG will be involved in key ethical considerations. Service user participants will be under the care of the Mental Health Trusts involved and the MINDS team includes clinical professionals from each Trust. Service user participant's care professionals will be aware of their participation. This will enable rapid access to mental health support if required. There is the potential for participants to become distressed when talking about their experiences of discharge or for researchers to identify unmet need in participants. Participants are also made aware of the nature of the project through the PIS, ahead of taking part, to reduce the chance of unanticipated distress.

All participants will be under the care of participating mental health services meaning that will be in receipt of specialist support. Where there are concerns, the researcher will have access to the participant's mental health professional to report and discuss these (participants will be aware of this). Participating local service helpline and third sector helpline details will also be given. Should concerns be identified, or the participant appear distressed, the researcher may, if this is indicated, discuss this with the participant's clinical team. The researcher will confirm that participants are followed up by the local clinical team, in line with trust policy.

There is a risk that confidentiality will need to be broken if a participant discloses a risk of harm to themselves or others. In such cases their mental health professional will be informed. Participants will be made aware of the potential of this happening in advance where appropriate. Researchers carrying out these appointments will have access to both research supervision through the trial manager and local supervision and advice via the local PI.

## 9.1 Consent

Consent to participate by all participants (service users, staff, and family members wherever appropriate) will be informed, voluntary and be ongoing. All participants will be made aware that it is their choice to take part in the study and if they chose not to take part this will not affect clinical care, or for staff their working relationships with colleagues or other aspects of their employment. Informed consent will be through discussions with the researcher and the use of Participant Information Sheets.

Service users may be classed as vulnerable in some instances due to their how their difficulties, conditions and reason for admission affect their cognitive abilities. The researcher will assess the person's capacity to consent during conversations with the service user about the research. Assessment of capacity will follow criteria set out in the Mental Capacity Act (2005); that the person has understood the purpose of the research, that they understand what their involvement in the study will entail or that they have the right to decide not to participate and this decision will not affect their care, and that they have been able to retain the information about the study and use it to inform their decision of whether or not to take part. Capacity to participate in research will be documented using a Capacity Assessment Tool. Where the researcher judges capacity to consent is lacking, we will seek advice from a family member and/or appropriate staff member for whether or not to include the person in ward-based observations.

Consent in the moment: Consent to participate may fluctuate for some service users. During interviews, focus groups and observations, the researcher will be sensitive to the mood and verbal and non-verbal communication that might suggest the decision to consent has changed. If this is the case, the researcher will stop data collection and revisit initial consent with the person in full. The participant will be informed they can stop at any time and do not have to answer questions they do not wish to. If the person indicates they wish data collection to stop, it will be terminated. Before interviews and focus groups, the researcher will make the person aware that their participation can be paused at any time without needing to give a reason.

## 9.2 Confidentiality

All information about participants will be kept confidential and they will not be identifiable in any written reports. All participants will be reassured that everything they say will remain confidential, unless there is a risk of harm to self or others. If this occurs the researcher will follow the MINDS trial specific 'Safeguarding Protocol': a protocol which sets out the actions for the researcher to take if there are concerns about the safety, care, and safeguarding of people involved in the study.

*Safeguarding: Actual or suspected abuse, neglect, risk of harm, or unreported criminality*

Where the researcher witnesses or is told about actual or suspected abuse, neglect, there is risk of harm, or unreported criminality, the researcher has a responsibility to report their concerns immediately to the relevant research team member (e.g., local PI), relevant members of the clinical team, Ward Manager, or Trust Safeguarding team – as set out in the Safeguarding Protocol.

• All cases of suspected or actual abuse will be treated seriously from minor to serious incidents. If the researcher has concerns, these will be raised and reported as set out in the Safeguarding Protocol.

• The researcher will act promptly and report concerns. This will allow staff involved in the care of the patient, or the safeguarding teams within the Trust to address the concerns and follow the Trust protocols to protect the patient

Further information for the procedures the researcher will follow, including timeframes for identified risks, are set out in the Safeguarding Protocol.

## 9.3 Anonymity

Participating wards will not be identifiable in any publications or reports produced from the study. From recruitment to the study, participating wards will be allocated a unique code and this will be used to anonymise any data collected from the sites. Participants from the sites will be allocated a code upon recruitment to the study and these will replace their names from any data collected, such as interview and focus group transcripts. Additionally, any names of individuals or places mentioned during interviews and focus groups will be anonymised when recordings are transcribed. Participant names will only appear on the consent form they sign.

## 9.4 Risks and Burdens

Study involvement might pose a possible risk to participants. There is a possibility that interview and focus group discussions might trigger participants' difficult memories and emotions around their past experiences of being discharged from an adult acute mental health ward. In case this happens during an interview, the researcher will validate participants' emotional responses, offer a break or the termination of the interview. All focus groups will be conducted by two facilitators. In case a participant becomes distressed during a focus group, they will be supported by the second facilitator in a different room away from the group (or breakout room in the case the group is conducted online), if appropriate. In case there are concerns during an interview or a focus group, the local PI will be informed, and a follow-up wellbeing phone call will be made after the interview or focus group. Participants will have the research team's contact information, if they become distressed during an interview or focus group. If participants continue to experience distress following an interview or focus

group, the local PI will be informed and, if appropriate, they will liaise with clinical staff who are involved in participants' care.

During interviews or focus groups, staff members might feel burdened or distressed due to discussing their experiences. In case participating staff experience distress, the researchers will offer to pause or terminate their participation. Staff will be given the research team's contact details in case of distress and needing additional support. The research team will have the contact details of agencies that staff can be referred to, if necessary. Staff members may consider their contribution in the study rewarding, and they will receive a certificate that confirms their participation and can be used as evidence for their Continuing Professional Development (CPD). The members of the research team who will conduct the interviews and focus groups will either be experienced interviewers or psychology graduated with additional training from the research team.

## 9.5 Privacy and Intrusion

The ward-based observations may result in intrusion of privacy. All people being observed will be made aware that the observations are happening. Observations of service user and staff interactions will only take place in communal settings (e.g., communal sitting rooms or dining areas), researchers will not be observing private spaces. With verbal consent, observations may include clinical team meetings or clinical service user-staff interactions and meetings (e.g., ward rounds or discharge planning meetings). Observations may also be conducted in communal staff spaces, e.g., staff offices where patient notes are recorded. There is the potential for intrusion of privacy during observations. Observations will be conducted as unobtrusively as possible. There will be no observations of personal care. If restraint procedures are undertaken, observations will be stopped. Observations will be undertaken by either graduate psychologists on the MINDS research team or the study manager with additional training. Ward-based observations have been deemed extremely beneficial to this study as they will allow for a different perspective and more nuanced understanding of staff to service user interactions than will be elicited by the interviews and focus groups. Any concerns that arise during ward-based observations (e.g., concerns about staff professional conduct) will be raised with the local PI (all PIs are experienced and senior clinicians working within participating mental health trusts) and appropriate action will be taken.

### 9.6 Data protection

Upon entry into the study, participants will be given a unique identifier. This will be used on all data that is collected with them. Data will be collected anonymously or made anonymise at the researcher's earliest opportunity (for example during transcription of audio material). Data collected will be stored in a locked cabinet, in a locked office either at participating mental health trusts (e.g., in Research and Development Departmental offices) or at the premises of the participating Trusts. Researchers will use opaque folders to transfer data from the ward to the locked cabinets. Information relating to personal information, such as collected using consent and capacity forms, will be kept in a separate locked cabinet away from the data files. Electronic data will be stored securely on the Trusts computers and servers conforming to General Data Protection Regulations (GDPR). Only the research team will have access to the data. At the end of the study, personal data, audio recordings and research data in paper formats, such as fieldnotes, will be destroyed at the local Trust site. Anonymised electronic research data will be securely transferred to Norfolk and Suffolk Foundation Trust and will be archived and kept securely for 10 years.

### 9.7 COVID-19 adaptations

All proposed research activity can be conducted remotely if required. We have developed standards for the remote delivery of interviews and focus groups for other projects[30]. The ward-based observations could be conducted with full PPE and social distancing measures. Alternatively, if necessary, we could use a variety of methods to remotely collect observation data. These could include online conversations that may be synchronous (conversations and interviews conducted via online platforms or via telephone) or asynchronous (e.g., email conversations). Online discussion platforms could facilitate group discussions.

## 10. Dissemination

The outputs of the MINDS project will be disseminated across the different systemic levels outlined in the proposal:

**Public/policy**

• Building on our extensive discussion and engagement with NICE, we have clarified their different adoption/dissemination routes as appropriate to the SDCA's final components/form:

o Endorsement programme: reviews and appropriately recommends resources and tools supporting implementation of NICE recommendations; o Learning programme: NICE website case studies demonstrating their guidance and standards improving local health and social care services;

o Technology appraisal: interventions with evidenced benefits authorised for NHS and social care use

• This is an East of England NIHR ARC affiliated project and, as such, the findings will also be disseminated via ARC platforms and networks.

**Community**

• We will disseminate the findings via coproduced and co-delivered high impact peer reviewed publications in journals and conference presentations and posters, including those with service user and mental health professional audiences.

**Organisational**

• Key outputs will be shared with professional bodies, e.g. the Royal Colleges of Psychiatrists and Nursing.

• Wide dissemination to NHS Mental Health Trusts via promotional materials.

**Individual**

• We will establish routes to engage with public and service user communities including blogs, podcasts and short videos via our established partners including Mind and the National Survivor User Network (NSUN) – both of which have agreed to disseminate the findings from the MINDS project.

# 11. Version Control

| Protocol version | Protocol date | Summary of changes |
|---|---|---|
| V1.0 | 22nd April 2022 | n/a |
| V2.0 | 02Feb2023 | Added WP1 IRAS number |
| V3.0 | 24May2023 | Added WP2 IRAS number |

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