

University of Essex



**South West London and
St George's Mental Health**
NHS Trust

FULL STUDY TITLE

An evaluation of factors affecting nurse patient relationships and outcomes in acute mental health inpatient settings.

SHORT STUDY TITLE

Exploring nurse-patient relationships on acute mental health wards.

CHIEF INVESTIGATOR

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STUDY PROTOCOL

An evaluation of factors affecting nurse patient relationships and outcomes in acute mental health inpatient settings.

1 BACKGROUND

This study will explore how nurses and patients interact on acute mental health wards. It will examine factors which may influence interactions and how they develop into relationships. It aims to find out whether the presence or absence of a relationship has any impact on the outcome of an inpatient admission. The study builds on the work of Bowers (2006) on conflict in acute mental health wards, and Nolan's analysis of Protected Engagement Time (PET) and is part of a programme of work initiated in 2006 with a Mental Health Research Network (MHRN) funded group of mental health experts who developed research ideas specifically investigating acute care. It will continue to investigate nurse-patient relationships on acute mental health wards using quantitative measures initially developed for the NIHR RfPB funded PET study, then shared with the NIHR SDO funded study to compare crisis houses with acute wards (Sweeney, 2014), supplemented by qualitative interviews with staff and patients. This mixed methods approach will be used to explore convergence and divergence between different sources of data in order to develop a model of the relationship between nurses and patients on acute mental health wards. Using qualitative methods as part of this study will allow understanding of the experiences and beliefs of nurses and patients. Crawford et al (2002) suggest that qualitative methods also have a valid use in the interpretation of quantitative outcomes. It will give patients and staff more opportunity to define issues of importance to them, and to expand and add to areas identified in the structured questionnaires.

2 RATIONALE

A therapeutic relationship between a nurse and a patient is one that brings about positive change for both parties (Benner, 1984). Whether therapeutic nurse-patient relationships can develop in the challenging context of an acute ward, what they might look like, what fosters their development and, vitally, whether they contribute to quality of care are all in question. Theorists such as Peplau (1952) attempted to describe the process of forming a therapeutic relationship, and more recently, the Tidal Model (Barker, 2001) has sought to guide the formation of recovery-focused relationships with patients. However, the existence and the nature of this relationship have remained elusive. Altschul's (1972) study of acute psychiatric wards found that therapeutic relationships between nurses and patients were not observable. Subsequent reports seem to indicate that this is still the case: Acute Problems (Sainsbury Centre for Mental Health, 1998,) reported a lack of engagement between staff and patients in acute wards, a finding replicated in Behind Closed Doors (Rethink, 2004).

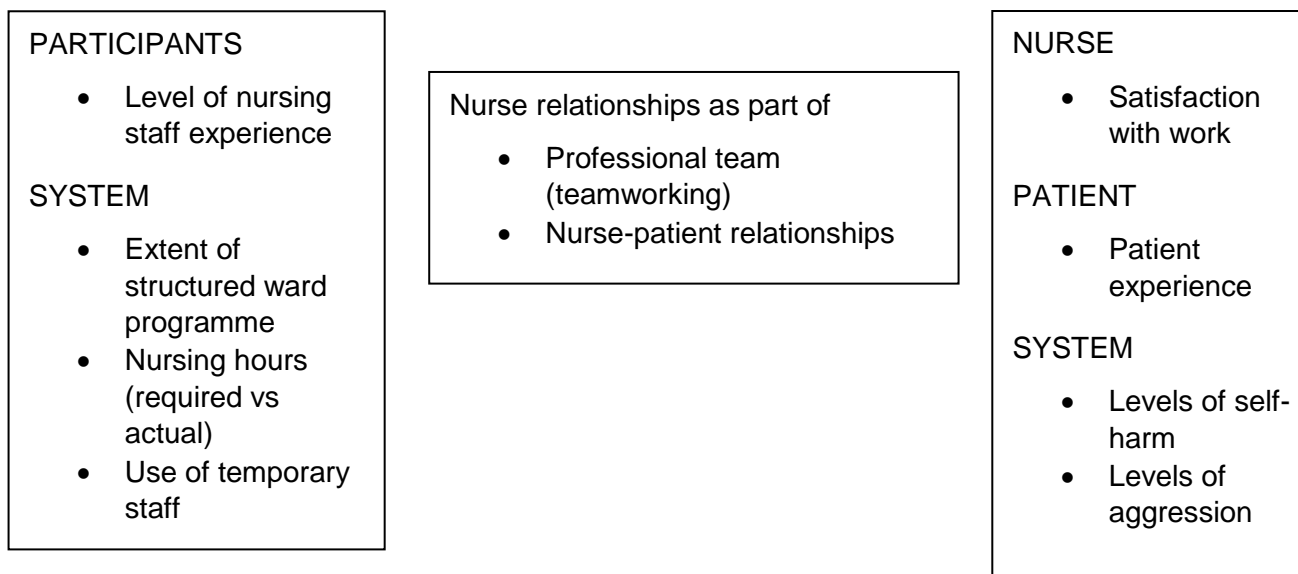
Although the therapeutic relationship is reported to be valued by patients, staff and nursing theorists as above, the link between a therapeutic relationship and the outcomes for patients and staff has not been clearly demonstrated. The therapeutic relationship has been found to be a predictor of outcome in psychotherapy, but few studies have investigated this link in acute psychiatric settings (McCabe and Priebe, 2004). Interim results of a feasibility study of Protected Engagement Time (planned hours of each day reserved for staff-patient interaction without interruptions) in mental health acute wards (PET) (Nolan, 2016) found no significant relationships between whether PET was in place on a ward, the amount of time staff spent with patients, and any of a broad range of outcomes, including satisfaction with treatment, therapeutic engagement, perceptions of the ward atmosphere, and staff levels of burnout. Sweeney et al (2014) proposed that the culture and practices on acute wards can create poor nurse-patient relationships and recommended that further research should be done to explore potential contributory factors.

3 THEORETICAL FRAMEWORK

Acute mental health wards are complex environments and outcomes are dependent on many variables. A framework which identifies and categorises the possible variables associated with therapeutic relationships is useful to enable the development of hypotheses for testing. This study uses Duffy's (2003) Quality-Caring Model which has been tested in physical health settings but not in mental health. Donabedian's (1966) quality evaluation framework forms the overarching framework for Duffy's (2003) model. He described three categories of quality measure in health care: structure, process and outcome and defined these respectively as resources and administration, culture and professional co-operation and, goal or competence achievement. Donabedian (1966, p. 713) argued that "the relationships between process and outcome, and between structure and both process and outcome, are not fully understood". This is because of the number and complexity of factors involved in each type of measure. In a later paper on measuring the quality of nursing care, he concluded: "A well-rounded system of quality appraisal would probably include concurrent or coordinate assessments of structure, process, and end results, to the extent that each of these is observable and measurable under the constraints inherent in any given setting." (Donabedian, 1969, p.1834).

This is the approach to be taken in this study in that Duffy's (2003) model is used as the framework for assessment of structure, process and outcome variables. The Chief Investigator conducted a review of the literature pertaining to nurse-patient relationships on acute mental health wards, through which the factors in the table below were identified as important in influencing nurse-patient relationships. The table also shows outcomes identified in the literature as possibly associated with nurse-patient relationships.

STRUCTURE	PROCESS	OUTCOMES
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The rationale for this study is based on theory and evidence about the therapeutic relationships between nurses and patients. Donabedian's (1966) framework as used by Duffy (2003) provides a theoretical framework for analysing practice environments, while the evidence from the literature suggests both the specific variables to include in the model and the hypothetical links between them. This study is timely for the following reasons: Polacek et al (2015) for example describe the setting up of a research programme in the US to explore the relationship between therapeutic engagement and patient safety in psychiatric settings (findings yet to be reported). In the UK, NICE (2015) guidelines on management of violence and aggression indicate that more research needs to be done to explore any impact of therapeutic relationships on aggressive behaviour.

Literature was reviewed for this study using NVivo software which enabled an analysis of the relative frequency of occurrence of key themes within studies. Relationships between variables were also analysed as part of the literature review. However, the evidence base is weak, consisting mainly of qualitative studies, so a key aim of this study design was to include collection and analysis of quantitative data related to structure and outcomes. Quantitative data can be enhanced by qualitative information in relation to the context in which relationships are developed and the meaning of these for nurses and patients on an acute ward. Narrative inquiry is a form of qualitative research which uses interviews to capture stories of experience, in this case that of therapeutic relationships as described by nurses and patients. The study uses Mixed Methods Research (MMR), specifically an explanatory sequential design to allow for explanation of quantitative measures through qualitative methodology.

4 RESEARCH QUESTION/AIM(S)

- In what way, if any, do structural factors (level of nursing staff experience, hours of structured activity, required vs actual nursing hours, and use of temporary staff) affect the development of therapeutic relationships between nurses and patients on acute mental health wards?
- Does the quality of therapeutic relationships between nurses and patients on acute mental health wards affect the outcomes of staff satisfaction, patient satisfaction, number of self-harm incidents and number of violent incidents?
- What are the views of patients and nurses in relation to how they interact on the ward?

4.1 Objectives

- To understand the content, context and experience of therapeutic relationships between nurses and patients
- To analyse associations between key structural factors, a measure of therapeutic relationships and outcomes for patients and nurses

4.2 Outcome

A framework for analysing nurse-patient relationships on acute mental health wards

5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYSIS

To meet the research objectives, the study uses a mixed methods approach to collect and analyse quantitative data and qualitative data. The study has three overlapping modules or stages of data collection:

Module 1: Information which is routinely collected around

a) aggression and self-harm

b) structural measures; required vs actual staffing hours, use of temporary staff, and hours of structured ward programme.

Module 2: Questionnaire data will be collected from

- 1) All staff from all professional groups working on host wards – measuring ward atmosphere, burnout, teamworking, years of experience, and reported quality of therapeutic relationship. Demographic information on gender, age and ethnicity will also be sought.
- 2) Patients – measuring satisfaction, ward atmosphere, and reported quality of therapeutic relationship. Key demographic data will also be sought, including age, gender, ethnicity and MHA status.

Module 3: Individual interviews will be carried out with registered nursing staff and also with patients using a narrative inquiry (Holloway and Freshwater, 2007) approach. Participants will be asked to 'tell their story' of being on the ward describe their experience of forming and maintaining therapeutic relationships with registered nurses.

Module 1: Ward data collection.

Prior to data collection, the researcher will publicise the study by attending senior staff meetings and service user forums to give information on the study. The researcher will attend meetings at ward level in order to discuss the study with staff and patients prior to data collection. Three acute mental health wards for adults aged 18-65 will be identified in one NHS trust. The researcher has conducted an initial scoping exercise to ascertain that sufficient wards will be available at the primary inpatient site run by the host Trust.

Data collection will include:

- incident rates as measured by Ulysses reports (the system used for reporting all adverse incidents in the host Trust) Only incidents of self-harm and aggression will be requested from the Trust information team.
- Nurse staffing variables at ward level for each participating ward including: use of agency or bank staff for each shift over the previous month, required vs actual nursing hours for the previous month. These data will be obtained from the electronic rostering system used within the Trust. This programme records dependency and nursing staff requirements (projected and actual) three times each day. The administrator for this system has confirmed that the data needed is available.
- hours of structured/programmed activity on each participating ward as reported by the ward manager

The anonymity of the Trust will be maintained in any published findings

Module 2: staff and patient questionnaires

Ward staff will be asked to complete a questionnaire with the following content:

- Maslach Burnout Inventory (MBI) (Maslach and Jackson, 1981) – a 22 item staff report measure of burnout and morale, consisting of three subscales: depersonalisation, emotional exhaustion and personal accomplishment.
- Ward Atmosphere Scale (WAS) (Moos, 1974) – Form S (shortened version), 40 item questionnaire consisting of 6 subscales: involvement, support, practical orientation, order and organisation, angry and aggressive behaviour, and staff control.
- Scale to Assess Therapeutic Relationships in mental health care (STAR) (McGuire-Snieckus et al, 2007) – staff version asks staff to assess in relation to three patients
- Items from the national mental health inpatient staff morale study (Johnson et al, 2010) addressing team working

- Staff will also be asked to provide demographic data (age, gender, ethnicity, number of years of experience of working in mental health and of working on the specific ward).

All ward based health care staff on the participating wards will be eligible to complete the questionnaire as this will allow for some comparison between nurses and other staff groups. In addition, patients will be able to include any member of staff they have had contact with.

Patients will be asked to complete a questionnaire which will be administered by the researcher, although they will have a choice to complete it alone if preferred. The questionnaire will include the following measures;

- Client Satisfaction Questionnaire (CSQ-8) (Larsen et al, 1979) – a measure of satisfaction with treatment. The CSQ-8 is scored by summing the individual item scores to produce a range of 8 to 32, with high scores indicating greater satisfaction. This will be the primary outcome of the study.
- Ward Atmosphere Scale (WAS) (Moos, 1974) – Form S (shortened version), 40 item questionnaire consisting of 6 subscales: involvement, support, practical orientation, order and organisation, angry and aggressive behaviour, and staff control.
- A measure of therapeutic relationships (STAR, McGuire-Snieckus et al 2007). In order to obtain a measure of overall alliance with health care staff, patients will be asked to complete this 12-item measure in relation to 3 staff (one to be primary or associate nurse) who have been important during their stay on the ward. The mean of these three scores will be used in analyses.
- Participants will be asked to provide brief demographic data (age, gender, ethnic group) and clinical details, (date of admission to ward and Mental Health Act status). They will be assured that they can refuse consent to give this information and can still participate in the study by completing the other sections of the questionnaire

Data from Modules 1 and 2 will be collected by the researcher.

Patients will be given £5 as a token in lieu of their time spent in completing the questionnaire.

No access to medical notes will be sought. All data will be anonymised and stored securely.

Questionnaires will be distributed by the researcher and a participant number ascribed.

Questionnaires will be returned in a sealed envelope to a box left on each ward.

Descriptive data will be presented for each variable. Univariate analysis will be carried out to explore any differences between demographic groups. Bivariate analysis will analyse correlations between variables. If appropriate, modelling will be used to analyse the contribution of variables to the outcome measures.

Module 3: Qualitative interviews

The narrative aspect of this study uses the views of key informants (staff and patients) to tell a particular story about the ward. In this case, this is a rich, behavioural description of interaction between nursing staff and patients on an acute ward. Only registered nursing staff will be approached in this module as the focus of the study is nurse-patient relationships and the interviews aim to elicit detailed data around issues related to developing therapeutic relationships in order to understand what factors might help or hinder this process. Links between interview data and quantitative data will be explored, giving a fuller understanding of associations between quantitative measures as well as possible identification of factors not included in quantitative data.

Interviews will be recorded electronically and then transcribed in full. The aim is to interview approximately 10% of the sample included in questionnaire data collection – this would mean interviews with 4 nursing staff and 4 patients. Participants will be purposively selected to access the widest diversity in a range of relevant characteristics of the types of staff and patient groups (in terms of experience, gender and ethnicity).

Patients who have consented to take part in Module 2 of the study may be asked to participate in module 3, however as data collection for module 3 will take place after collection of quantitative data, many patients will have been discharged so new patients who meet the inclusion criteria may also be approached. Informed consent will be sought for all interviews. Patients without capacity to consent will not be approached. The researcher will ask ward staff to identify patients who may be approached to take part in patient interviews. **Ward staff regularly carry out assessments of capacity as part of their routine work and will therefore have an understanding of which patients may be approached. This is important to prevent possible distress to very unwell patients.** As in module 2, the Chief Investigator will ask ward staff to identify patients who may be approached to take part. and they will be given £15 in lieu of their time for participating in the interview.

NVivo software will be used to aid qualitative analysis. Concepts and categories from the interviews will be initially extracted using thematic framework analysis, which will allow participant-relevant issues to be explored and developed as themes. The qualitative data will elucidate participants' experiences using a framework analytic approach to analysis (Braun and Clarke, 2006)

Activities to be carried out by the CI while on the ward:

- **Attending staff and patient meetings to introduce self and give an overview of the study**
- **Asking ward staff to identify patients who have capacity to consent to taking part in the study**
- **Asking ward staff to introduce the CI to identified patients and ascertain whether they are interested in participating**
- **Giving Participant Information Sheets to staff and patients**
- **Clarifying any questions about the PIS raised by staff or patients**
- **Seeking written consent from: staff wishing to be interviewed, patients wishing to complete the questionnaire, and patients wishing to be interviewed**
- **Distributing questionnaires to staff and patients**
- **Collecting completed questionnaires either from individuals or from a box left for this purpose on the ward**
- **Carrying out interviews with staff and patients who have given written consent**

- **Reviewing transcripts of interviews with staff and patients**

6 STUDY SETTING

Participating wards will be identified in one NHS trust. Three acute mental health wards for adults aged 18-65 on one Trust site will be included.

7 SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

Healthcare staff and patients on the three participating wards during the 3 months of the study will be eligible for inclusion.

7.1.1 Inclusion criteria

All healthcare staff who have responsibility for delivering care to patients on the ward will be included in the study: nursing staff only will be the focus of module 3.

All patients who have been in hospital for 7 days or more will be eligible to be included in the study, as this will allow an adequate period in which to have experienced life on the ward. Only patients thought by staff to have the capacity to give informed consent to the study will be approached, and this will also be checked by the researcher prior to obtaining written consent.

Only participants who have good command of English will be approached as translation of materials and hiring of interpreters is not within the scope of this research, which is not funded.

7.1.2 Exclusion criteria

- Patients assessed by staff as lacking capacity to consent
- Patients who have been admitted to the ward for less than 7 days
- Patients lacking a good command of written and spoken English

7.2 Sampling

Sampling will be purposive in that staff and patients from acute mental health wards volunteering to take part in the study will be included.

7.2.1 Size of sample

Nursing staff establishments of approximately 20 per ward mean that a maximum of approximately 60 participants can be included in the sample. We will aim to recruit 40 ward staff

Our target sample size for patient participants is 40. This is based on the available number of patients on four wards: each ward has 16 beds which provides a maximum sample size of 48 at any one time, although a proportion of these will not have capacity to consent. Additional patients will enter the study as it progresses allowing for a higher number of questionnaires to be returned.

A similar response rate was obtained in the study by Sweeney et al (2014).

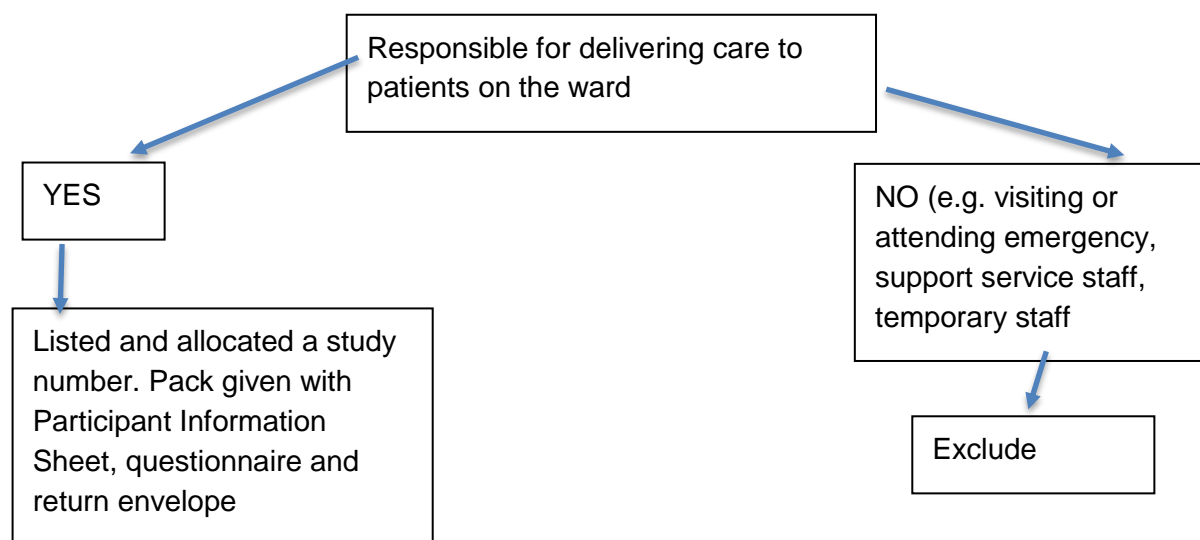
We also aim to recruit 4-6 nurses and 4-6 patients to take part in interviews, giving a total sample size of 92.

7.3 Recruitment

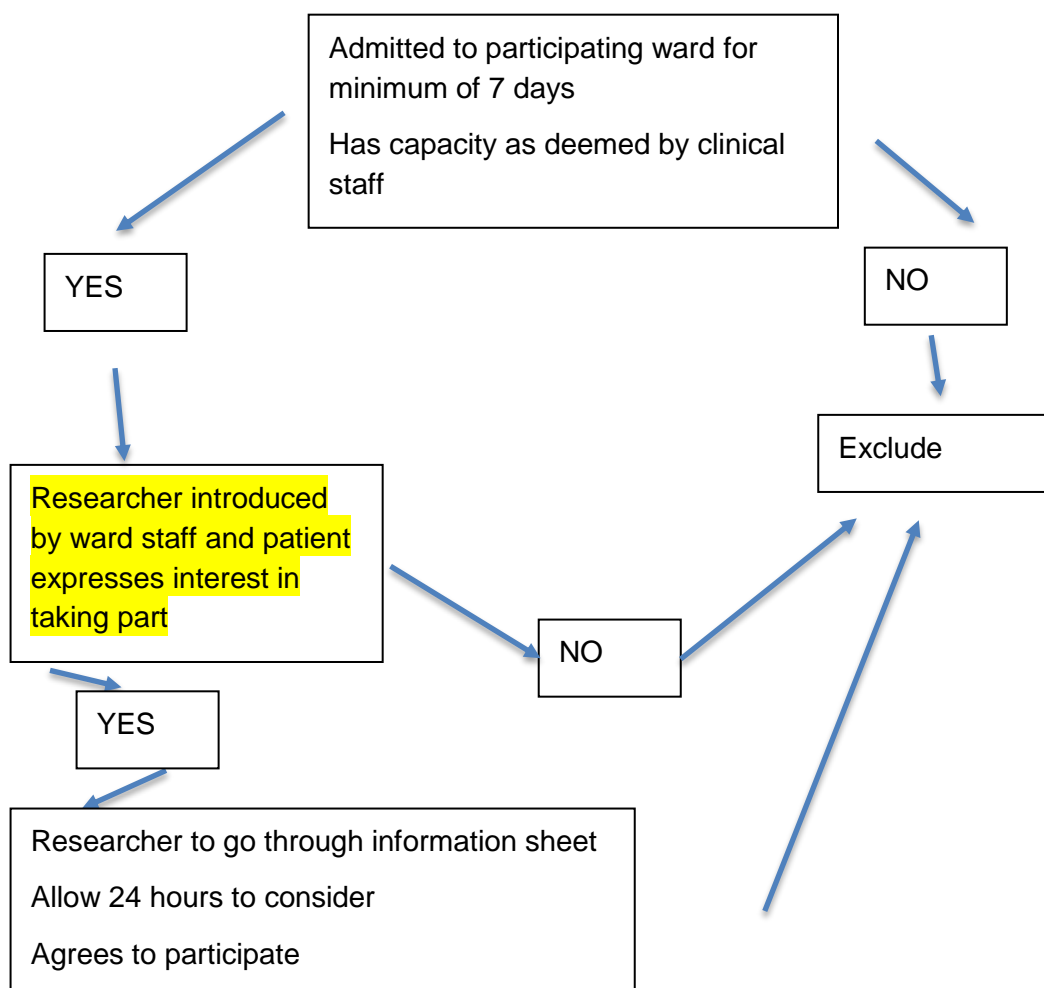
Procedure for approaching staff to participate in the study

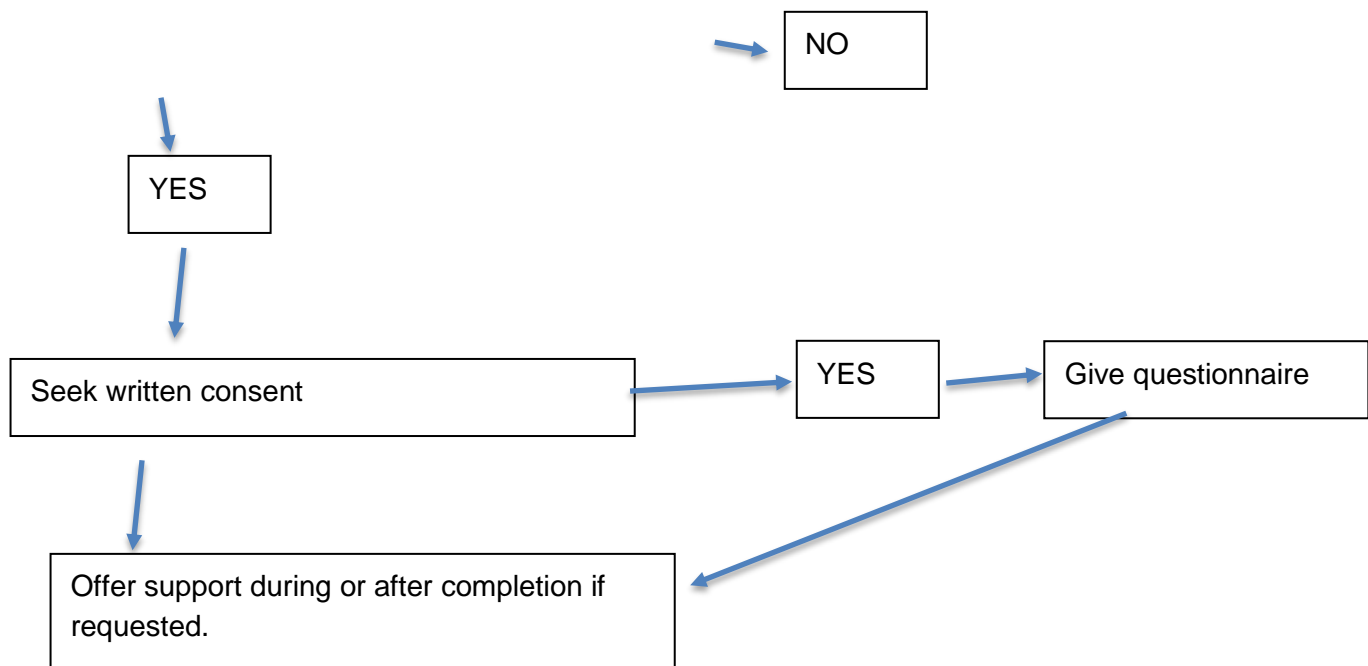
The researcher will attend ward meetings and handovers to give information about the study initially, and will deliver each questionnaire to staff by hand, which will give further opportunity to discuss the study and answer any questions. The questionnaires will be returned to the researcher using a box which will be placed in the ward office. Written consent to participate in this part of the study will not be sought from staff, as their consent will be inferred by completing the questionnaire. All responses will be anonymised using participant numbers.

Flow chart for staff participants in module 2:



Flow chart for patient participants in module 2:





7.3.2 Consent

Informed consent from patient participants will be required in module 2 and from both staff and patients in module 3.

Module 2: Written consent to participate in this part of the study will not be sought from staff, as their consent will be implied by completing the questionnaire. This will be made clear on the questionnaire. All staff will be given a participant information sheet. All responses will be anonymised using participant numbers.

A member of staff will identify patients who are well enough to be approached. **Staff will introduce the researcher to identified patients and the researcher will give information about the study.** The researcher will meet each person who has expressed willingness to be approached to explain what the study involves, providing them with a copy of the information sheet, reading through it with them if required, and answering any questions. Patients will be encouraged to think about whether they want to participate and will be given a minimum period of 24 hours in which to do this. There will be no maximum period, and patients can take as long as they like to consider participation and discuss this with their friends or family. The researcher will come back to see the patient after 24 hours initially, and if they are willing and then help them to complete the questionnaire. Written consent will be sought and if given a copy will be given to the patient and included in clinical notes.

If required, a quiet room on each ward will be available for staff and patients to complete the questionnaire in private.

Module 3: Only staff who have consented to take part in module 2 of the study by completing a questionnaire will be approached to take part in module 3. Written consent will be sought for qualitative interviews with staff.

Patients who have already taken part in module 2 of the study, can be approached again to take part in an interview, if this is deemed appropriate by the clinical staff. Patients who had not participated in module 2 may also be approached to participate in the qualitative interviews.

Clinical staff will identify patients with capacity to consent, who have been on the ward for a minimum of 7 days, and will introduce the researcher. The researcher will provide information about the qualitative interviews, then take written consent prior to conducting them.

8 ETHICAL AND REGULATORY CONSIDERATIONS

8.1 Assessment and management of risk

Participants are directly involved in Modules 2 and 3 of this study.

Module 2: The questionnaires for patients are quite lengthy, which may be a challenge for some. The CI will encourage patient participants to take breaks during completion as they need them, or to complete them at more than one sitting if required. However, experience from previous studies involving hundreds of participants, carried out by the supervisor in inpatient settings has provided reassurance that patients generally value lengthy interactions with researchers if these are conducted in an appropriate and empathetic manner. The CI is a mental health nurse with many years' experience of working with patients in acute mental health inpatient settings and is therefore well positioned to conduct these interviews.

The staff questionnaires may also raise some issues which may be emotive for participants.

Should it occur, the staff member will be encouraged to discuss the issue with the researcher or other staff member if preferred. Following discussion, appropriate support will be sought if required.

This may involve the staff member speaking to his ward supervisor or to a colleague. The PIS and consent form will state that in the unlikely event that the staff member discloses any information which indicates a risk of harm to the staff member or to others, the researcher will be obliged to report this to the staff member's line manager.

Module 3: There is a risk that staff and patients may become distressed when talking about their experiences in an interview. All participants will be informed that they can stop the interview at any time should this occur. Patients will be advised that they can seek support from their keyworker or primary nurse if needed. Staff will be able to access line managers for support. The CI is an experienced senior mental health nurse who can also access support from her supervisor. Participant identification numbers will be used on all transcripts to preserve anonymity, although participants will be advised before interview that any issues which affect safety may have to be disclosed to ward

managers. The PIS and consent form will state that in the unlikely event that the staff member or patient discloses any information which indicates a risk of harm to the staff member or to others, the researcher will be obliged to report this to the staff member's line manager or to clinical staff in the case of patients.

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

- Before the start of the study, a favourable opinion will be sought from a REC for the study protocol, participant information sheets, consent forms and other relevant documents.
- Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at site.
- All correspondence with the REC will be retained.
- It is the Chief Investigator's responsibility to produce the annual reports as required.
- The Chief Investigator will notify the REC of the end of the study.
- An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended.
- If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination.
- Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

Regulatory Review & Compliance

A research passport will be applied for in order to enable access to Trust sites.

Amendments

Amendments will be submitted to the REC prior to implementation. The supervisor will decide whether amendments are necessary.

8.3 Peer review

This protocol has been reviewed by an educational supervisor and by the Research Governance office of the sponsoring organisation.

8.4 Patient & Public Involvement

This protocol has been reviewed by a service user researcher.

8.5 Protocol compliance

Accidental protocol deviations can happen at any time. They will be documented on the relevant forms and reported to the Supervisor and Sponsor immediately.

8.6 Data protection and patient confidentiality

The researcher will comply with the requirements of the Data Protection Act 2018 with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles.

No personal information will be sought or stored as part of this study.

8.7 Access to the final study dataset

The researcher and two educational supervisors will have access to the final study dataset.

9 DISSEMINATION POLICY

9.1 Dissemination policy

- Data from the study will be owned by the sponsor and participating organisation
- On completion of the study, the data will be analysed and tabulated and a Final Study Report prepared which will be accessible through the researcher
- Results of the study will be presented and discussed at forums within the participating organisation.
- All participating investigators will have rights to publish from the study, but only with the agreement of the Chief Investigator
- We will keep a record of participants who requested to be notified of the final results and a copy of the final report will be sent to the host organisation for dissemination through their communication channels.
- The protocol will be registered with <https://www.isrctn.com/page/why-register> and will be publicly available

9.2 Authorship eligibility guidelines and any intended use of professional writers

The author will be the Chief Investigator

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