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Title

Coproducing improved **M**ental health **In**patient **Di**scharge using a **S**ystems approach (MINDS): Study Protocol

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ABSTRACT

Introduction

Transition following discharge from mental health hospital is high risk in terms of relapse, readmission, and suicide. Discharge planning supports transition and reduces risk. It is a complex activity involving interacting systemic elements. The MINDS study aims to improve the process for people being discharged, their carers/supporters and staff who work in mental health services, by understanding, co-designing and evaluating implementation of a systemic approach to discharge planning.

Methods and analysis

The MINDS study integrates realist research and an engineering-informed systems approach across three Work Packages (WP). WP1 integrates realist methods with a systems approach to develop programme theories of discharge planning. WP2 uses an engineering systems approach to co-design a novel Systemic Discharge Care Approach, which will be subject to process and economic evaluation in WP3. The programme theories and resulting care planning approach will be refined throughout the study ready for a future clinical trial. MINDS is co-led by an expert by experience, with researchers with lived experience co-leading each WP.

Ethics and dissemination

MINDS WP1 has received ethical approval (REC ref: 22/YH/0122). Findings from MINDS will be disseminated via high impact journal publications and conference presentations, including those with service user and mental health professional audiences. We will establish routes to engage with public and service user communities and NHS professionals including blogs, podcasts and short videos.

Registration

MINDS is funded by the National Institute of Health Research (NIHR 133013) https://fundingawards.nihr.ac.uk/award/NIHR133013 The realist review protocol is registered on PROSPERO (CRD42021293255).

STRENGHTS AND LIMITATIONS OF THIS STUDY

- MINDS was conceived from lived experience and is aiming for high standards of co-production
- MINDS incorporates realist methods with a systems-based engineering approach to understand and improve discharge experience and outcomes
- The complexity and pace of delivery and funding constraints might be barriers to co-production, but the team have extensive experience, is evaluating levels of co-production and will report these
- Some aspects of the MINDS project, including the translation of lived experience into outputs, are flexible and responsive to emerging discoveries; consequently, there may be refinements to the protocol – these will be outlined in related MINDS publications

INTRODUCTION

The transition period following discharge is high risk; around 13% of people are quickly readmitted[1] and rates of suicide have been found to be 191 times higher for working age adults compared to matched-age comparators.[2] A wide range of factors contribute to relapse following discharge,

including feeling overwhelmed, managing mental health symptoms, returning to roles and day-to-day pressures of life.[3,4,5] Discharge planning supports transition and reduces risk by identifying post-discharge needs and how to manage these.[3,6] National Institute of Health and Care Excellence (NICE) guidance and the Care Quality Commission identify that discharge planning should be collaborative and person centred[7,8] but provide limited clarity on how this should be achieved.

Evidence suggests that discharge is often inadequately planned with little involvement from the person being discharged and their carers/supporters, resulting in poor transition and increased risk.[9-12] The charity Mind surveyed 1,221 people who had experienced discharge finding that 33% were given either no or insufficient notice of discharge, and for 37% there was no plan post discharge.[13]

Discharge planning is complex and involves many multi-faceted interacting systemic elements. People are heterogenous in terms of needs. Mental health service delivery is reliant on the reasoning, reactions and actions of staff, which are influenced by the wider system. Discharge planning therefore needs to address the needs of the person being discharged while working within organisational complexity, constraints and priorities.

Previous interventions neglect complex systemic factors that either support or undermine discharge planning.[14] Neglecting the wider system, including systemic pressures and the needs of staff, is likely to explain why previous attempts to improve discharge have failed. To establish effective discharge planning procedures, it is critical to understand the ward as a complex system (operating within wider systems and national policy). Acknowledging such complexity reframes health services research "from investigations of complex social interventions to interventions in complex social systems",[15] echoing perspectives articulated across public health and global health systems research.[16,17] Despite growing recognition of the need for systems approaches in healthcare,[18-21] to date no research has used this to improve mental health discharge.

METHODS AND ANALYSIS

Study design

Realist reviews[22] and evaluations[23] explain how and why change occurs through causal mechanisms.[24] We will use a healthcare-based systems approach as a framework for building and refining programme theories of discharge planning that set out relationships of components across system-levels in a socio-technical context (that is, people interacting with each other and technical components such as electronic records). This will comprise multiple context-mechanism-outcome configurations (CMOCs) to explain what works, for whom and in what circumstances. The programme theories will inform system design solutions for discharge.

Engineering Better Care (EBC) is an established engineering systems approach for the design of safe and successful healthcare delivery.[25-27] The EBC framework involves four key perspectives:[28] 1) 'People' focusses on the needs of key stakeholders; 2) 'Systems' explores the interactions between stakeholders and layers of the system; 3) 'Design' encourages innovation and investigates issues before proposing solutions; 4) 'Risk' predicts and models the risks associated with all proposed solutions. EBC will inform the co-design of a systemic approach to discharge. Implementation and economic implications will be evaluated to refine the discharge process.

Project aim

Co-produce and evaluate implementation and cost impact of a systemic approach to discharge.

Project objectives

1. ***Understand*** discharge planning as a complex intervention
2. ***Co-design*** a Systemic Discharge Care Approach (SDCA)
3. ***Evaluate*** acceptability, implementation and cost-impact of the SDCA

Research questions

1. How and in what contexts is mental health discharge currently performed?
2. Who are the primary stakeholders (e.g., service users,[a] carers/supporters, NHS staff), how can they be characterised, and what are their needs?
3. What are the successful outcomes for mental health discharge, how do these relate to contexts across the system, and what are the mechanisms underlying this?
4. How can mental health discharge be improved?
5. How can this be implemented and measured?

Patient and Public Involvement

The MINDS study is co-led by SR, who conceived the idea from lived experience of unhelpful discharge. Each WP is co-led by researchers with relevant lived experience. MINDS includes a Lived Experience Advisory Group (LEAG) comprised of people with relevant lived experience or experience of being a significant carer or supporter. The LEAG will offer governance and support co-production and key strategic decision-making throughout the project. The study Steering Committee (SSC) includes two members with lived experience, one of whom is co-chair. The methodological approaches adopted align with current empirical healthcare research theory including MRC complex intervention guidance.[29] Systems and realist approaches were selected as they also intrinsically value and prioritise key stakeholder perspectives and an iterative approach to knowledge generation.

Study sites

Sites were purposively sampled to represent geographically distinct (serving rural and urban communities) statutory mental healthcare organisations with different demographic profiles and mixed public inspection (CQC) ratings. Three mental healthcare sites are included. Two wards will be selected from each site for ward observations and evaluation of the SDCA. MINDS recognises that minority ethnic service users are disproportionately detained under the UK Mental Health Act[30-32] and overrepresented among psychiatric in-patients in UK statutory provision.[33] Consequently, we will monitor recruitment and employ targeted strategies to ensure the study sample reflects diversity of experience.

Recruitment

Figure 1 details recruitment aims across the MINDS project. There will be diverse promotion of the study to ensure broad access to participation, including (but not limited to) posters in clinical areas, participation newsletters, attendance at participation events. Additionally, eligible individuals may be

[a] The MINDS research team's preferred term for people who have lived experience of accessing mental services is 'people'. However, we have used the term 'service user' where discussing participants in the research project to delineate between different groups

contacted by their clinical team, or where they have signed-up to be contacted for research, by the research team to enquire if they are interested in participation.

Figure 1 [here]

Recruitment aims across the three WPs

Inclusion criteria

Service users

Interviews, focus groups and workshops: all service users (18 years and over), accessing community mental health services in the research sites, discharged within the previous 12 months (WP1), or being discharged from a research site ward (WP3), will be eligible.

Ward-based observations: all service users (18 years and over) currently admitted on selected wards.

Staff

Staff, working in participating mental healthcare organisations, whose role impacts (directly or indirectly) on inpatient discharge.

Carers/supporters

Carers/supporters (people who identify as having a significant caring or supportive role) for people who have experienced inpatient discharge in one of the participating mental healthcare organisations within the last 12 months.

RESEARCH PLAN

The MINDs study operates across three WPs.

WP1: Understand discharge planning as a complex intervention

WP1 Aim

Build, test and refine evidence-based programme theories of discharge planning and preparation as a complex intervention

WP1 Objectives

1) Conduct a realist review integrating the EBC systems approach to map and explain the relationship between key factors involved in discharge planning
2) Identify service user needs for discharge planning
3) Test programme theories in a realist evaluation across three case study sites

4) Refine programme theories to inform co-design work in WP2

WP1 Design

Realist Review

A realist review will synthesise quantitative and qualitative evidence on service user, carer and staff experiences of, and interventions for, discharge planning. The review will result in evidence-based theories that include factors across all system levels to explain post-discharge outcomes. The review will consist of three iterative stages:

1) Defining review scope, concept mining and initial theory development: a series of meetings with the research team and LEAG will be used to define the system of interest. Initial programme theories will be developed from literature identified from a systematic review[14] and an internal systematic search with supplementary searches for existing programme theories of mental health discharge planning.
2) Theory testing and refinement: the core review team will test and refine theories against evidence, conducting additional searches and discussions with the wider research team and LEAG. There are inherent biases in the literature and the lived experience perspective will help ensure that theories are relevant to those accessing services.
3) Analysis and synthesis: NVivo will be used to organise and track analysis. Tabulation and narrative write-up of evidence related to each programme theory will be shared with the research team and LEAG to support transparency and rigour in the analysis process. For more detail see realist review protocol on PROSPERO (CRD42021293255).

Realist Evaluation

We will conduct service user, carer and staff interviews, focus groups[34] and ward observations to refine the programme theories. An embedded case study design[35] will test programme theory components across systems within and between sites.

Interviews and focus groups will take the form of a 'teacher-learner' cycle,[36] inviting participants to confirm, refute or expand components of the programme theories based on their experience. Staff whose roles directly or indirectly impact discharge will be recruited across different levels of the system. Relevant sections of medical notes of service users recruited to interviews and focus groups will be reviewed. Anonymised data will be collected to provide aggregated service user characteristics and map the discharge process.

The observations will include communal areas, discharge conversations, relevant meetings, and ward rounds.[37-39] They aim to support understanding of interpersonal nuance, the way that contextual factors relate to outcomes and insights into causal mechanisms. Data will be collected using a template reflecting the programme theories. We will conduct a review of policy and strategy documents to provide an account of stated organisational aims and priorities for discharge and how documents are structured to support the process.

WP1 Analysis

The analysis will follow Realist and Meta-narrative Evidence Syntheses: Evolving Standards quality standards,[40] using realist logic.[22,23] A core team will work with LEAG members to iteratively evaluate

data in relation to the programme theories to facilitate theory refinement. NVivo[41] will support data management and analysis. Data coding will be deductive (informed by our initial programme theories), inductive (derived from the collected data) and reproductive (making inferences about mechanisms based on interpretations of our data to infer underlying causal processes). Evidence tables will be produced to demonstrate theory refinement.

WP1 Outputs

- Evidence-based programme theories of discharge preparation and planning
- A rich understanding of context, including the stakeholders involved and their wants and needs from the discharge process
- A set of causal mechanisms operating within the discharge contexts

WP2: Co-design a Systemic Discharge Care Approach

WP2 Aim

Translate the programme theory into a sustainable Systemic Discharge Care Approach (SDCA) that meets service user needs, is compatible with how staff work, and feasible to implement.

WP2 Objectives

Use a healthcare engineering systems approach as a framework to develop:

1) An agreed scope for the factors that can be changed within the discharge planning approach
2) An SDCA solution that has the potential to balance key wants and needs of all stakeholders
3) Methods for measuring the performance of the proposed solution against key wants and needs of service users and other stakeholders

WP2 Design

WP2 uses the EBC framework and Improving Improvement toolkit (IItoolkit, www.iitoolkit.com).[42] This is a systems-based engineering approach that aligns with complex intervention development, as it is non-linear, creative, and forward looking to future evaluation.

Prioritisation Workshop

The wants and needs service users and other key stakeholders may conflict. In this case the research team and LEAG will review these, in combination with the agreed scope. The following structure (MoSCoW method)[43] will be used:

- **M**ust haves: Core essential needs for an improved discharge process
- **S**hould haves: Highest priority 'wants'
- **C**ould haves: Secondary priority 'wants'
- **W**on't haves: rejected as being incompatible with the agreed scope.

The prioritised wants and needs embody what a 'better' solution would mean, across the perspectives of stakeholders, whilst acknowledging the pragmatic reality of delivery and resource limitations.

Exploratory Design Workshops

Iterative 3-hour exploratory design workshops will be conducted at each study site with service users, staff and carers/supporters. The research team will use the IItoolkit to develop ideas and proposals for an improved discharge process. The tools and activities within the IItoolkit will be used to support an iterative process of problem-finding and -solving, in a systems context. This encourages divergent thinking to stimulate ideas about how the discharge process can be improved, and convergent thinking to consider how these ideas can be selected, refined, and developed to produce a small set of feasible concepts. This will challenge the understanding and insights gathered from WP1 and the scope of what can be delivered.

Review and Refinement Workshop

The exploratory design workshop outputs will be considered at two 3-hour sessions with the research team and LEAG. The research team and LEAG will review, refine and evaluate the ideas and concepts from the exploratory workshops, to give a recommended lead proposal for an improved discharge process (the SDCA). This may involve developing tools to better assist discharge planning, and/or reconfiguring the discharge process and/or updating the guidance for the discharge process. Team members involved in this work contribute skills in systems engineering, risk assessment and design, psychology, nursing, psychiatry and lived experience of discharge.

Feedback Sessions

The SDCA will be further evaluated and refined during feedback sessions, with service users, carers/supporters and clinical staff. Assessment will be based on the prioritised wants and needs that informed the SDCA design, together with the success measures.

Explanatory Model

The research team and LEAG members will agree how the proposed solution could be practically measured against agreed wants and needs. The outputs from WP1 & 2 will be used by the research team and LEAG to develop a realist-informed explanatory model including resources, activities, and measurable process indicators for implementation. This will support data collection for WP3

WP2 Outputs

- Prioritised wants and needs for an improved discharge process
- Practical measures of success that are aligned with these prioritised wants and needs
- The SDCA as an improved discharge process
- Explanatory model to support implementation and evaluation

WP3: Evaluate acceptability, implementation, and cost-impact of the SDCA

WP3 Aims

1) Evaluate acceptability and implementation of the SDCA
2) Explore resource and cost implications, and determine feasibility of collecting data for a future economic evaluation
3) Inform a final specification for the SDCA that can be tested in a future Hybrid Type II trial that will determine effectiveness and impact, including economics, of the SDCA.

WP3 Objectives

1) Understand acceptability, barriers, and facilitators to implementation of the SDCA
2) Evaluate how delivery and fidelity is shaped by the healthcare context
3) Measure reach, adoption, and maintenance
4) Risk-assess the use of the SDCA
5) Estimate resource and associated costs impact
6) Identify recommendations for optimisation, wider implementation, and future evaluation
7) Evaluate feasibility of collecting service user outcome and economic evaluation data

WP3 Design

A parallel, mixed methods process evaluation will assess implementation and use of the SDCA. The explanatory model will specify steps for implementation, key stakeholders, process and quality indicators, and outcomes.

Ward-based observations

Ward-based observations will be conducted to investigate implementation of the SDCA and how this interacts with the ward and wider contexts. This will include observing SDCA consultations and system strengthening components (e.g., training) as well as ward-based processes that impact on delivery.

Semi-structured interviews with service users, carers/supporters and staff

Interviews will elicit service user perspectives on the acceptability of the SDCA, with a specific focus on how the resulting discharge planning supported discharge transition. Interviews with staff will be carried out six months after commencing use of the SDCA to allow it to be embedded into routine practice, obtaining perspectives on acceptability, barriers and facilitators to implementation, impact on quality of care over time, and recommendations for wide-scale implementation.

Service user and outcome data

The feasibility of collecting service user demographics and outcome data from routine medical records and questionnaires will be assessed, including readmission, suicidality, mental health symptoms, personal recovery and quality of life. Participants will complete a questionnaire containing selected measures and resource use questions to inform data collection feasibility for future evaluation, resource use and associated cost analysis. Medical records will be reviewed to assess the reach, adoption, and maintenance of the SDCA.

Data Analysis WP3a (Implementation of the SDCA)

Qualitative analysis

Observational fieldnotes and document reviews will be analysed to describe the sequence and structure of different discharge planning processes as well as activities and critical points relating to discharge outcomes. Data from interviews and observations will iteratively 'test out' and extend analytical interpretations, enabling refinements to the programme theory. We will evaluate how the process and content of the SDCA 'worked' from the participants' perspective, aiming to understand the quality of collaboration, usefulness of discharge planning outputs, and 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 sites. We will also analyse how different intervention components interact with relevant macro (e.g., national policy); meso (e.g., in-patient ward protocols, staff arrangements, other services); and micro (e.g., communication and behaviour within discharge planning encounters) contextual features relevant to scaled-up implementation. This will be undertaken with support of the LEAG.

Quantitative analysis

Statistical analysis will include descriptive analyses of changes over time (e.g., numbers of discharge plans), and graphical plotting of changes, comparing trends between wards, both descriptively and potentially with regression. Additional analyses prompted by qualitative findings (e.g., effects of SDCA on specific groups or diagnoses) will be explored. Completion rates and patterns of data collection tools will be descriptively analysed to inform the data collection feasibility for future trialling.

Resource use and costing analysis

Recorded resource use will be multiplied by standard unit costs.[44] A key costing perspective will be that of the NHS and Social Services, but we will also disaggregate costs to consider those incurred by 1) the inpatient wards; 2) other providers; and 3) service users (e.g., out of pocket costs). This will consider which costs are one-off (e.g., training) and recurring across levels of the system. Return rates and levels/patterns of missing data on the resource use questions will be descriptively analysed to inform the feasibility of a future economic evaluation and refinements to the questionnaires to improve completion rates. Extraction of related data from routine sources will also be explored to further inform future evaluation.

Stakeholder focus groups

Two stakeholder focus groups (6-8 participants per group, 12-16 in total) will be carried out towards the end of WP3 to identify how to optimise the SDCA intervention for wide-scale implementation and to determine priorities for a future trial. The key stakeholders will include a mixture of key stakeholders including mental health staff, service directors 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 map components

against the implementation strategies identified by the Expert Recommendations for Implementing Change[45] to finalise the SDCA.

WP3 Outputs

- Finalised SDCA ready for implementation and trialling
- Refined programme theory
- Recommendations for implementation of the SDCA
- Estimation of the cost and resource impact of the SDCA
- Initial feasibility data for a Hybrid Type 2 trial of the SDCA including identified service user outcomes, process/implementation indicators and economic measures

CONSENT

We are consenting five groups of service users, carers/supporters, and staff (see Figure 1):

1. Service users who are currently admitted for the ward-based observations (WP1)
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 (WP1 & 2)
3. Service users who are being discharged (WP3)
4. Carers/supporters of people who have been discharged in the last 12 months (WP1, 2 & 3)
5. Staff who have roles that impact on inpatient discharge (WP1, 2 & 3)

For interviews, focus groups and workshops, a research team member will arrange a consent meeting at least 48 hours after receipt of the Participant Information Sheet (PIS). It will be established that the participant has read this, understands the study and implications of participation and any questions are answered. Capacity to consent will be assessed.

On the days of the ward 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 consent to the observations. This simplified consent process has been designed to minimise burden and confusion for service users. Observers will be wearing a lanyard that makes it clear who they are and that they are undertaking observations. If approached, they will answer any questions transparently. Service users will be informed that they can choose to opt out of the observations at any time (they are also free to leave the observed space). Staff will be asked to opt out if they do not want to be observed. Staff will 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 can ask for the observation to be moved or terminated.

All service-users who are discharged from the 3 study sites within the first 6 months of WP3 will be asked whether they wish to opt out of their routine data being used for research purposes.[46-48]

ETHICS AND DISSEMINATION

Ethical Considerations

MINDS includes protocols for managing distress or safety issues relating to interviews, focus groups and ward observations, that have received ethical approval for WP1. These will also be applied to the activity for WPs 2 & 3. The SSC and LEAG will support ethical issues encountered during the study.

Dissemination

We have engaged with NICE, to consider different adoption/dissemination routes for the outputs from this programme of work (including future clinical trial findings). This is NIHR Applied Research Collaboration (ARC) East of England (EoE) affiliated project and findings will be disseminated via ARC platforms and networks. We will work with the LEAG, to develop journal publications and conference presentations. Key outputs will be shared with professional bodies, e.g., the Royal Colleges of Psychiatrists and Nursing. We will establish routes to engage with public and service user communities including blogs, podcasts and videos via partner Mind and reaching out to other organisations e.g., National Survivor User Network (NSUN).

Author Contributions

CH took the lead role in design, coordinating the design and writing the protocol. SR, JW, AK and LG had substantial roles in design and writing the protocol across all WPs. MH, JM, APW, SW, EK, HZ, JJ, SB had substantial roles in designing and writing aspects of specific WPs. All authors were involved in the conception and design of the project and editing and protocol across all WPs.

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Competing interests statement

We declare no competing interests.

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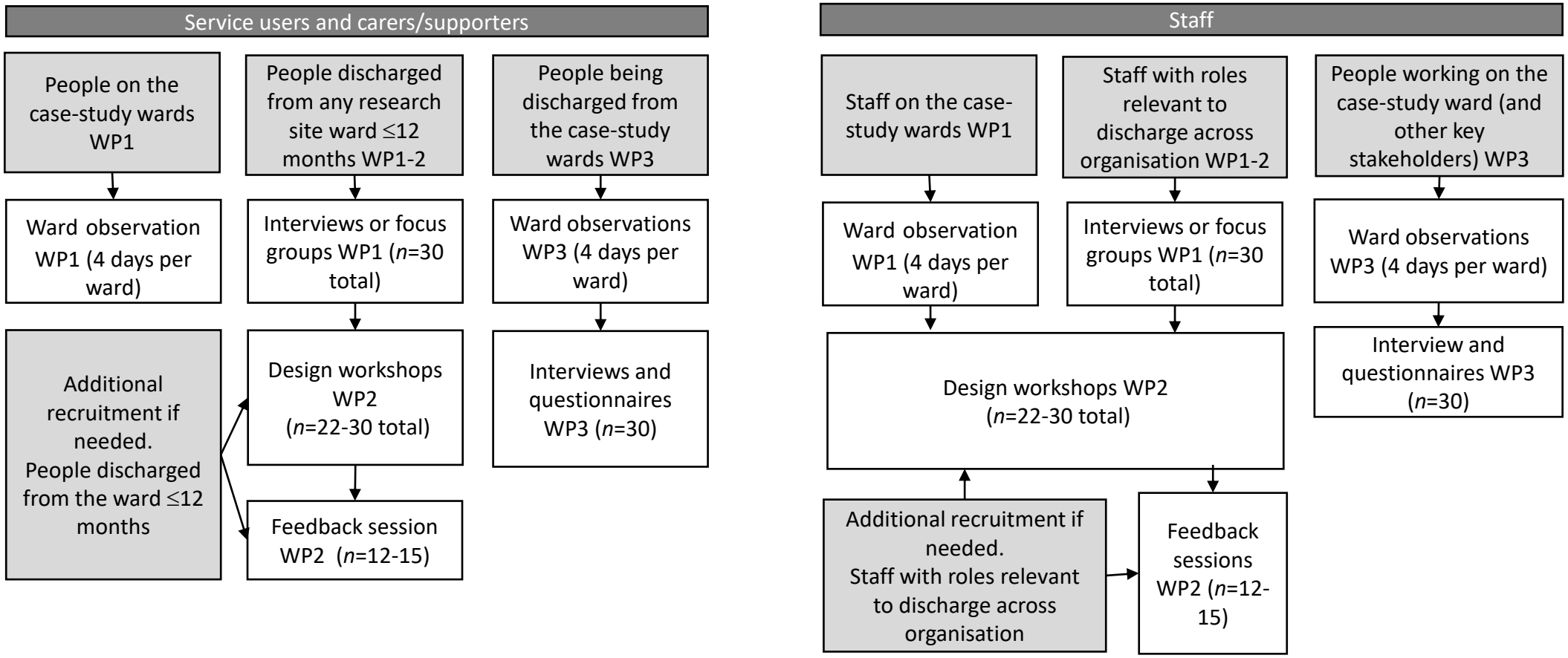
Figure 1

Figure 1, Recruitment Aims across Work Packages



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Co-designing a systemic mental health inpatient discharge intervention (MINDS): a protocol for integrating realist evaluation and an engineering-based systems approach

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ABSTRACT

Introduction

Transition following discharge from mental health hospital is high risk in terms of relapse, readmission, and suicide. Discharge planning supports transition and reduces risk. It is a complex activity involving interacting systemic elements. The MINDS study aims to improve the process for people being discharged, their carers/supporters and staff who work in mental health services, by understanding, co-designing and evaluating implementation of a systemic approach to discharge planning.

Methods and analysis

The MINDS study integrates realist research and an engineering-informed systems approach across three stages. Stage 1 applies realist review and evaluation using a systems approach to develop programme theories of discharge planning. Stage 2 uses an Engineering Better Care framework to co-design a novel systemic discharge intervention, which will be subject to process and economic evaluation in Stage 3. The programme theories and resulting care planning approach will be refined throughout the study ready for a future clinical trial. MINDS is co-led by an expert by experience, with researchers with lived experience co-leading each stage.

Ethics and dissemination

MINDS stage 1 has received ethical approval from Yorkshire & The Humber - Bradford Leeds (Research Ethics Committee (22/YH/0122). Findings from MINDS will be disseminated via high impact journal publications and conference presentations, including those with service user and mental health professional audiences. We will establish routes to engage with public and service user communities and NHS professionals including blogs, podcasts and short videos.

Registration

MINDS is funded by the National Institute of Health Research (NIHR 133013) https://fundingawards.nihr.ac.uk/award/NIHR133013 The realist review protocol is registered on PROSPERO (CRD42021293255).

STRENGHTS AND LIMITATIONS OF THIS STUDY

- MINDS was conceived from lived experience and is aiming for high standards of co-production
- MINDS incorporates realist methods with a systems-based engineering approach to understand and improve discharge experience and outcomes
- The complexity and pace of delivery and funding constraints might be barriers to co-production, but the team have extensive experience, is evaluating levels of co-production and will report these
- Some aspects of the MINDS project, including the translation of lived experience into outputs, are flexible and responsive to emerging discoveries; consequently, there may be refinements to the protocol – these will be outlined in related MINDS publications

INTRODUCTION

The transition period following discharge is high risk; around 13% of people are quickly readmitted[1] and rates of suicide have been found to be 191 times higher for working age adults compared to

matched-age comparators.[2] A wide range of factors contribute to relapse following discharge, including feeling overwhelmed, managing mental health symptoms, returning to roles and day-to-day pressures of life.[3,4,5] Discharge planning supports transition and reduces risk by identifying post-discharge needs and how to manage these.[3,6] National Institute of Health and Care Excellence (NICE) guidance and the Care Quality Commission identify that discharge planning should be collaborative and person centred[7,8] but provide limited clarity on how this should be achieved.

Evidence suggests that discharge is often inadequately planned with little involvement from the person being discharged and their carers/supporters, resulting in poor transition and increased risk.[9-12] The charity Mind surveyed 1,221 people who had experienced discharge finding that 33% were given either no or insufficient notice of discharge, and for 37% there was no plan post discharge.[13]

Discharge planning is complex and involves many multi-faceted interacting systemic elements. People are heterogenous in terms of needs. Mental health service delivery is reliant on the reasoning, reactions and actions of staff, which are influenced by the wider system. Discharge planning therefore needs to address the needs of the person being discharged while working within organisational complexity, constraints and priorities.

Previous interventions neglect complex systemic factors that either support or undermine discharge planning.[14] Neglecting the wider system, including systemic pressures and the needs of staff, is likely to explain why previous attempts to improve discharge have failed. To establish effective discharge planning procedures, it is critical to understand the ward as a complex system (operating within wider systems and national policy). Acknowledging such complexity reframes health services research "from investigations of complex social interventions to interventions in complex social systems",[15] echoing perspectives articulated across public health and global health systems research.[16,17] Despite growing recognition of the need for systems approaches in healthcare,[18-21] to date no research has used this to improve mental health discharge.

METHODS AND ANALYSIS

Study design

The MINDS study commenced 01/01/2022 and ends 01/01/2025. The MINDS study will innovatively integrate realist research and an engineering-informed systems approach to co-design a systemic approach to discharge. Realist reviews[22] and evaluations[23] can be foundational for complex intervention development as they explain how and why change occurs through causal mechanisms.[24] Discharge planning is a multifaceted activity involving many systemic elements including service users, healthcare staff, policy, documentation, information systems and external bodies. We will use a healthcare-based systems approach as a framework for building and refining programme theories of discharge planning that set out relationships of components across system-levels in a socio-technical context (that is, people interacting with each other and technical components such as electronic records). This will comprise multiple context-mechanism-outcome configurations to explain what works, for whom and in what circumstances. The programme theories will inform system design solutions for discharge (see below for an example).

Engineering Better Care is an established engineering systems approach for the design of safe and successful healthcare delivery.[25-27] The framework involves four key perspectives:[28] 1) 'People' focusses on the needs of key stakeholders; 2) 'Systems' explores the interactions between stakeholders and layers of the system; 3) 'Design' encourages innovation and investigates issues before proposing solutions; 4) 'Risk' predicts and models the risks associated with all proposed solutions. This framework will inform the co-design of a systemic approach to discharge. Implementation and economic implications will be evaluated to refine the discharge process.

Across the stages of the study, we will build evidence-based theories to co-design and trial a Systemic Discharge Approach that promotes collaborative discharge planning. For the purposes of this protocol, this will be referred to as 'the intervention'. It is anticipated that the intervention will be multifaceted, this may include training, changes to processes and documentation. It will be designed to address factors inhibiting collaborative discharge planning across the levels of the system with consideration to potential unintended consequences arising from new ways of working.

Project aim

Co-produce and evaluate implementation and cost impact of a systemic approach to discharge.

Project objectives

1. ***Understand*** discharge planning as a complex intervention
2. ***Co-design*** a systemic discharge intervention
3. ***Evaluate*** acceptability, implementation, and cost-impact of the new discharge intervention

Research questions

1. How and in what contexts is mental health discharge currently performed?
2. Who are the primary stakeholders (e.g., service users,[a] carers/supporters, NHS staff), how can they be characterised, and what are their needs?
3. What are the successful outcomes for mental health discharge, how do these relate to contexts across the system, and what are the mechanisms underlying this?
4. How can mental health discharge be improved?
5. How can this be implemented and measured?

Patient and Public Involvement

The MINDS study is co-led by SR, who conceived the idea from lived experience of unhelpful discharge. Each stage is co-led by researchers with relevant lived experience. MINDS includes a Lived Experience Advisory Group (LEAG) comprised of people with relevant lived experience or experience of being a significant carer or supporter. The LEAG will offer governance and support co-production and key strategic decision-making throughout the project. The study Steering Committee (SSC) includes two members with lived experience, one of whom is co-chair. The methodological approaches adopted align with current empirical healthcare research theory including MRC complex intervention guidance.[29] Systems and realist approaches were selected as they also intrinsically value and prioritise key stakeholder perspectives and an iterative approach to knowledge generation.

Study sites

Sites were purposively sampled to represent geographically distinct (serving rural and urban communities) statutory mental healthcare organisations with different demographic profiles and mixed public inspection ratings. Three mental healthcare sites are included. Two wards will be selected from each site for ward observations and evaluation of the new intervention. MINDS

[a] The MINDS research team's preferred term for people who have lived experience of accessing mental services is 'people'. However, we have used the term 'service user' where discussing participants in the research project to delineate between different groups

recognises that minority ethnic service users are disproportionately detained under the UK Mental Health Act[30-32] and overrepresented among psychiatric in-patients in UK statutory provision.[33] Consequently, we will monitor recruitment and employ targeted strategies to ensure the study sample reflects diversity of experience.

Recruitment

Figure 1 details recruitment aims across the MINDS project. There will be diverse promotion of the study to ensure broad access to participation, including (but not limited to) posters in clinical areas, participation newsletters, attendance at participation events. Additionally, eligible individuals may be contacted by their clinical team, or where they have signed-up to be contacted for research, by the research team to enquire if they are interested in participation.

Figure 1 [here]

Figure 1, Recruitment aims across the three stages

Inclusion criteria

Service users

Interviews, focus groups and workshops: all service users (18 years and over), accessing community mental health services in the research sites, discharged within the previous 12 months (stage 1), or being discharged from a research site ward (stage 3), will be eligible.

Ward-based observations: all service users (18 years and over) currently admitted on selected wards.

Staff

Staff, working in participating mental healthcare organisations, whose role impacts (directly or indirectly) on inpatient discharge.

Carers/supporters

Carers/supporters (people who identify as having a significant caring or supportive role) for people who have experienced inpatient discharge in one of the participating mental healthcare organisations within the last 12 months.

RESEARCH PLAN

The MINDs study operates across three stages.

Stage 1: Understand discharge planning as a complex intervention

Aim

Build, test and refine evidence-based programme theories of discharge planning and preparation

Objectives

1) Conduct a realist review integrating the Engineering Better Care systems approach to map and explain the relationship between key factors involved in discharge planning
2) Identify service user needs for discharge planning
3) Test programme theories in a realist evaluation across three case study sites
4) Refine programme theories to inform co-design work in stage 2

Design

Realist Review

A realist review will synthesise quantitative and qualitative evidence on service user, carer, and staff experiences of, and interventions for, discharge planning. The review will result in evidence-based theories that include factors across all system levels to explain post-discharge outcomes. The review will consist of three iterative phases:

1) Defining review scope, concept mining and initial theory development: a series of meetings with the research team and LEAG will be used to define the system of interest. Initial programme theories will be developed from literature identified from a systematic review[14] and an internal systematic search with supplementary searches for existing programme theories of mental health discharge planning. This will involve extraction of data, initially from key papers, on contexts relevant to discharge planning, the outcomes relating to these contexts, and the mechanisms underlying the observed relationships between context and outcome. These will be formulated into 'IF, THEN, BECAUSE' statements, e.g., IF discharge is planned with involvement from service user, THEN the person if less likely to relapse post discharge, BECAUSE the discharge meets the needs of the service user. Numerous theories are likely to be identified, therefore the credibility and relevance to the scope of the review will be regularly assessed by the research team and LEAG members to retain the focus to the system of interest (i.e., mental health inpatient discharge planning). Programme theories will be mapped against the levels of the system to ensure sufficient spread and attention to factors relevant for subsequent stages of the study.
2) Theory testing and refinement: the core review team will test and refine the IF, THEN, BECAUSE statements iteratively against findings from additional research papers, this will include discussions with the wider research team and LEAG. There are inherent biases in the literature and the lived experience perspective will help ensure that theories are relevant to those accessing services.
3) Analysis and synthesis: The engineering-based systems approach will provide a framework for analysis to ensure; programme theories, articulated as Context-Mechanism-Outcome Configurations (CMOCs), map across macro, meso and micro levels of the system. An example of 'efficiency' is illustrated in see Figure 2 for how the concept might operate across the different system levels. Other factors might include risk management or social/clinical narrative about specific diagnoses). NVivo will be used to organise and track analysis. Tabulation and narrative write-up of evidence related to each programme theory will be shared with the research team and LEAG to support transparency and rigour

in the analysis process. For more detail see realist review protocol on PROSPERO (CRD42021293255).

Figure 2 [here]

Figure 2, Example of efficiency as a Context Mechanism Outcome Configuration across macro, meso and micro levels of the system

Realist Evaluation

We will conduct service user, carer and staff interviews, focus groups[34] and ward observations to refine the programme theories. An embedded case study design[35] will test programme theory components across systems within and between sites. Findings will be compared across the sites and participants to identify similarities and differences related to the CMOCs. We will look specifically to see how differences are linked to the contextual features of the sites and characteristics of the participants to understand how this affects the behaviour of mechanisms (i.e., in which circumstances are they triggered or not and with what outcome). This is key to ensuring transferability and acceptability of the new approach.

The interviews and focus groups will serve two purposes. Firstly, service users and carers will be asked about their experiences prior to, during and post the inpatient admission that relate to discharge planning. Staff will be asked to explain their role in the trust, any processes, resources, or strategies they use and their experiences of discharge planning with service users. This will establish the personal and professional context of participants and allow for new concepts to be identified. Secondly, the interviews and focus groups will take the form of a 'teacher-learner' cycle,[36] inviting participants to confirm, refute or expand components of the programme theories based on their experience. Participant deliberations of the programme theories will be contrast against the original assumptions to identify where there are disagreements and alternative explanations. This will strengthen understanding of how the context in which discharge planning takes place impacts service user and staff experience, thereby elucidating the circumstances in which mechanisms are triggered. Staff whose roles directly or indirectly impact discharge will be recruited across different levels of the system. Relevant sections of medical notes of service users recruited to interviews and focus groups (who consent to this) will be reviewed to further understand the discharge process. This includes data on route of admission, route of discharge, and any documentation of discharge planning and the discharge meeting. Anonymised data will be collected to provide aggregated service user characteristics and map the discharge process.

Ward observations be conducted at each of the participating wards and will include observations in communal areas and of discharge conversations, relevant meetings, and ward rounds.[37-39] They aim to support understanding of interpersonal nuance, the way that contextual factors relate to outcomes and insights into causal mechanisms. Data will be collected using a template reflecting the programme theories. We will conduct a review of policy and strategy documents to provide an account of stated organisational aims and priorities for discharge and how documents are structured to support the process.

Analysis

The analysis will follow Realist and Meta-narrative Evidence Syntheses: Evolving Standards quality standards,[40] using realist logic.[22,23] A core team will work with LEAG members to iteratively evaluate

data in relation to the programme theories to facilitate theory refinement. NVivo[41] will support data management and analysis. Data coding will be deductive (informed by our initial programme theories), inductive (derived from the collected data) and reproductive (making inferences about mechanisms based on interpretations of our data to infer underlying causal processes). Evidence tables will be produced to demonstrate theory refinement.

Outputs

The outputs for stage 1 will include an evidence-based programme theories of discharge preparation and planning, a rich understanding of context, including the stakeholders involved and their wants and needs from the discharge process and a set of causal mechanisms operating within the discharge contexts.

Stage 2: Co-design a systemic discharge intervention

Aim

Informed by the programme theories, co-design a sustainable systemic discharge intervention that meets service user needs, is compatible with how staff work, and feasible to implement.

Objectives

Use a healthcare engineering-based systems approach as a framework to develop:

1) An agreed scope for the factors that can be changed within the discharge planning approach
2) A systemic discharge solution that has the potential to balance key wants and needs of all stakeholders
3) Methods for measuring the performance of the proposed solution against key wants and needs of service users and other stakeholders

Design

Stage 2 uses the Engineering Better Care framework and Improving Improvement toolkit (IItoolkit, www.iitoolkit.com).[42] This is a systems-based engineering approach that aligns with complex intervention development, as it is non-linear, creative, and forward looking to future evaluation. The programme theories from stage 1 will provide an understanding of the context and definition of the problem across the wider system of interest (critical stages for EBC prior to designing the solution).

Prioritisation Workshop

The wants and needs service users and other key stakeholders may conflict. In this case the research team and LEAG will review these, in combination with the agreed scope. The following structure (MoSCoW method) [43] will be used. This will categorise wants and needs into ‘must haves’ (core essential needs for an improved discharge process), ‘should haves’ (highest priority 'wants'), ‘could

haves' (secondary priority 'wants'), and 'won't haves' (rejected as being incompatible with the agreed scope).

The prioritised wants and needs embody what a 'better' solution would mean, across the perspectives of stakeholders, whilst acknowledging the pragmatic reality of delivery and resource limitations.

Exploratory Design Workshops

Iterative 3-hour exploratory design workshops will be conducted at each study site with service users, staff and carers/supporters. The research team will use the IItoolkit to develop ideas and proposals for an improved discharge process to meet the discharge needs of service users identified from the realist review and evaluation. The tools and activities within the IItoolkit will be used to support an iterative process of problem-finding and -solving, in a systems context. This encourages divergent thinking to stimulate ideas about how the discharge process can be improved, and convergent thinking to consider how these ideas can be selected, refined, and developed to produce a small set of feasible concepts. This will challenge the understanding and insights gathered from the realist evaluation and the scope of what can be delivered.

Review and Refinement Workshop

The exploratory design workshop outputs will be considered at two 3-hour sessions with the research team and LEAG. The research team and LEAG will review, refine and evaluate the ideas and concepts from the exploratory workshops, to give a recommended lead proposal for an improved discharge process. This may involve developing tools and/or materials to better assist discharge planning, and/or reconfiguring the discharge process and/or updating the guidance for the discharge process. Examples might include a combination of training materials, clinical supervision or reflective practice templates, a discharge planning group outline, or collaborative discharge planning tools or documentation. Team members involved in this work contribute skills in systems engineering, risk assessment and design, psychology, nursing, psychiatry and lived experience of discharge.

Feedback Sessions

The new discharge intervention will be reviewed and refined during feedback sessions, with service users, carers/supporters and clinical staff from the design workshops. This will focus on acceptability and implimentability of the new approach. Assessment will be based on the prioritised wants and needs that informed the design of the new intervention, together with the success measures. Staff will be asked to develop an implementation plan with the research team to support use of the new discharge approach on their ward. These plans will be taken to additional meetings with staff on the research wards to agree plans for implementation of the new approach on their wards.

Explanatory Model

The research team and LEAG members will agree how the proposed solution could be practically measured against agreed wants and needs. The programme theories, prioritised discharge needs and identified outcomes associated with these and the tools and/or materials for the new systemic

discharge intervention will be used by the research team and LEAG to develop a realist-informed explanatory model including resources, activities, and measurable process indicators for implementation. This will include the components of the discharge intervention to be implemented, steps to implementation, process indicators of successful implementation, measures of acceptability, cost impact and outcomes of effective discharge. This will support data collection for stage 3

Outputs

The outputs for stage 2 will include a prioritised wants and needs for an improved discharge process, practical measures of success that are aligned with these prioritised wants and needs, the SDCA as an improved discharge process, and an explanatory model to support implementation and evaluation.

Stage 3: Evaluate acceptability, implementation, and cost-impact of the new discharge intervention

Aims

1) Evaluate acceptability and implementation of the discharge intervention
2) Explore resource and cost implications, and determine feasibility of collecting data for a future economic evaluation
3) Inform a final specification for the discharge intervention that can be tested in a future Hybrid Type II trial that will determine its effectiveness and impact, including economics.

Objectives

1) Understand acceptability, barriers, and facilitators to implementation of the SDCA
2) Evaluate how delivery and fidelity is shaped by the healthcare context
3) Measure reach, adoption, and maintenance
4) Risk-assess the use of the intervention
5) Estimate resource and associated costs impact
6) Identify recommendations for optimisation, wider implementation, and future evaluation
7) Evaluate feasibility of collecting service user outcome and economic evaluation data

Design

The explanatory model will support implementation and a process evaluation for stage 3. A parallel, mixed methods process evaluation will assess the feasibility of implementation, acceptability, risks and benefits, and cost impact of the discharge intervention.

Ward-based observations

Ward-based observations will be conducted to investigate implementation of the discharge intervention and how this interacts with the ward and wider contexts. This will include observing

discharge planning consultations and system strengthening components (e.g., training) as well as ward-based processes that impact on delivery. Researchers will attend relevant meetings (e.g., reviews and discharge planning meetings), observe training sessions or other relevant interactions and collect data in the form of field notes. This will evaluate whether the components of the discharge approach have fidelity in terms of what was designed in the workshops, and whether it impacts the areas of service user discharge need identified and prioritised from the programme theories.

Semi-structured interviews with service users, carers/supporters, and staff

Interviews with service users will gain perspectives on the acceptability of the discharge intervention, with a specific focus on how the resulting discharge plan supported their transition from the ward to home, the quality of collaboration between themselves and ward staff, and whether their discharge plans were supportive of a safe and effective transition from the ward to home. This will be informed by the programme theories and prioritised needs. Interviews with staff will be carried out six months after commencing use of the discharge intervention to allow it to be embedded into routine practice, obtaining perspectives on acceptability, barriers and facilitators to implementation, impact on quality of care over time, and recommendations for wide-scale implementation. Interviews will be semi-structured with topic guides informed by the prioritised discharge needs of service users and possible barriers and facilitators in terms of implementation.

Service user and outcome data

The feasibility of collecting service user demographics and outcome data from routine medical records and questionnaires will be assessed, including readmission, suicidality, mental health symptoms, personal recovery and quality of life. Participants will complete a questionnaire containing selected measures and resource use questions to inform data collection feasibility for future evaluation, resource use and associated cost analysis. This will include the outcome measures identified from the programme theories and a resource use questionnaire. Medical records will be reviewed to assess the reach, adoption, and maintenance of the discharge intervention.

Data Analysis

Qualitative analysis

Fieldnotes from the ward-based observations, the data from document reviews and interviews with staff and service users will be compared with the context-mechanism-outcome configurations identified in stage 1 and the realist-informed explanatory model to explore whether changes to practice occurred and met the prioritised needs as theorised. This will follow the realist logic of analysis used in stage 1. The observations and document review data will be used as measures of process indication for implementation identified in the explanatory model. This will indicate fidelity to implementation. We will also use descriptive analysis of the data from the document reviews to describe reach and adoptions (i.e., the extent of use and who it is being used with). The interviews evaluate how the process and content of the discharge intervention 'worked' from the participants' perspective, aiming to understand the quality of collaboration, usefulness of the discharge intervention, and 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 sites. We will also analyse how different intervention components interact with relevant macro (e.g., national policy); meso (e.g., in-patient ward protocols, staff arrangements, other services); and micro (e.g., communication and behaviour within discharge planning encounters) contextual features relevant to scaled-up implementation. This will be undertaken with support of the LEAG.

Quantitative analysis

Statistical analysis will include descriptive analyses of changes over time (e.g., numbers of discharge plans), and graphical plotting of changes, comparing trends between wards, both descriptively and potentially with regression. Additional analyses prompted by qualitative findings (e.g., effects of the discharge intervention on specific groups or diagnoses) will be explored. Completion rates and patterns of data collection tools will be descriptively analysed to inform the data collection feasibility for future trialling.

Resource use and costing analysis

Recorded resource use will be multiplied by standard unit costs.[44] A key costing perspective will be that of the NHS and Social Services, but we will also disaggregate costs to consider those incurred by 1) the inpatient wards; 2) other providers; and 3) service users (e.g., out of pocket costs). This will consider which costs are one-off (e.g., training) and recurring across levels of the system. Return rates and levels/patterns of missing data on the resource use questions will be descriptively analysed to inform the feasibility of a future economic evaluation and refinements to the questionnaires to improve completion rates. Extraction of related data from routine sources will also be explored to further inform future evaluation.

Stakeholder focus groups

Two stakeholder focus groups (6-8 participants per group, 12-16 in total) will be carried out towards the end of stage 3 to identify how to optimise the discharge intervention for wide-scale implementation and to determine priorities for a future trial. The key stakeholders will include a mixture of key stakeholders including mental health staff, service directors and policymakers who can provide critical insight on wider implementation. We will share findings 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 map components against the implementation strategies identified by the Expert Recommendations for Implementing Change[45] to finalise the SDCA.

Stage 3 Outputs

The outputs for stage 3 will include a finalised systemic discharge intervention ready for implementation and trialling, refined programme theories setting out the factors necessary for implementation, estimation of the cost and resource impact, initial feasibility data for a Hybrid Type 2 trial of the intervention including identified service user outcomes, process/implementation indicators and economic measures.

RECRUITMENT AND CONSENT

We are recruiting and consenting five groups of service users, carers/supporters, and staff (see Figure 1):

1. Service users who are currently admitted for the ward-based observations (stages 1 and 3)
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 (stages 1 and 2)
3. Service users who are being discharged (stage 3)
4. Carers/supporters of people who have been discharged in the last 12 months (stages 1, 2 and 3)
5. Staff who have roles that impact on inpatient discharge (stages 1, 2 and 3)

Recruitment of service users, carers/supporters and staff for interviews, surveys and groups will be purposive. The LEAG will advise on ways to maximise access and participation – including groups that may be at risk of under-representation due to diagnosis, ethnic background, or other demographic factors. Potential participants will be approached via multiple channels to increase access and participation, including, via clinical teams, though participation channels, and promotion including posters on wards and other service-user facing clinical spaces.

For interviews, focus groups and workshops, a research team member will arrange a consent meeting at least 48 hours after receipt of the Participant Information Sheet (PIS). It will be established that the participant has read this, understands the study and implications of participation and any questions are answered. Capacity to consent will be assessed.

On the days of the ward 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 consent to the observations. This simplified consent process has been designed to minimise burden and confusion for service users. Observers will be wearing a lanyard that makes it clear who they are and that they are undertaking observations. If approached, they will answer any questions transparently. Service users will be informed that they can choose to opt out of the observations at any time (they are also free to leave the observed space). Staff will be asked to opt out if they do not want to be observed. Staff will 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 can ask for the observation to be moved or terminated.

All service-users who are discharged from the 3 study sites within the first 6 months of stage 3 will be asked whether they wish to opt out of their routine data being used for research purposes.[46-48]

ETHICS AND DISSEMINATION

MINDS includes protocols for managing distress or safety issues relating to interviews, focus groups and ward observations, that have received ethical approval for stage 1. These will also be applied to the activity for stages 2 & 3. The Study Steering Committee and LEAG will support ethical issues encountered during the study.

Dissemination

We will work with the LEAG, to develop open access peer reviewed journal publications and conference presentations. We will establish routes to engage with public and service user communities including blogs, podcasts and videos via partner Mind and reaching out to other organisations e.g., National Survivor User Network (NSUN). This is NIHR Applied Research Collaboration (ARC) East of England (EoE) affiliated project and findings will be disseminated in an assessable form via ARC platforms and networks.

Author Contributions

CHac took the lead role in design, coordinating the design and writing the protocol. MH, EK, JJ, HZ, SD and CHai led the design of stage 1. AK, CHac, SW, SB, TK and JC led the design of stage 2. JM and APW led the design of stage 3. SR, JW and LG contributed to the design across the project and the writing and editing of the protocol. SR, HZ and SB led on the lived-experience input to the conception and design across the project. JB, AS, JW, FR, GB, ZT and CHac led on clinical perspectives, clinical governance, distress management and staff input across the design of the protocol. All authors were involved in editing the protocol.

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Competing interests statement

We declare no competing interests.

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Figure 1

Figure 1, Recruitment aims across project stages

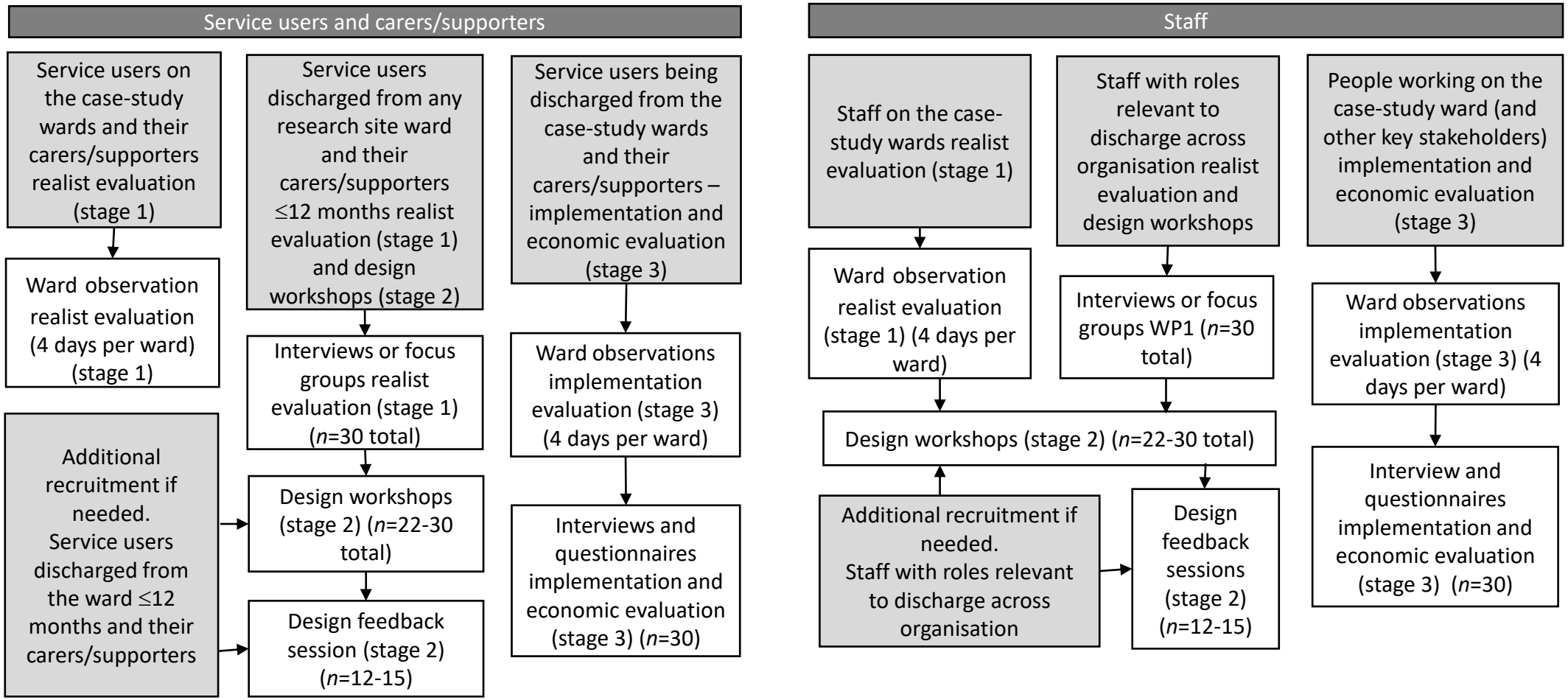

Figure 2, example of efficiency as a Context-Mechanism-Outcome Configuration across macro, meso and micro levels of the system

MACRO

MESO

MICRO

DIRECTION OF INFLUENCE

System level	Context	Mechanism	Outcome
Public policy	Prioritisation of efficiency in public sector services	Public accountability and responsibility to the taxpayer	Policy that operationalises emphasis on efficiency
Community	Efficiency measures set and monitored by government and public bodies such as the CQC	Need to operationalise and quantify efficiency for demonstration to taxpayer	National targets set to demonstrate efficiency quantitatively – e.g. waiting times
Organisational	Local policy and protocols to meet national and local targets and priorities, capture and demonstrate this	Need to demonstrate efficiency to inspection bodies and commissioners	Local targets, documentation and data capture to demonstrate efficient use of resources.
Interpersonal	Efficiency prioritised across social organisational hierarchy – executive to managers, mangers to frontline staff, registered staff to non-registered staff, ultimately frontline staff to service users	Pressure to demonstrate efficient use of resources to senior members of staff	Care can become 'task-focussed' rather then person centred. Discharge choices prioritise system need (releasing beds) rather than service user need
Individual	Limited resources to meet service user need Staff internalise pressure to deliver efficient care (meet the needs of the system) Care does not meet service user's mental health needs	Service user: aware of staff pressure or subject to stresses in ward environment Staff: pressure to demonstrate efficacy causes stress and moral distress as it conflicts with desire to deliver person-centred care	Discharge planning is rushed, non-collaborative and does not meet service user's needs Staff experience high rates of stress, moral distress, and burn-out. This limits ability to deliver compassionate person-centred care

Point of discharge planning delivery

BMJ Open

Co-designing a systemic discharge intervention for inpatient mental health settings (MINDS): a protocol for integrating realist evaluation and an engineering-based systems approach

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Title

Co-designing a systemic discharge intervention for inpatient mental health settings (MINDS): a protocol for integrating realist evaluation and an engineering-based systems approach

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ABSTRACT

Introduction

Transition following discharge from mental health hospital is high risk in terms of relapse, readmission, and suicide. Discharge planning supports transition and reduces risk. It is a complex activity involving interacting systemic elements. The MINDS study aims to improve the process for people being discharged, their carers/supporters and staff who work in mental health services, by understanding, co-designing and evaluating implementation of a systemic approach to discharge planning.

Methods and analysis

The MINDS study integrates realist research and an engineering-informed systems approach across three stages. Stage 1 applies realist review and evaluation using a systems approach to develop programme theories of discharge planning. Stage 2 uses an Engineering Better Care framework to co-design a novel systemic discharge intervention, which will be subject to process and economic evaluation in Stage 3. The programme theories and resulting care planning approach will be refined throughout the study ready for a future clinical trial. MINDS is co-led by an expert by experience, with researchers with lived experience co-leading each stage.

Ethics and dissemination

MINDS stage 1 has received ethical approval from Yorkshire & The Humber - Bradford Leeds (Research Ethics Committee (22/YH/0122). Findings from MINDS will be disseminated via high impact journal publications and conference presentations, including those with service user and mental health professional audiences. We will establish routes to engage with public and service user communities and NHS professionals including blogs, podcasts and short videos.

Registration

MINDS is funded by the National Institute of Health Research (NIHR 133013) https://fundingawards.nihr.ac.uk/award/NIHR133013 The realist review protocol is registered on PROSPERO (CRD42021293255).

STRENGHTS AND LIMITATIONS OF THIS STUDY

- MINDS was conceived from lived experience and is aiming for high standards of co-production
- MINDS incorporates realist methods with a systems-based engineering approach to understand and improve discharge experience and outcomes
- The complexity and pace of delivery and funding constraints might be barriers to co-production, but the team have extensive experience, is evaluating levels of co-production and will report these
- Some aspects of the MINDS project, including the translation of lived experience into outputs, are flexible and responsive to emerging discoveries; consequently, there may be refinements to the protocol – these will be outlined in related MINDS publications

INTRODUCTION

The transition period following discharge is high risk; around 13% of people are quickly readmitted[1] and rates of suicide have been found to be 191 times higher for working age adults compared to

matched-age comparators.[2] A wide range of factors contribute to relapse following discharge, including feeling overwhelmed, managing mental health symptoms, returning to roles and day-to-day pressures of life.[3,4,5] Discharge planning supports transition and reduces risk by identifying post-discharge needs and how to manage these.[3,6] National Institute of Health and Care Excellence (NICE) guidance and the Care Quality Commission identify that discharge planning should be collaborative and person centred[7,8] but provide limited clarity on how this should be achieved.

Evidence suggests that discharge is often inadequately planned with little involvement from the person being discharged and their carers/supporters, resulting in poor transition and increased risk.[9-12] The charity Mind surveyed 1,221 people who had experienced discharge finding that 33% were given either no or insufficient notice of discharge, and for 37% there was no plan post discharge.[13]

Discharge planning is complex and involves many multi-faceted interacting systemic elements. People are heterogenous in terms of needs. Mental health service delivery is reliant on the reasoning, reactions and actions of staff, which are influenced by the wider system. Discharge planning therefore needs to address the needs of the person being discharged while working within organisational complexity, constraints and priorities.

Previous interventions neglect complex systemic factors that either support or undermine discharge planning.[14] Neglecting the wider system, including systemic pressures and the needs of staff, is likely to explain why previous attempts to improve discharge have failed. To establish effective discharge planning procedures, it is critical to understand the ward as a complex system (operating within wider systems and national policy). Acknowledging such complexity reframes health services research "from investigations of complex social interventions to interventions in complex social systems",[15] echoing perspectives articulated across public health and global health systems research.[16,17] Despite growing recognition of the need for systems approaches in healthcare,[18-21] to date no research has used this to improve mental health discharge.

METHODS AND ANALYSIS

Study design

The MINDS study commenced 01/01/2022 and ends 01/01/2025. The MINDS study will innovatively integrate realist research and an engineering-informed systems approach to co-design a systemic approach to discharge. Realist reviews[22] and evaluations[23] can be foundational for complex intervention development as they explain how and why change occurs through causal mechanisms.[24] Discharge planning is a multifaceted activity involving many systemic elements including service users, healthcare staff, policy, documentation, information systems and external bodies. We will use a healthcare-based systems approach as a framework for building and refining programme theories of discharge planning that set out relationships of components across system-levels in a socio-technical context (that is, people interacting with each other and technical components such as electronic records). This will comprise multiple context-mechanism-outcome configurations to explain what works, for whom and in what circumstances. The programme theories will inform system design solutions for discharge (see below for an example).

Engineering Better Care is an established engineering systems approach for the design of safe and successful healthcare delivery.[25-27] The framework involves four key perspectives:[28] 1) 'People' focusses on the needs of key stakeholders; 2) 'Systems' explores the interactions between stakeholders and layers of the system; 3) 'Design' encourages innovation and investigates issues before proposing solutions; 4) 'Risk' predicts and models the risks associated with all proposed solutions. This framework will inform the co-design of a systemic approach to discharge. Implementation and economic implications will be evaluated to refine the discharge process.

Across the stages of the study, we will build evidence-based theories to co-design and trial a Systemic Discharge Approach that promotes collaborative discharge planning. For the purposes of this protocol, this will be referred to as 'the intervention'. It is anticipated that the intervention will be multifaceted, this may include training, changes to processes and documentation. It will be designed to address factors inhibiting collaborative discharge planning across the levels of the system with consideration to potential unintended consequences arising from new ways of working.

Project aim

Co-produce and evaluate implementation and cost impact of a systemic approach to discharge.

Project objectives

1. ***Understand*** discharge planning as a complex intervention
2. ***Co-design*** a systemic discharge intervention
3. ***Evaluate*** acceptability, implementation, and cost-impact of the new discharge intervention

Research questions

1. How and in what contexts is mental health discharge currently performed?
2. Who are the primary stakeholders (e.g., service users,[a] carers/supporters, NHS staff), how can they be characterised, and what are their needs?
3. What are the successful outcomes for mental health discharge, how do these relate to contexts across the system, and what are the mechanisms underlying this?
4. How can mental health discharge be improved?
5. How can this be implemented and measured?

Patient and Public Involvement

The MINDS study is co-led by SR, who conceived the idea from lived experience of unhelpful discharge. Each stage is co-led by researchers with relevant lived experience. MINDS includes a Lived Experience Advisory Group (LEAG) comprised of people with relevant lived experience or experience of being a significant carer or supporter. The LEAG will offer governance and support co-production and key strategic decision-making throughout the project. The study Steering Committee (SSC) includes two members with lived experience, one of whom is co-chair. The methodological approaches adopted align with current empirical healthcare research theory including MRC complex intervention guidance.[29] Systems and realist approaches were selected as they also intrinsically value and prioritise key stakeholder perspectives and an iterative approach to knowledge generation.

Case Study sites

Sites were purposively sampled to represent geographically distinct (serving rural and urban communities) statutory mental healthcare organisations with different demographic profiles and mixed public inspection ratings. Three mental healthcare sites are included. Two wards will be selected from each site for ward observations and evaluation of the new intervention. MINDS

[a] The MINDS research team's preferred term for people who have lived experience of accessing mental services is 'people'. However, we have used the term 'service user' where discussing participants in the research project to delineate between different groups

recognises that minority ethnic service users are disproportionately detained under the UK Mental Health Act[30-32] and overrepresented among psychiatric in-patients in UK statutory provision.[33] Consequently, we will monitor recruitment and employ targeted strategies to ensure the study sample reflects diversity of experience.

Recruitment

Figure 1 details recruitment aims across the MINDS project. There will be diverse promotion of the study to ensure broad access to participation, including (but not limited to) posters in clinical areas, participation newsletters, attendance at participation events. Additionally, eligible individuals may be contacted by their clinical team, or where they have signed-up to be contacted for research, by the research team to enquire if they are interested in participation.

Figure 1 [here]

Figure 1, Recruitment aims across the three stages

Inclusion criteria

Service users

Interviews, focus groups and workshops: all service users (18 years and over), accessing community mental health services in the case study sites, discharged within the previous 12 months (stage 1), or being discharged from a case study site ward (stage 3), will be eligible.

Ward-based observations: all service users (18 years and over) currently admitted on selected wards.

Staff

Staff, working in participating mental healthcare organisations, whose role impacts (directly or indirectly) on inpatient discharge.

Carers/supporters

Carers/supporters (people who identify as having a significant caring or supportive role) for people who have experienced inpatient discharge in one of the participating mental healthcare organisations within the last 12 months.

RESEARCH PLAN

The MINDs study operates across three stages.

Stage 1: Understand discharge planning as a complex intervention

Aim

Build, test and refine evidence-based programme theories of discharge planning and preparation

Objectives

1) Conduct a realist review integrating the Engineering Better Care systems approach to map and explain the relationship between key factors involved in discharge planning
2) Identify service user needs for discharge planning
3) Test programme theories in a realist evaluation across three case study sites
4) Refine programme theories to inform co-design work in stage 2

Design

Realist Review

A realist review will synthesise quantitative and qualitative evidence on service user, carer, and staff experiences of, and interventions for, discharge planning. The review will result in evidence-based theories that include factors across all system levels to explain post-discharge outcomes. The review will consist of three iterative phases:

1) Defining review scope, concept mining and initial theory development: a series of meetings with the research team and LEAG will be used to define the system of interest. Initial programme theories will be developed from literature identified from a systematic review[14] and an internal systematic search with supplementary searches for existing programme theories of mental health discharge planning. This will involve extraction of data, initially from key papers, on contexts relevant to discharge planning, the outcomes relating to these contexts, and the mechanisms underlying the observed relationships between context and outcome. These will be formulated into 'IF, THEN, BECAUSE' statements, e.g., IF discharge is planned with involvement from service user, THEN the person if less likely to relapse post discharge, BECAUSE the discharge meets the needs of the service user. Numerous theories are likely to be identified, therefore the credibility and relevance to the scope of the review will be regularly assessed by the research team and LEAG members to retain the focus to the system of interest (i.e., mental health inpatient discharge planning). Programme theories will be mapped against the levels of the system to ensure sufficient spread and attention to factors relevant for subsequent stages of the study.
2) Theory testing and refinement: the core review team will test and refine the IF, THEN, BECAUSE statements iteratively against findings from additional research papers, this will include discussions with the wider research team and LEAG. There are inherent biases in the literature and the lived experience perspective will help ensure that theories are relevant to those accessing services.
3) Analysis and synthesis: The engineering-based systems approach will provide a framework for analysis to ensure; programme theories, articulated as Context-Mechanism-Outcome Configurations (CMOCs), map across macro, meso and micro levels of the system. An example of 'efficiency' is illustrated in see Figure 2 for how the concept might operate across the different system levels. Other factors might include risk management or social/clinical narrative about specific diagnoses). NVivo will be used to organise and track analysis. Tabulation and narrative write-up of evidence related to each programme theory will be shared with the research team and LEAG to support transparency and rigour

in the analysis process. For more detail see realist review protocol on PROSPERO (CRD42021293255).

Figure 2 [here]

Figure 2, Example of efficiency as a Context Mechanism Outcome Configuration across macro, meso and micro levels of the system

Realist Evaluation

We will conduct service user, carer and staff interviews, focus groups[34] and ward observations to refine the programme theories. An embedded case study design[35] will test programme theory components across systems within and between sites. Findings will be compared across the sites and participants to identify similarities and differences related to the CMOCs. We will look specifically to see how differences are linked to the contextual features of the sites and characteristics of the participants to understand how this affects the behaviour of mechanisms (i.e., in which circumstances are they triggered or not and with what outcome). This is key to ensuring transferability and acceptability of the new approach.

The interviews and focus groups will serve two purposes. Firstly, service users and carers will be asked about their experiences prior to, during and post the inpatient admission that relate to discharge planning. Staff will be asked to explain their role in the trust, any processes, resources, or strategies they use and their experiences of discharge planning with service users. This will establish the personal and professional context of participants and allow for new concepts to be identified. Secondly, the interviews and focus groups will take the form of a 'teacher-learner' cycle,[36] inviting participants to confirm, refute or expand components of the programme theories based on their experience. Participant deliberations of the programme theories will be contrast against the original assumptions to identify where there are disagreements and alternative explanations. This will strengthen understanding of how the context in which discharge planning takes place impacts service user and staff experience, thereby elucidating the circumstances in which mechanisms are triggered. Staff whose roles directly or indirectly impact discharge will be recruited across different levels of the system. Relevant sections of medical notes of service users recruited to interviews and focus groups (who consent to this) will be reviewed to further understand the discharge process. This includes data on route of admission, route of discharge, and any documentation of discharge planning and the discharge meeting. Anonymised data will be collected to provide aggregated service user characteristics and map the discharge process.

Ward observations be conducted at each of the participating wards and will include observations in communal areas and of discharge conversations, relevant meetings, and ward rounds.[37-39] They aim to support understanding of interpersonal nuance, the way that contextual factors relate to outcomes and insights into causal mechanisms. Data will be collected using a template reflecting the programme theories. We will conduct a review of policy and strategy documents to provide an account of stated organisational aims and priorities for discharge and how documents are structured to support the process.

Analysis

The analysis will follow Realist and Meta-narrative Evidence Syntheses: Evolving Standards quality standards,[40] using realist logic.[22,23] A core team will work with LEAG members to iteratively evaluate

data in relation to the programme theories to facilitate theory refinement. NVivo[41] will support data management and analysis. Data coding will be deductive (informed by our initial programme theories), inductive (derived from the collected data) and reproductive (making inferences about mechanisms based on interpretations of our data to infer underlying causal processes). Evidence tables will be produced to demonstrate theory refinement.

Outputs

The outputs for stage 1 will include an evidence-based programme theories of discharge preparation and planning, a rich understanding of context, including the stakeholders involved and their wants and needs from the discharge process and a set of causal mechanisms operating within the discharge contexts.

Stage 2: Co-design a systemic discharge intervention

Aim

Informed by the programme theories, co-design a sustainable systemic discharge intervention that meets service user needs, is compatible with how staff work, and feasible to implement.

Objectives

Use a healthcare engineering-based systems approach as a framework to develop:

1) An agreed scope for the factors that can be changed within the discharge planning approach
2) A systemic discharge solution that has the potential to balance key wants and needs of all stakeholders
3) Methods for measuring the performance of the proposed solution against key wants and needs of service users and other stakeholders

Design

Stage 2 uses the Engineering Better Care framework and Improving Improvement toolkit (IItoolkit, www.iitoolkit.com).[42] This is a systems-based engineering approach that aligns with complex intervention development, as it is non-linear, creative, and forward looking to future evaluation. The programme theories from stage 1 will provide an understanding of the context and definition of the problem across the wider system of interest (critical stages for EBC prior to designing the solution).

Prioritisation Workshop

The wants and needs service users and other key stakeholders may conflict. In this case the research team and LEAG will review these, in combination with the agreed scope. The following structure (MoSCoW method) [43] will be used. This will categorise wants and needs into ‘must haves’ (core essential needs for an improved discharge process), ‘should haves’ (highest priority 'wants'), ‘could

haves' (secondary priority 'wants'), and 'won't haves' (rejected as being incompatible with the agreed scope).

The prioritised wants and needs embody what a 'better' solution would mean, across the perspectives of stakeholders, whilst acknowledging the pragmatic reality of delivery and resource limitations.

Exploratory Design Workshops

Iterative 3-hour exploratory design workshops will be conducted at each study site with service users, staff and carers/supporters. The research team will use the IItoolkit to develop ideas and proposals for an improved discharge process to meet the discharge needs of service users identified from the realist review and evaluation. The tools and activities within the IItoolkit will be used to support an iterative process of problem-finding and -solving, in a systems context. This encourages divergent thinking to stimulate ideas about how the discharge process can be improved, and convergent thinking to consider how these ideas can be selected, refined, and developed to produce a small set of feasible concepts. This will challenge the understanding and insights gathered from the realist evaluation and the scope of what can be delivered.

Review and Refinement Workshop

The exploratory design workshop outputs will be considered at two 3-hour sessions with the research team and LEAG. The research team and LEAG will review, refine and evaluate the ideas and concepts from the exploratory workshops, to give a recommended lead proposal for an improved discharge process. This may involve developing tools and/or materials to better assist discharge planning, and/or reconfiguring the discharge process and/or updating the guidance for the discharge process. Examples might include a combination of training materials, clinical supervision or reflective practice templates, a discharge planning group outline, or collaborative discharge planning tools or documentation. Team members involved in this work contribute skills in systems engineering, risk assessment and design, psychology, nursing, psychiatry and lived experience of discharge.

Feedback Sessions

The new discharge intervention will be reviewed and refined during feedback sessions, with service users, carers/supporters and clinical staff from the design workshops. This will focus on acceptability and implimentability of the new approach. Assessment will be based on the prioritised wants and needs that informed the design of the new intervention, together with the success measures. Staff will be asked to develop an implementation plan with the research team to support use of the new discharge approach on their ward. These plans will be taken to additional meetings with staff on the research wards to agree plans for implementation of the new approach on their wards.

Explanatory Model

The research team and LEAG members will agree how the proposed solution could be practically measured against agreed wants and needs. The programme theories, prioritised discharge needs and identified outcomes associated with these and the tools and/or materials for the new systemic

discharge intervention will be used by the research team and LEAG to develop a realist-informed explanatory model including resources, activities, and measurable process indicators for implementation. This will include the components of the discharge intervention to be implemented, steps to implementation, process indicators of successful implementation, measures of acceptability, cost impact and outcomes of effective discharge. This will support data collection for stage 3

Outputs

The outputs for stage 2 will include a prioritised wants and needs for an improved discharge process, practical measures of success that are aligned with these prioritised wants and needs, the SDCA as an improved discharge process, and an explanatory model to support implementation and evaluation.

Stage 3: Evaluate acceptability, implementation, and cost-impact of the new discharge intervention

Aims

1) Evaluate acceptability and implementation of the discharge intervention
2) Explore resource and cost implications, and determine feasibility of collecting data for a future economic evaluation
3) Inform a final specification for the discharge intervention that can be tested in a future Hybrid Type II trial that will determine its effectiveness and impact, including economics.

Objectives

1) Understand acceptability, barriers, and facilitators to implementation of the SDCA
2) Evaluate how delivery and fidelity is shaped by the healthcare context
3) Measure reach, adoption, and maintenance
4) Risk-assess the use of the intervention
5) Estimate resource and associated costs impact
6) Identify recommendations for optimisation, wider implementation, and future evaluation
7) Evaluate feasibility of collecting service user outcome and economic evaluation data

Design

The explanatory model will support implementation and a process evaluation for stage 3. A parallel, mixed methods process evaluation will assess the feasibility of implementation, acceptability, risks and benefits, and cost impact of the discharge intervention.

Ward-based observations

Ward-based observations will be conducted to investigate implementation of the discharge intervention and how this interacts with the ward and wider contexts. This will include observing

discharge planning consultations and system strengthening components (e.g., training) as well as ward-based processes that impact on delivery. Researchers will attend relevant meetings (e.g., reviews and discharge planning meetings), observe training sessions or other relevant interactions and collect data in the form of field notes. This will evaluate whether the components of the discharge approach have fidelity in terms of what was designed in the workshops, and whether it impacts the areas of service user discharge need identified and prioritised from the programme theories.

Semi-structured interviews with service users, carers/supporters, and staff

Interviews with service users will gain perspectives on the acceptability of the discharge intervention, with a specific focus on how the resulting discharge plan supported their transition from the ward to home, the quality of collaboration between themselves and ward staff, and whether their discharge plans were supportive of a safe and effective transition from the ward to home. This will be informed by the programme theories and prioritised needs. Interviews with staff will be carried out six months after commencing use of the discharge intervention to allow it to be embedded into routine practice, obtaining perspectives on acceptability, barriers and facilitators to implementation, impact on quality of care over time, and recommendations for wide-scale implementation. Interviews will be semi-structured with topic guides informed by the prioritised discharge needs of service users and possible barriers and facilitators in terms of implementation.

Service user and outcome data

The feasibility of collecting service user demographics and outcome data from routine medical records and questionnaires will be assessed, including readmission, suicidality, mental health symptoms, personal recovery and quality of life. Participants will complete a questionnaire containing selected measures and resource use questions to inform data collection feasibility for future evaluation, resource use and associated cost analysis. This will include the outcome measures identified from the programme theories and a resource use questionnaire. Medical records will be reviewed to assess the reach, adoption, and maintenance of the discharge intervention.

Data Analysis

Qualitative analysis

Fieldnotes from the ward-based observations, the data from document reviews and interviews with staff and service users will be compared with the context-mechanism-outcome configurations identified in stage 1 and the realist-informed explanatory model to explore whether changes to practice occurred and met the prioritised needs as theorised. This will follow the realist logic of analysis used in stage 1. The observations and document review data will be used as measures of process indication for implementation identified in the explanatory model. This will indicate fidelity to implementation. We will also use descriptive analysis of the data from the document reviews to describe reach and adoptions (i.e., the extent of use and who it is being used with). The interviews evaluate how the process and content of the discharge intervention 'worked' from the participants' perspective, aiming to understand the quality of collaboration, usefulness of the discharge intervention, and 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 case study sites. We will also analyse how different intervention components interact with relevant macro (e.g., national policy); meso (e.g., in-patient ward protocols, staff arrangements, other services); and micro (e.g., communication and behaviour within discharge planning encounters) contextual features relevant to scaled-up implementation. This will be undertaken with support of the LEAG.

Quantitative analysis

Statistical analysis will include descriptive analyses of changes over time (e.g., numbers of discharge plans), and graphical plotting of changes, comparing trends between wards, both descriptively and potentially with regression. Additional analyses prompted by qualitative findings (e.g., effects of the discharge intervention on specific groups or diagnoses) will be explored. Completion rates and patterns of data collection tools will be descriptively analysed to inform the data collection feasibility for future trialling.

Resource use and costing analysis

Recorded resource use will be multiplied by standard unit costs.[44] A key costing perspective will be that of the NHS and Social Services, but we will also disaggregate costs to consider those incurred by 1) the inpatient wards; 2) other providers; and 3) service users (e.g., out of pocket costs). This will consider which costs are one-off (e.g., training) and recurring across levels of the system. Return rates and levels/patterns of missing data on the resource use questions will be descriptively analysed to inform the feasibility of a future economic evaluation and refinements to the questionnaires to improve completion rates. Extraction of related data from routine sources will also be explored to further inform future evaluation.

Stakeholder focus groups

Two stakeholder focus groups (6-8 participants per group, 12-16 in total) will be carried out towards the end of stage 3 to identify how to optimise the discharge intervention for wide-scale implementation and to determine priorities for a future trial. The key stakeholders will include a mixture of key stakeholders including mental health staff, service directors and policymakers who can provide critical insight on wider implementation. We will share findings 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 map components against the implementation strategies identified by the Expert Recommendations for Implementing Change[45] to finalise the SDCA.

Stage 3 Outputs

The outputs for stage 3 will include a finalised systemic discharge intervention ready for implementation and trialling, refined programme theories setting out the factors necessary for implementation, estimation of the cost and resource impact, initial feasibility data for a Hybrid Type 2 trial of the intervention including identified service user outcomes, process/implementation indicators and economic measures.

RECRUITMENT AND CONSENT

We are recruiting and consenting five groups of service users, carers/supporters, and staff (see Figure 1):

1. Service users who are currently admitted for the ward-based observations (stages 1 and 3)
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 (stages 1 and 2)
3. Service users who are being discharged (stage 3)
4. Carers/supporters of people who have been discharged in the last 12 months (stages 1, 2 and 3)
5. Staff who have roles that impact on inpatient discharge (stages 1, 2 and 3)

Recruitment of service users, carers/supporters and staff for interviews, surveys and groups will be purposive. The LEAG will advise on ways to maximise access and participation – including groups that may be at risk of under-representation due to diagnosis, ethnic background, or other demographic factors. Potential participants will be approached via multiple channels to increase access and participation, including, via clinical teams, though participation channels, and promotion including posters on wards and other service-user facing clinical spaces.

For interviews, focus groups and workshops, a research team member will arrange a consent meeting at least 48 hours after receipt of the Participant Information Sheet (PIS). It will be established that the participant has read this, understands the study and implications of participation and any questions are answered. Capacity to consent will be assessed.

On the days of the ward 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 consent to the observations. This simplified consent process has been designed to minimise burden and confusion for service users. Observers will be wearing a lanyard that makes it clear who they are and that they are undertaking observations. If approached, they will answer any questions transparently. Service users will be informed that they can choose to opt out of the observations at any time (they are also free to leave the observed space). Staff will be asked to opt out if they do not want to be observed. Staff will 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 can ask for the observation to be moved or terminated.

All service-users who are discharged from the 3 study sites within the first 6 months of stage 3 will be asked whether they wish to opt out of their routine data being used for research purposes.[46-48]

ETHICS AND DISSEMINATION

MINDS includes protocols for managing distress or safety issues relating to interviews, focus groups and ward observations, that have received ethical approval for stage 1. These will also be applied to the activity for stages 2 & 3. The Study Steering Committee and LEAG will support ethical issues encountered during the study.

Dissemination

We will work with the LEAG, to develop open access peer reviewed journal publications and conference presentations. We will establish routes to engage with public and service user communities including blogs, podcasts and videos via partner Mind and reaching out to other organisations e.g., National Survivor User Network (NSUN). This is NIHR Applied Research Collaboration (ARC) East of England (EoE) affiliated project and findings will be disseminated in an assessable form via ARC platforms and networks.

Author Contributions

CHac took the lead role in design, coordinating the design and writing the protocol. MH, EK, JJ, HZ, SD and CHai led the design of stage 1. AK, CHac, SW, SB, TK and JC led the design of stage 2. JM and APW led the design of stage 3. SR, JW and LG contributed to the design across the project and the writing and editing of the protocol. SR, HZ and SB led on the lived-experience input to the conception and design across the project. JB, AS, JW, FR, GB, ZT and CHac led on clinical perspectives, clinical governance, distress management and staff input across the design of the protocol. All authors were involved in editing the protocol.

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Competing interests statement

We declare no competing interests.

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Figure 1

Figure 1, Recruitment aims across project stages

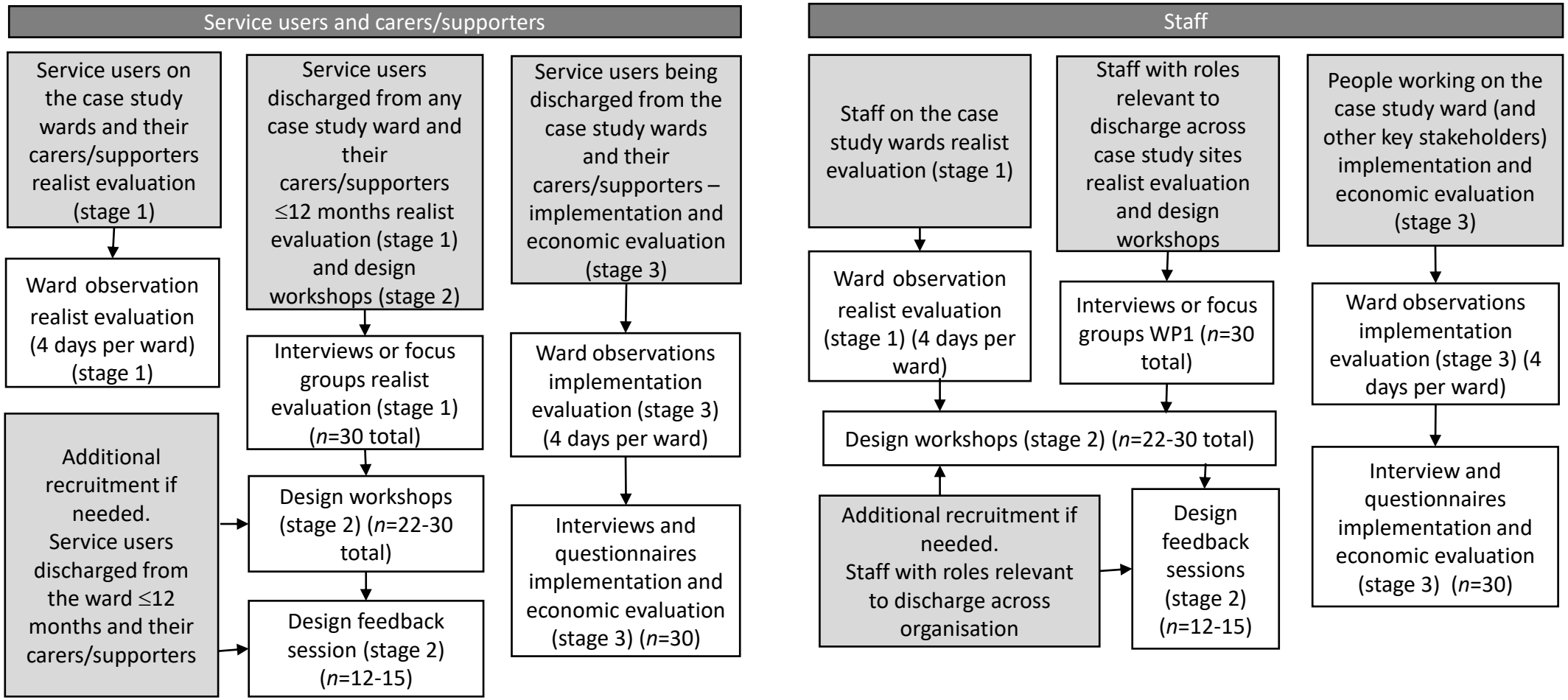

Figure 2, example of efficiency as a Context-Mechanism-Outcome Configuration across macro, meso and micro levels of the system

MACRO

MESO

MICRO

DIRECTION OF INFLUENCE

System level	Context	Mechanism	Outcome
Public policy	Prioritisation of efficiency in public sector services	Public accountability and responsibility to the taxpayer	Policy that operationalises emphasis on efficiency
Community	Efficiency measures set and monitored by government and public bodies such as the CQC	Need to operationalise and quantify efficiency for demonstration to taxpayer	National targets set to demonstrate efficiency quantitatively – e.g. waiting times
Organisational	Local policy and protocols to meet national and local targets and priorities, capture and demonstrate this	Need to demonstrate efficiency to inspection bodies and commissioners	Local targets, documentation and data capture to demonstrate efficient use of resources.
Interpersonal	Efficiency prioritised across social organisational hierarchy – executive to managers, mangers to frontline staff, registered staff to non-registered staff, ultimately frontline staff to service users	Pressure to demonstrate efficient use of resources to senior members of staff	Care can become 'task-focussed' rather then person centred. Discharge choices prioritise system need (releasing beds) rather than service user need
Individual	Limited resources to meet service user need Staff internalise pressure to deliver efficient care (meet the needs of the system) Care does not meet service user's mental health needs	Service user: aware of staff pressure or subject to stresses in ward environment Staff: pressure to demonstrate efficacy causes stress and moral distress as it conflicts with desire to deliver person-centred care	Discharge planning is rushed, non-collaborative and does not meet service user's needs Staff experience high rates of stress, moral distress, and burn-out. This limits ability to deliver compassionate person-centred care

Point of discharge planning delivery