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Time Together: A study protocol of a multi-site nursing intervention project using a single system experimental design

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Time Together: A study protocol of a multi-site nursing intervention project using a single system experimental design.

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ABSTRACT

Introduction: Despite the long known significance of the nurse-patient relationship, research in psychiatric inpatient care still reports unfulfilled expectations of, and difficulties in, interactions and relationships between patients and staff. Interventions that create structures to allow quality interactions between patients and staff are needed to solve these problems. The aim of this project is to test effects of the nursing intervention Time Together and to evaluate the intervention process.

Methods and analysis: This is a multi-site study with a single-system experimental design using frequent measures. The primary outcomes are quality interactions for patients and perceived stress for staff. Secondary outcomes are levels of symptoms of anxiety and depression for patients and stress of conscience for staff. A process evaluation is performed to describe contextual factors and experiences. Data are collected using questionnaires, participant observations, and semi-structured interviews. For analysis of quantitative data, both visual and statistical methods will be used. Qualitative data will be analyzed using qualitative content analysis.

Ethics and dissemination: Ethical approval was granted by the Ethical Review Board in the region (Dnr 2016/339-31). The findings will contribute to the development of nursing interventions in general, but more specifically to the development of the intervention. This is relevant both nationally and internationally as similar interventions are needed but sparse. The findings will be disseminated through conference presentations and peer-reviewed publications.

Trial registration number: NCT02981563

Keywords: engagement, complex interventions, multi-site study, nursing, process evaluation, protocol, single system design, psychiatric inpatient care, quality interactions

ARTICLE SUMMARY

Strengths and limitations of this study

- Multi-site study performed at three different wards
- Process evaluation integrated in the study
- Relatively small scale could pose a threat to generalisation
- An SSED design enables us to closely follow the outcome measures

INTRODUCTION

It is well known that the nurse-patient relationship is the core of mental health nursing.[1-4] To create such relationships, it is essential that interactions contain emotional communication,[1, 5] and to convey such care in their responses, staff should reach out to the patient as a first step in sharing that person's experiences.[6] Barker and Buchanan-Barker[2, 6] conceptualised such human processes as *engagement* and later renamed it *bridging*.

Despite the long-known significance of the nurse-patient relationship, research in psychiatric inpatient care still reports unfulfilled expectations of, and difficulties in, interactions and relationships between staff and patients. Patients express a need for human relations with staff and for something to do, while staff say that they have ideals about providing good care but their time spent with patients is limited by organisational chaos.[7-12] Patients and staff also seem to share negative experiences of the environment, the lack of structure and activities, the disorganization, and the substantial power relationships.[9, 13-15] Together, these leads to counterproductive care, experiences of stigma among patients,[14, 16] and signs of moral distress among staff.[15, 17]

In response to the challenges outlined above, we need to proceed from descriptions to action. Several researchers raise nurses' need for time to devote to their patients.[11, 12, 14, 18] Similar ideas are discussed by Cleary et al.[19] and Polacek et al.,[20] who suggest that the

focus should be on creating conditions that enable engagement and the development of therapeutic interaction skills with a "human touch".[21] It has also been suggested that being given the responsibility and the ability to work in line with their ideals and engage with their patients could reduce moral distress among staff and improve both the quality of care and the chances of recovery for patients.[15, 17, 22-28] Together this indicates that nursing interventions focusing on quality interactions could be help to solve the described shortcomings in care. However, in a review, Mullen[29] reported that such interventions, for example planned dialogues and psychoeducation, are complex and difficult to implement in psychiatric inpatient care because of the demanding and chaotic context. This seems to still be the case, as such interventions are sparsely described in the scientific literature, which implies a need for interventions that create structures to allow quality interactions between staff and patients.

As a grassroots initiative, one intervention aimed to create structures for quality interactions between staff and patients was developed in the UK in the early 2000s.[30] There are some descriptions of the practical structures of Protected Engagement Time (PET) in the literature,[30-34] and evaluations of PET are ongoing in the UK.[33] The theoretical framework of PET is vaguely described in the early literature. However, according to Nolan et al.[33], the intervention is rooted in practice with a starting point in the staffs' situation as PET was developed on the basis of Karasek and Theorells theory on job strain[35] but with the nurse-patient relationship in the center. The structure of PET requires that staff, for a fixed time during the day, dedicate their time exclusively to interacting with the patients. Other more administrative duties, visits and meetings are organised to be performed at other times during the day.[33] Through this, opportunities for interaction are both created and protected.

During the development of our intervention, Barker and Buchanan-Barker's theoretical framework [2] was added to highlight the centrality of needs of the patients and engagement among staff. There are obvious parallels between the content of PET and the philosophy of Barker and Buchanan-Barker.[2] They share an emphasis on engagement; both describe levels of engagement in supporting patients in psychiatric inpatient care, but they also take a pragmatic approach to interventions that should be shaped by prevailing requirements and available resources.[36]

Our intervention builds on PET, but expands the theoretical framework by adding Barker and Buchanan-Barker's theory.[2] To emphasize this theoretical expansion and to adapt the intervention to the Swedish context and language, the intervention described in this project is named Time Together (TT).

STUDY AIMS

The overall aim of this project is to test the effects of the nursing intervention TT and to evaluate the intervention process. The main research questions are:

- Does TT influence the quality of interactions between staff and patients?
- Does TT influence patients' levels of anxiety and depressive symptoms?
- Does TT influence staffs' levels of perceived stress and levels of stress of conscience?
- Does TT influence the prevalence of coercive measures, mean length of hospital stay, and the use of PRN medication?

Because this will be the first use of TT in Swedish psychiatric inpatient care there is also a need to evaluate the process of introducing it as a nursing intervention. Through this process evaluation we aim to answer questions such as:

- How do staff and patients describe their experiences of the intervention and how do contextual factors influence the effects of the intervention?
- What are the relationships between the outcome variables and the degree of compliance with the intended intervention?
- What problems are there with recruitment and dropouts?

METHODS

This is a multi-site nursing intervention project using a single-system experimental design (SSED).[37]

SSED studies focus primarily on changes in one system and not differences between systems. Each system works as its own control and therefore a smaller number of systems are required than in other experimental models.[38] The process evaluation is performed in parallel to describe experiences and contextual factors of importance.

In this project, the evaluation of TT will consist of two phases (A and B) and follow-up, in line with the SSED. In the A phase, where the baseline is established, outcomes will be measured once every seventh day (weekends not included) for approximately five weeks. In B phase, TT will be introduced on the wards and outcomes will be measured once every seventh day (weekends not included) for three months. The follow-up will take place six months after the B phase. Both patients and staff will complete questionnaires and participate in interviews to assess whether the possible effects of TT are sustainable.

The project will be conducted from January 2017 to May 2018 at three psychiatric clinics located at three hospitals in two county councils in the north of Sweden. One psychiatric

inpatient care ward at each clinic will participate. Each ward constitutes one system and data for each system will consist of aggregated measurements from admitted patients and staff working on each ward.[37, 39]

Description of Time Together

A description similar to that of Nolan et al.,[33] in combination with Barker and Buchanan-Barker's description of levels of engagement [2] will be used as the basis for the introduction of TT. The basic model for the intervention will therefore be:

- Regular times for TT will be established on Mondays-Fridays, for a total of 5 hours.
- Registered nurses (RNs) and enrolled nurses (ENs) will be engaged in joint activities with the patients during TT.
- Engagement should involve interactions in either one-on-one sessions or group sessions including joint activities chosen by the patients.
- During TT, only 1 or 2 of the ward staff will manage the administrative ward duties. All other members of staff will engage with the patients.
- During TT, the ward will be closed to visitors and professionals from outside the ward.

For the intervention to be feasible, TT will be tailored to local circumstances at each ward with the points above as a basic guide.[40]

Setting

The patients on the participating wards, admitted voluntarily or involuntarily, suffer from different kinds of mental ill health or substance-related and addictive disorders. In general, the wards have rules and routines, locked doors, fixed times for meals, smoking breaks, and

opportunities to walk outdoors. Nursing interventions such as joint activities, planned dialogues, and psychoeducation are usually rare, and medical treatment is the norm instead. Those working on the wards are ENs in mental health, RNs, some of whom have specialist training in mental health nursing, a ward manager, residents, and consultant psychiatrists. Other professions can be consulted when necessary.

Participants

All patients admitted to the wards during phase A, phase B, and the follow-up of the intervention will be informed about the ongoing project by a research assistant. During phase A, all patients admitted to the wards will be invited to participate in the study by completing questionnaires. During phase B, the patients who participated in at least one TT session will be invited to participate through questionnaires, semi-structured interviews, and participant observations.

Inclusion criteria for patients: 18 years or older, admitted to the wards during phase A, phase B, and/or follow-up. Experience of at least one TT session is required.

Exclusion criteria for patients: not fluent enough in the Swedish language to complete questionnaires and participate in interviews.

The researchers will invite all staff working on the wards during phase A, phase B, and follow-up of the intervention to participate in the evaluation of TT.

Inclusion criteria for staff: staff employed at the ward during phase A, phase B, and/or follow-up.

Data collection

Data will be collected through questionnaires and ward registers. In the evaluation of the process, semi-structured interviews and participant observations will be conducted by the researchers and logbooks will be kept by the research assistants at each ward.

Questionnaires

The primary outcome measure for patients will be the quality of interactions with members of staff, based on the results of previous studies[14, 41] that showed that, according to patients in psychiatric inpatient care, the quality of interactions influences everyday life in psychiatric inpatient care. Secondary outcome measures will be levels of anxiety and depressive symptoms. For staff, the primary outcome measure will be perceived stress, based on the results of previous studies[15, 17, 26] that showed that staff in interprofessional teams in psychiatric inpatient care moved from ideals to resignation because of organisational and structural obstacles. Secondary outcome measures will be stress of conscience, satisfaction of interactions with patients, and quality of care. Demographic data will be collected for all participants.

Patient related questionnaires

The Caring Professional Scale (CPS)[42] will be used to measure the quality of the interactions. CPS consists of 14 items answered on a 5-point Likert scale. Validity and reliability has been reported as satisfactory (Cronbach's alpha nurses 0.97).[42]

The widely used and well-tested *Visual Analogue Scale* (VAS)[43] will be used to measure satisfaction with the interactions. The scale will be 100 mm in length, ranging from "very unsatisfactory" to "very satisfactory".

The self-assessment scale *The Hospital Anxiety and Depression Scale* (HAD)[44] will be used to measure anxiety and depressive symptoms. All items are scored on a 4-point scale. HAD appears to be reliable and valid and is shown to be sensitive to changes in response to psychosocial interventions.[44, 45] The Swedish version was tested and shown to have satisfactory validity and reliability (Cronbach's alpha 0.90).[46]

Staff related questionnaires

The Perceived Stress Scale (PSS)[47] will be used to measure stress among staff. PSS consists of 10 items answered on a 5-point Likert scale. The Swedish version of the 10-item PSS has proved to have satisfactory validity and reliability (Cronbach's alpha 0.84).[48]

The Stress of Conscience Questionnaire (SCQ)[49] will be used to measure the frequencies of stressful situations and the degree to which these lead to stress of conscience among staff. SCQ consists of nine items in two parts. The first part uses a 6-point scale ranging from never (0) to every day (5) for each of the nine items and the second part uses a 100 mm VAS ranging from 'No, not at all' (0) to 'Yes, it gives me a very troubled conscience' (5) for those same items. Previous studies have reported satisfactory validity and reliability (Cronbach's alpha 0.83 for the total SCQ).[50]

The *VAS*[43] will be used to measure staff satisfaction with their interactions with patients. The scale will be 100 mm in length, ranging from "very unsatisfactory" to "very satisfactory".

The Quality in Psychiatric Care-Inpatient Staff (QPC-IPS) [51, 52] questionnaire will be used to measure quality of care. This instrument is part of the QPC family of instruments that

originate from the QPC study.[51, 52] Psychometric tests have been conducted internationally and are ongoing nationally. No results have yet been published.

Data from ward registers

Data regarding PRN medication, hospital stays, use of coercion, and violent situations will be collected from the participating wards' existing registers.

Semi-structured interviews

Both patients and staff will be individually interviewed by the researchers, using a semi-structured format.[53] During phase B, patients will be interviewed just before or shortly after their discharge from the ward and staff will be interviewed at the end of the phase. The participants will be asked to share their experience of TT's impact on the quality of the interactions. For staff there will also be questions about TT's impact on their daily work and organisational issues that facilitate and complicates TT. The sample will be selected purposively by the researchers and the estimated number of participants will be 30 staff members and 30 patients (10 from each ward).

Participant observations

Participant observations will be used during phase B. This approach, aimed to describe patterns of behaviours among individuals and groups in a particular culture, gives researchers the opportunity to share certain experiences with both patients and staff on the wards. In this project, observations with a focused approach will allow researchers to describe activities and interactions between patients and staff during TT.[54]

Log

During phase B, the research assistant at each ward will keep a log recording the number of TT sessions, their duration, the kinds of activities engaged in, and reflections upon each session.

Analysis

Quantitative data

Demographic data for participants will be presented as means and proportions. To evaluate changes during the intervention, both visual and statistical methods will be used to analyse data.[55] The visual inspection of data in SSED studies is described as a viable and approved method to analyse and compare levels, trends, and variability between intervention phases.[38] For the statistical calculations, *percentage of non-overlapping data* statistics will be used. This is a calculation of the percentage of treatment data that overlaps with the most extreme data point exhibited at baseline.[38]

Qualitative data

Both the participant observations and the semi-structured interviews will be analysed using qualitative content analysis (QCA). In QCA the focus is on variations in participants' experiences and presenting the results in categories and/or themes.[56]

ETHICS AND DISSEMINATION

The study has been approved by the heads of the clinical departments of psychiatry involved and the regional Ethical Review Board (Dnr 2016/339-31). All participants will receive written and verbal information about the aim of the study. They will be informed that participation is voluntary, that they have the right to withdraw without specifying why, and that confidentiality will be assured. Informed consent will be assigned by all participants. The

findings will be disseminated through conference presentations and peer-reviewed publications.

DISCUSSION

Introducing TT is not only an attempt to meet the needs described by patients and staff in psychiatric inpatient care, but also an attempt to come to terms with some of the shortcomings described in the evidence (i.e., lack of structure and unmanaged chaos).[14,15] To our knowledge, similar studies are sparse in the international evidence and no similar projects have been tested or implemented in the context of Swedish psychiatric inpatient care.

The project, including the SSED and the process evaluation, will provide a first description of TT in a Swedish context. It is significant because studies of this type are sparse both nationally and internationally. Research in mental health nursing has a responsibility to take the next step since many of the problematic circumstances now are known. The development of interventions is a step in the right direction towards solving some of these problems.[57]

This study is performed at three hospital wards. Even though this may be considered a small sample with a limited generalizability, this study will still assess the effect of TT in this context. Such knowledge will provide a basis for further development and indications of what adjustments needs to be done to better suit psychiatric inpatient care nationally and possibly, even internationally in similar context.

Combining the SSED with a process evaluation has been described as highly valuable.[58] Collecting both quantitative and qualitative data will offer us opportunities to describe the introduction of TT from different viewpoints, enable us to capture a broad picture of the

effects of TT, and enable us to evaluate the trustworthiness and quality of the introduction of the intervention.[58] This in turn could contribute to the development and dissemination of TT.

According to Craig et al.,[40] a distinct theoretical framework is the basis of sustainable interventions and allows for better evaluations. Barker and Buchanan-Barker's concept of engagement[2] is added as a theoretical framework for this project. This stance, combined with the introduction of TT to the Swedish context will provide opportunities for further development of the intervention.

The composition of the research team provides a mix of experience in the context and the methods used for evaluation. JM, BML, and UHG are experienced mental health nurses and AR and UHG have use SSED, including the quantitative methods used during analysis. All authors are experienced in qualitative methods.

In the first descriptions, the PET intervention is described to have its roots in practice rather than in theory.[30] This pragmatic approach has been preserved in the design of TT which will be tailored to local circumstances at each participating ward. This has been done in collaboration with staff working on the wards and patients have been asked about what joint activities they want to be offered during TT.[55] This could be seen as a study limitation as it is less standardised. However, it has been key to introducing a feasible intervention that would be realistic to implement if it is proven to be effective. As described, we see the potential of the intervention because it does not require additional staff or costs, being in line with the wishes of the patients and the ideals of the staff.[14, 15]

DECLARATIONS

Competing interests

The authors report no conflict of interest.

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Data sharing

No additional data available.

Authors' contributions

Study design: JM, AR, BML, UHG. Manuscript preparation: JM, AR, BML, UHG. All authors read and approved the final manuscript.

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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym P. 1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry P. 2
	2b	All items from the World Health Organization Trial Registration Data Set N/A
Protocol version	3	Date and version identifier
Funding	4	Sources and types of financial, material, and other support P. 14
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors P. 1
	5b	Name and contact information for the trial sponsor N/A (no sponsor)
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities N/A
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) N/A
Introduction		
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention P. 3 - 5
	6b	Explanation for choice of comparators N/A
Objectives	7	Specific objectives or hypotheses P. 5
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) P. 6

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained P. 7
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) P. 6
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered P. 7
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) P. 11
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended P. 9 - 10
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) P. 6
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations P. 6
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size P. 5

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions

N/A - not randomized

Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned N/A
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions p. 8
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how N/A
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial N/A
Methods: Data collection, management, and analysis		
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol p. 8
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols —
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol N/A
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol p. 11
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses) —
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) N/A
Methods: Monitoring		
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed N/A

	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct P12
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor N/A
Ethics and dissemination		
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval P. 12
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) P12
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) P12, 8
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial P12
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site P14
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators -
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions P.12
	31b	Authorship eligibility guidelines and any intended use of professional writers N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code N/A

BMJ Open

Time Together: A study protocol of a multi-site nursing intervention project using a single system experimental design

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Does "Time Together" increase quality of interaction and decrease stress? A study protocol of a multi-site nursing intervention in psychiatric in-patient care, using a single system experimental design and a process evaluation.

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ABSTRACT

Introduction: Despite the long known significance of the nurse-patient relationship, research in psychiatric inpatient care still reports unfulfilled expectations of, and difficulties in, interactions and relationships between patients and staff. Interventions that create structures to allow quality interactions between patients and staff are needed to solve these problems. The aim of this project is to test effects of the nursing intervention Time Together and to evaluate the intervention process.

Methods and analysis: This is a multi-site study with a single-system experimental design using frequent measures. The primary outcomes are quality interactions for patients and perceived stress for staff. Secondary outcomes are levels of symptoms of anxiety and depression for patients and stress of conscience for staff. A process evaluation is performed to describe contextual factors and experiences. Data are collected using questionnaires, participant observations, and semi-structured interviews. For analysis of quantitative data, both visual and statistical methods will be used. Qualitative data will be analyzed using qualitative content analysis.

Ethics and dissemination: Ethical approval was granted by the Ethical Review Board in the region (Dnr 2016/339-31). The findings will contribute to the development of nursing interventions in general, but more specifically to the development of the intervention. This is relevant both nationally and internationally as similar interventions are needed but sparse. The findings will be disseminated through conference presentations and peer-reviewed publications.

Trial registration number: NCT02981563

Keywords: engagement, complex interventions, multi-site study, nursing, process evaluation, protocol, single system design, psychiatric inpatient care, quality interactions

ARTICLE SUMMARY

Strengths and limitations of this study

- Multi-site study performed at three different wards
- Process evaluation integrated in the study
- Relatively small scale could pose a threat to generalisation
- An SSED design enables us to closely follow the outcome measures

INTRODUCTION

It is well known that the nurse-patient relationship is the core of mental health nursing.[1-4] To create such relationships, it is essential that interactions contain emotional communication,[1, 5] and to convey such care in their responses, staff should reach out to the patient as a first step in sharing that person's experiences.[6] Barker and Buchanan-Barker[2, 6] conceptualised such human processes as *engagement* and later renamed it *bridging*.

Despite the long-known significance of the nurse-patient relationship, research in psychiatric inpatient care still reports unfulfilled expectations of, and difficulties in, interactions and relationships between staff and patients. Patients express a need for human relations with staff and for something to do, while staff say that they have ideals about providing good care but their time spent with patients is limited by organisational chaos.[7-12] Patients and staff also seem to share negative experiences of contextual factors such as the environment, the lack of structure and activities, the disorganization, and the substantial power relationships.[9, 13-15] Together, these leads to counterproductive care, experiences of stigma among patients,[14, 16] and signs of moral distress among staff.[15, 17]

In response to the challenges outlined above, we need to proceed from descriptions to action. Several researchers raise nurses' need for time to devote to their patients.[11, 12, 14, 18] Similar ideas are discussed by Cleary et al.[19] and Polacek et al.,[20] who suggest that the

focus should be on creating conditions that enable engagement and the development of therapeutic interaction skills with a “human touch”.[21] It has also been suggested that being given the responsibility and the ability to work in line with their ideals and engage with their patients could reduce moral distress among staff and improve both the quality of care and the chances of recovery for patients.[15, 17, 22-28] Together this indicates that nursing interventions focusing on quality interactions could be help to solve the described shortcomings in care. However, in a review, Mullen[29] reported that such interventions, for example planned dialogues and psychoeducation, are complex and difficult to implement in psychiatric inpatient care because of the demanding and chaotic context. This seems to still be the case, as such interventions are sparsely described in the scientific literature, which implies a need for interventions that create structures to allow quality interactions between staff and patients.

As a grassroots initiative, one intervention aimed to create structures for quality interactions between staff and patients was developed in the UK in the early 2000s.[30] There are some descriptions of the practical structures of Protected Engagement Time (PET) in the literature,[30-34] and evaluations of PET are ongoing in the UK.[33] The theoretical framework of PET is vaguely described in the early literature. However, according to Nolan et al.[33], the intervention is rooted in practice with a starting point in the staffs’ situation as PET was developed on the basis of Karasek and Theorells theory on job strain[35] but with the nurse-patient relationship in the center. The structure of PET requires that staff, for a fixed time during the day, dedicate their time exclusively to interacting with the patients. Other more administrative duties, visits and meetings are organised to be performed at other times during the day.[33] Through this, opportunities for interaction are both created and protected.

During the development of our intervention, Barker and Buchanan-Barker's theoretical framework [2] was added to highlight the centrality of needs of the patients and engagement among staff. There are obvious parallels between the content of PET and the philosophy of Barker and Buchanan-Barker.[2] They share an emphasis on engagement; both describe levels of engagement in supporting patients in psychiatric inpatient care, but they also take a pragmatic approach to interventions that should be shaped by prevailing requirements and available resources.[36]

Our intervention builds on PET, but expands the theoretical framework by adding Barker and Buchanan-Barker's theory.[2] To emphasize this theoretical expansion and to adapt the intervention to the Swedish context and language, the intervention described in this project is named Time Together (TT).

STUDY AIMS

The overall aim of this project is to test the effects of the nursing intervention TT and to evaluate the intervention process. The main research questions are:

- Does TT influence the quality of interactions between staff and patients?
- Does TT influence patients' levels of anxiety and depressive symptoms?
- Does TT influence staffs' levels of perceived stress and levels of stress of conscience?
- Does TT influence the prevalence of coercive measures, mean length of hospital stay, and the use of PRN medication?

Because this will be the first use of TT in Swedish psychiatric inpatient care there is also a need to evaluate the process of introducing it as a nursing intervention. Through this process evaluation we aim to answer questions such as:

- How do staff and patients describe their experiences of the intervention and how do contextual factors influence the effects of the intervention?
- What are the relationships between the outcome variables and the degree of compliance with the intended intervention?
- What problems are there with recruitment and dropouts?

METHODS

This is a multi-site nursing intervention project using a single-system experimental design (SSED).[37]

SSED studies focus primarily on changes in one system and not differences between systems. Each system works as its own control and therefore a smaller number of systems are required than in other experimental models.[38] The process evaluation is performed in parallel to describe experiences and contextual factors of importance.

In this project, the evaluation of TT will consist of two phases (A and B) and follow-up, in line with the SSED. In the A phase, where the baseline is established, outcomes will be measured once every seventh day (weekends not included) for approximately five weeks. In B phase, TT will be introduced on the wards and outcomes will be measured once every seventh day (weekends not included) for three months. The follow-up will take place six months after the B phase. Both patients and staff will complete questionnaires and participate in interviews to assess whether the possible effects of TT are sustainable.

The project will be conducted from January 2017 to May 2018 at three psychiatric clinics located at three hospitals in two county councils in the north of Sweden. One psychiatric

inpatient care ward at each clinic will participate. Each ward constitutes one system and data for each system will consist of aggregated measurements from admitted patients and staff working on each ward.[37, 39] This implies that that the total number of individuals in the SSED study is largely dependent on a) the number of patients admitted to the ward at each point of measurement, and b) the number of staff members working at the ward.

Description of Time Together

A description similar to that of Nolan et al.,[33] in combination with Barker and Buchanan-Barker's description of levels of engagement [2] will be used as the basis for the introduction of TT. The basic model for the intervention will therefore be:

- Regular times for TT will be established on Mondays-Fridays, for a total of 5 hours.
- Registered nurses (RNs) and enrolled nurses (ENs) will be engaged in joint activities with the patients during TT.
- Engagement should involve interactions in either one-on-one sessions or group sessions including joint activities chosen by the patients.
- During TT, only 1 or 2 of the ward staff will manage the administrative ward duties. All other members of staff will engage with the patients.
- During TT, the ward will be closed to visitors and professionals from outside the ward.

For the intervention to be feasible, TT will be tailored to local circumstances at each ward with the points above as a basic guide.[40]

Setting

The patients on the participating wards, admitted voluntarily or involuntarily, suffer from different kinds of mental ill health or substance-related and addictive disorders. In general, the wards have rules and routines, locked doors, fixed times for meals, smoking breaks, and opportunities to walk outdoors. Nursing interventions such as joint activities, planned dialogues, and psychoeducation are usually rare, and medical treatment is the norm instead. Those working on the wards are ENs in mental health, RNs, some of whom have specialist training in mental health nursing, a ward manager, residents, and consultant psychiatrists. Other professions can be consulted when necessary. For a description of the intervention wards, please refer to Table 1.

Participants

All patients admitted to the wards during phase A, phase B, and the follow-up of the intervention will be informed about the ongoing project by a research assistant. During phase A, all patients admitted to the wards will be invited to participate in the study by completing questionnaires. During phase B, the patients who participated in at least one TT session will be invited to participate through questionnaires, semi-structured interviews, and participant observations.

Inclusion criteria for patients: 18 years or older, admitted to the wards during phase A, phase B, and/or follow-up. Experience of at least one TT session is required.

Exclusion criteria for patients: not fluent enough in the Swedish language to complete questionnaires and participate in interviews.

The researchers will invite all staff working on the wards during phase A, phase B, and follow-up of the intervention to participate in the evaluation of TT.

Inclusion criteria for staff: staff employed at the ward during phase A, phase B, and/or follow-up.

Data collection

Data will be collected through questionnaires and ward registers. In the evaluation of the process, semi-structured interviews and participant observations will be conducted by the researchers and logbooks will be kept by the research assistants at each ward.

Questionnaires

The primary outcome measure for patients will be the quality of interactions with members of staff, based on the results of previous studies[14, 41] that showed that, according to patients in psychiatric inpatient care, the quality of interactions influences everyday life in psychiatric inpatient care. Secondary outcome measures will be levels of anxiety and depressive symptoms. For staff, the primary outcome measure will be perceived stress, based on the results of previous studies[15, 17, 26] that showed that staff in interprofessional teams in psychiatric inpatient care moved from ideals to resignation because of organisational and structural obstacles. Secondary outcome measures will be stress of conscience, satisfaction of interactions with patients, and quality of care. Demographic data will be collected for all participants.

Patient related questionnaires

The Caring Professional Scale (CPS)[42] will be used to measure the quality of the interactions. CPS consists of 14 items answered on a 5-point Likert scale. Validity and reliability has been reported as satisfactory (Cronbach's alpha nurses 0.97).[42]

The widely used and well-tested *Visual Analogue Scale* (VAS)[43] will be used to measure satisfaction with the interactions. The scale will be 100 mm in length, ranging from "very unsatisfactory" to "very satisfactory".

The self-assessment scale *The Hospital Anxiety and Depression Scale* (HAD)[44] will be used to measure anxiety and depressive symptoms. All items are scored on a 4-point scale. HAD appears to be reliable and valid and is shown to be sensitive to changes in response to psychosocial interventions.[44, 45] The Swedish version was tested and shown to have satisfactory validity and reliability (Cronbach's alpha 0.90).[46]

Staff related questionnaires

The Perceived Stress Scale (PSS)[47] will be used to measure stress among staff. PSS consists of 10 items answered on a 5-point Likert scale. The Swedish version of the 10-item PSS has proved to have satisfactory validity and reliability (Cronbach's alpha 0.84).[48]

The Stress of Conscience Questionnaire (SCQ)[49] will be used to measure the frequencies of stressful situations and the degree to which these lead to stress of conscience among staff. SCQ consists of nine items in two parts. The first part uses a 6-point scale ranging from never (0) to every day (5) for each of the nine items and the second part uses a 100 mm VAS ranging from 'No, not at all' (0) to 'Yes, it gives me a very troubled conscience' (5) for those same items. Previous studies have reported satisfactory validity and reliability (Cronbach's alpha 0.83 for the total SCQ).[50]

The *VAS*[43] will be used to measure staff satisfaction with their interactions with patients. The scale will be 100 mm in length, ranging from "very unsatisfactory" to "very satisfactory".

The Quality in Psychiatric Care-Inpatient Staff (QPC-IPS) [51, 52] questionnaire will be used to measure quality of care. This instrument is part of the QPC family of instruments that originate from the QPC study.[51, 52] Psychometric tests have been conducted internationally and are ongoing nationally. No results have yet been published.

Data from ward registers

Data regarding PRN medication, hospital stays, use of coercion, and violent situations will be collected from the participating wards' existing registers.

Semi-structured interviews

Both patients and staff will be individually interviewed by the researchers, using a semi-structured format.[53] During phase B, patients will be interviewed just before or shortly after their discharge from the ward and staff will be interviewed at the end of the phase. The participants will be asked to share their experience of TT's impact on the quality of the interactions. For staff there will also be questions about TT's impact on their daily work and organisational issues that facilitate and complicates TT. For this process evaluation component of the study, the sample will be selected purposively by the researchers and the estimated number of participants will be 30 staff members and 30 patients (10 from each ward), depending on the quality of the interviews [54].

Participant observations

Participant observations will be used during phase B. This approach, aimed to describe patterns of behaviours among individuals and groups in a particular culture, gives researchers the opportunity to share certain experiences with both patients and staff on the wards. In this

project, observations with a focused approach will allow researchers to describe activities and interactions between patients and staff during TT.[55]

Log

During phase B, the research assistant at each ward will keep a log recording the number of TT sessions, their duration, the kinds of activities engaged in, and reflections upon each session.

Analysis

Quantitative data

Demographic data for participants will be presented as means and proportions. To evaluate changes during the intervention, both visual and statistical methods will be used to analyse data.[56] The visual inspection of data in SSED studies is described as a viable and approved method to analyse and compare levels, trends, and variability between intervention phases.[38] For the statistical calculations, *percentage of non-overlapping data* statistics will be used. This is a calculation of the percentage of treatment data that overlaps with the most extreme data point exhibited at baseline.[38]

Qualitative data

Both the participant observations and the semi-structured interviews will be analysed using qualitative content analysis (QCA). In QCA the focus is on variations in participants' experiences and presenting the results in categories and/or themes.[57]

ETHICS AND DISSEMINATION

The study has been approved by the heads of the clinical departments of psychiatry involved and the regional Ethical Review Board (Dnr 2016/339-31). All participants will receive written and verbal information about the aim of the study. They will be informed that participation is voluntary, that they have the right to withdraw without specifying why, and that confidentiality will be assured. Informed consent will be assigned by all participants. The findings will be disseminated through conference presentations and peer-reviewed publications.

DISCUSSION

Introducing TT is not only an attempt to meet the needs described by patients and staff in psychiatric inpatient care, but also an attempt to come to terms with some of the shortcomings described in the evidence (i.e., lack of structure and unmanaged chaos).[14,15] To our knowledge, similar studies are sparse in the international evidence and no similar projects have been tested or implemented in the context of Swedish psychiatric inpatient care.

The project, including the SSED and the process evaluation, will provide a first description of TT in a Swedish context. It is significant because studies of this type are sparse both nationally and internationally. Research in mental health nursing has a responsibility to take the next step since many of the problematic circumstances now are known. The development of interventions is a step in the right direction towards solving some of these problems.[58]

This study is performed at three hospital wards. Even though this may be considered a small sample with a limited generalizability, this study will still assess the effect of TT in this context. Such knowledge will provide a basis for further development and indications of what

adjustments needs to be done to better suit psychiatric inpatient care nationally and possibly, even internationally in similar context.

Combining the SSED with a process evaluation has been described as highly valuable.[59] Collecting both quantitative and qualitative data will offer us opportunities to describe the introduction of TT from different viewpoints, enable us to capture a broad picture of the effects of TT, and enable us to evaluate the trustworthiness and quality of the introduction of the intervention.[59] This in turn could contribute to the development and dissemination of TT.

According to Craig et al.,[40] a distinct theoretical framework is the basis of sustainable interventions and allows for better evaluations. Barker and Buchanan-Barker's concept of engagement[2] is added as a theoretical framework for this project. This stance, combined with the introduction of TT to the Swedish context will provide opportunities for further development of the intervention.

The composition of the research team provides a mix of experience in the context and the methods used for evaluation. JM, BML, and UHG are experienced mental health nurses and AR and UHG have use SSED, including the quantitative methods used during analysis. All authors are experienced in qualitative methods.

In the first descriptions, the PET intervention is described to have its roots in practice rather than in theory.[30] This pragmatic approach has been preserved in the design of TT which will be tailored to local circumstances at each participating ward. This has been done in collaboration with staff working on the wards and patients have also been asked about what

joint activities they want to be offered during TT.[56] Such an approach, according to Storm and Edwards [60], is fundamental to promote user involvement. However, this could be seen as a study limitation as the intervention then is less standardised. Still, it has been key to introducing a feasible intervention that would be realistic to implement if it is proven to be effective. As described, we see the potential of the intervention because it does not require additional staff or costs, being in line with the wishes of the patients and the ideals of the staff.[14, 15]

DECLARATIONS

Competing interests

The authors report no conflict of interest.

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Data sharing

No additional data available.

Authors' contributions

Study design: JM, AR, BML, UHG. Manuscript preparation: JM, AR, BML, UHG. All authors read and approved the final manuscript.

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Table 1

Description of the three intervention wards

Ward no.	Sub-speciality	Number of beds	Total number of eligible staff
1	Substance and addictive syndroms	12	17
2	Substance and addictive syndroms	12	25
3	Acute mental health	13	19

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym P. 1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry P. 2
	2b	All items from the World Health Organization Trial Registration Data Set N/A
Protocol version	3	Date and version identifier
Funding	4	Sources and types of financial, material, and other support P. 14
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors P. 1
	5b	Name and contact information for the trial sponsor N/A (no sponsor)
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities N/A
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) N/A
Introduction		
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention P. 3 - 5
	6b	Explanation for choice of comparators N/A
Objectives	7	Specific objectives or hypotheses P. 5
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) P. 6

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained P. 7
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) P. 6
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered P. 7
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) P. 11
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended P. 9 - 10
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) P. 6
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations P. 6
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size P. 5

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions N/A - not randomized

Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned N/A
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions p. 8
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how N/A
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial N/A
Methods: Data collection, management, and analysis		
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol p. 8
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols —
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol N/A
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol p. 11
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses) —
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) N/A
Methods: Monitoring		
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed N/A

	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct P12
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor N/A
Ethics and dissemination		
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval P. 12
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) P12
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) P12, 8
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial P12
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site P14
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators -
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions P.12
	31b	Authorship eligibility guidelines and any intended use of professional writers N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code N/A

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Does "Time Together" increase quality of interaction and decrease stress? A study protocol of a multi-site nursing intervention in psychiatric in-patient care, using a mixed method approach

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Does "Time Together" increase quality of interaction and decrease stress? A study protocol of a multi-site nursing intervention in psychiatric in-patient care, using a mixed method approach

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ABSTRACT

Introduction: Despite the long known significance of the nurse-patient relationship, research in psychiatric inpatient care still reports unfulfilled expectations of, and difficulties in, interactions and relationships between patients and staff. Interventions that create structures to allow quality interactions between patients and staff are needed to solve these problems. The aim of this project is to test effects of the nursing intervention Time Together and to evaluate the intervention process.

Methods and analysis: This is a multi-site study with a single-system experimental design using frequent measures. The primary outcomes are quality interactions for patients and perceived stress for staff. Secondary outcomes are levels of symptoms of anxiety and depression for patients and stress of conscience for staff. A process evaluation is performed to describe contextual factors and experiences. Data are collected using questionnaires, participant observations, and semi-structured interviews. For analysis of quantitative data, both visual and statistical methods will be used. Qualitative data will be analyzed using qualitative content analysis.

Ethics and dissemination: Ethical approval was granted by the Ethical Review Board in the region (Dnr 2016/339-31). The findings will contribute to the development of nursing interventions in general, but more specifically to the development of the intervention. This is relevant both nationally and internationally as similar interventions are needed but sparse. The findings will be disseminated through conference presentations and peer-reviewed publications.

Trial registration number: NCT02981563

Keywords: engagement, complex interventions, multi-site study, nursing, process evaluation, protocol, single system design, psychiatric inpatient care, quality interactions

ARTICLE SUMMARY

Strengths and limitations of this study

- Multi-site study performed at three different wards
- Process evaluation integrated in the study
- Relatively small scale could pose a threat to generalisation
- An SSED design enables us to closely follow the outcome measures

INTRODUCTION

It is well known that the nurse-patient relationship is the core of mental health nursing.[1-4] To create such relationships, it is essential that interactions contain emotional communication,[1, 5] and to convey such care in their responses, staff should reach out to the patient as a first step in sharing that person's experiences.[6] Barker and Buchanan-Barker[2, 6] conceptualised such human processes as *engagement* and later renamed it *bridging*.

Despite the long-known significance of the nurse-patient relationship, research in psychiatric inpatient care still reports unfulfilled expectations of, and difficulties in, interactions and relationships between staff and patients. Patients express a need for human relations with staff and for something to do, while staff say that they have ideals about providing good care but their time spent with patients is limited by organisational chaos.[7-12] Patients and staff also seem to share negative experiences of contextual factors such as the environment, the lack of structure and activities, the disorganization, and the substantial power relationships.[9, 13-15] Together, these leads to counterproductive care, experiences of stigma among patients,[14, 16] and signs of moral distress among staff.[15, 17]

In response to the challenges outlined above, we need to proceed from descriptions to action. Several researchers raise nurses' need for time to devote to their patients.[11, 12, 14, 18] Similar ideas are discussed by Cleary et al.[19] and Polacek et al.,[20] who suggest that the

focus should be on creating conditions that enable engagement and the development of therapeutic interaction skills with a “human touch”.[21] It has also been suggested that being given the responsibility and the ability to work in line with their ideals and engage with their patients could reduce moral distress among staff and improve both the quality of care and the chances of recovery for patients.[15, 17, 22-28] Together this indicates that nursing interventions focusing on quality interactions could be help to solve the described shortcomings in care. However, in a review, Mullen[29] reported that such interventions, for example planned dialogues and psychoeducation, are complex and difficult to implement in psychiatric inpatient care because of the demanding and chaotic context. This seems to still be the case, as such interventions are sparsely described in the scientific literature, which implies a need for interventions that create structures to allow quality interactions between staff and patients.

As a grassroots initiative, one intervention aimed to create structures for quality interactions between staff and patients was developed in the UK in the early 2000s.[30] There are some descriptions of the practical structures of Protected Engagement Time (PET) in the literature,[30-34] and evaluations of PET are ongoing in the UK.[33] The theoretical framework of PET is vaguely described in the early literature. However, according to Nolan et al.[33], the intervention is rooted in practice with a starting point in the staffs’ situation as PET was developed on the basis of Karasek and Theorells theory on job strain[35] but with the nurse-patient relationship in the center. The structure of PET requires that staff, for a fixed time during the day, dedicate their time exclusively to interacting with the patients. Other more administrative duties, visits and meetings are organised to be performed at other times during the day.[33] Through this, opportunities for interaction are both created and protected.

During the development of our intervention, Barker and Buchanan-Barker's theoretical framework [2] was added to highlight the centrality of needs of the patients and engagement among staff. There are obvious parallels between the content of PET and the philosophy of Barker and Buchanan-Barker.[2] They share an emphasis on engagement; both describe levels of engagement in supporting patients in psychiatric inpatient care, but they also take a pragmatic approach to interventions that should be shaped by prevailing requirements and available resources.[36]

Our intervention builds on PET, but expands the theoretical framework by adding Barker and Buchanan-Barker's theory.[2] To emphasize this theoretical expansion and to adapt the intervention to the Swedish context and language, the intervention described in this project is named Time Together (TT).

STUDY AIMS

The overall aim of this project is to test the effects of the nursing intervention TT and to evaluate the intervention process. The main research questions are:

- Does TT influence the quality of interactions between staff and patients?
- Does TT influence patients' levels of anxiety and depressive symptoms?
- Does TT influence staffs' levels of perceived stress and levels of stress of conscience?
- Does TT influence the prevalence of coercive measures, mean length of hospital stay, and the use of PRN medication?

Because this will be the first use of TT in Swedish psychiatric inpatient care there is also a need to evaluate the process of introducing it as a nursing intervention. Through this process evaluation we aim to answer questions such as:

- How do staff and patients describe their experiences of the intervention and how do contextual factors influence the effects of the intervention?
- What are the relationships between the outcome variables and the degree of compliance with the intended intervention?
- What problems are there with recruitment and dropouts?

METHODS

This is a multi-site nursing intervention project using a single-system experimental design (SSED).[37]

SSED studies focus primarily on changes in one system and not differences between systems. Each system works as its own control and therefore a smaller number of systems are required than in other experimental models.[38] The process evaluation is performed in parallel to describe experiences and contextual factors of importance.

In this project, the evaluation of TT will consist of two phases (A and B) and follow-up, in line with the SSED. In the A phase, where the baseline is established, outcomes will be measured once every seventh day (weekends not included) for approximately five weeks. In B phase, TT will be introduced on the wards and outcomes will be measured once every seventh day (weekends not included) for three months. The follow-up will take place six months after the B phase. Both patients and staff will complete questionnaires and participate in interviews to assess whether the possible effects of TT are sustainable.

The project will be conducted from January 2017 to May 2018 at three psychiatric clinics located at three hospitals in two county councils in the north of Sweden. One psychiatric

inpatient care ward at each clinic will participate. The sample in this study are then the three wards. As single system designs aims at detecting changes *within* each system and not comparing these to each other, sample sizes in this tradition are comparably small and no sample size calculations are made [38]. Each ward constitutes one system and data for each system will consist of aggregated measurements from admitted patients and staff working on each ward.[37, 39] This implies that that the total number of individuals is largely dependent on a) the number of patients admitted to the ward at each point of measurement, and b) the number of staff members working at the ward.

Description of Time Together

A description similar to that of Nolan et al.,[33] in combination with Barker and Buchanan-Barker's description of levels of engagement [2] will be used as the basis for the introduction of TT. The basic model for the intervention will therefore be:

- Regular times for TT will be established on Mondays-Fridays, for a total of 5 hours.
- Registered nurses (RNs) and enrolled nurses (ENs) will be engaged in joint activities with the patients during TT.
- Engagement should involve interactions in either one-on-one sessions or group sessions including joint activities chosen by the patients.
- During TT, only 1 or 2 of the ward staff will manage the administrative ward duties. All other members of staff will engage with the patients.
- During TT, the ward will be closed to visitors and professionals from outside the ward.

For the intervention to be feasible, TT will be tailored to local circumstances at each ward with the points above as a basic guide.[40]

Setting

The patients on the participating wards, admitted voluntarily or involuntarily, suffer from different kinds of mental ill health or substance-related and addictive disorders. In general, the wards have rules and routines, locked doors, fixed times for meals, smoking breaks, and opportunities to walk outdoors. Nursing interventions such as joint activities, planned dialogues, and psychoeducation are usually rare, and medical treatment is the norm instead. Those working on the wards are ENs in mental health, RNs, some of whom have specialist training in mental health nursing, a ward manager, residents, and consultant psychiatrists. Other professions can be consulted when necessary. For a description of the intervention wards, please refer to Table 1.

Participants

All patients admitted to the wards during phase A, phase B, and the follow-up of the intervention will be informed about the ongoing project by a research assistant. During phase A, all patients admitted to the wards will be invited to participate in the study by completing questionnaires. During phase B, the patients who participated in at least one TT session will be invited to participate through questionnaires, semi-structured interviews, and participant observations.

Inclusion criteria for patients: 18 years or older, admitted to the wards during phase A, phase B, and/or follow-up. Experience of at least one TT session is required.

Exclusion criteria for patients: not fluent enough in the Swedish language to complete questionnaires and participate in interviews.

The researchers will invite all staff working on the wards during phase A, phase B, and follow-up of the intervention to participate in the evaluation of TT.

Inclusion criteria for staff: staff employed at the ward during phase A, phase B, and/or follow-up.

Data collection

Data will be collected through questionnaires and ward registers. In the evaluation of the process, semi-structured interviews and participant observations will be conducted by the researchers and logbooks will be kept by the research assistants at each ward.

Questionnaires

The primary outcome measure for patients will be the quality of interactions with members of staff, based on the results of previous studies[14, 41] that showed that, according to patients in psychiatric inpatient care, the quality of interactions influences everyday life in psychiatric inpatient care. Secondary outcome measures will be levels of anxiety and depressive symptoms. For staff, the primary outcome measure will be perceived stress, based on the results of previous studies[15, 17, 26] that showed that staff in interprofessional teams in psychiatric inpatient care moved from ideals to resignation because of organisational and structural obstacles. Secondary outcome measures will be stress of conscience, satisfaction of interactions with patients, and quality of care. Demographic data will be collected for all participants.

Patient related questionnaires

The Caring Professional Scale (CPS)[42] will be used to measure the quality of the interactions. CPS consists of 14 items answered on a 5-point Likert scale. Validity and reliability has been reported as satisfactory (Cronbach's alpha nurses 0.97).[42]

The widely used and well-tested *Visual Analogue Scale* (VAS)[43] will be used to measure satisfaction with the interactions. The scale will be 100 mm in length, ranging from "very unsatisfactory" to "very satisfactory".

The self-assessment scale *The Hospital Anxiety and Depression Scale* (HAD)[44] will be used to measure anxiety and depressive symptoms. All items are scored on a 4-point scale. HAD appears to be reliable and valid and is shown to be sensitive to changes in response to psychosocial interventions.[44, 45] The Swedish version was tested and shown to have satisfactory validity and reliability (Cronbach's alpha 0.90).[46]

Staff related questionnaires

The Perceived Stress Scale (PSS)[47] will be used to measure stress among staff. PSS consists of 10 items answered on a 5-point Likert scale. The Swedish version of the 10-item PSS has proved to have satisfactory validity and reliability (Cronbach's alpha 0.84).[48]

The Stress of Conscience Questionnaire (SCQ)[49] will be used to measure the frequencies of stressful situations and the degree to which these lead to stress of conscience among staff. SCQ consists of nine items in two parts. The first part uses a 6-point scale ranging from never (0) to every day (5) for each of the nine items and the second part uses a 100 mm VAS ranging from 'No, not at all' (0) to 'Yes, it gives me a very troubled conscience' (5) for those

same items. Previous studies have reported satisfactory validity and reliability (Cronbach's alpha 0.83 for the total SCQ).[50]

The *VAS*[43] will be used to measure staff satisfaction with their interactions with patients. The scale will be 100 mm in length, ranging from "very unsatisfactory" to "very satisfactory".

The Quality in Psychiatric Care-Inpatient Staff (QPC-IPS) [51, 52] questionnaire will be used to measure quality of care. This instrument is part of the QPC family of instruments that originate from the QPC study.[51, 52] Psychometric tests have been conducted internationally and are ongoing nationally. No results have yet been published.

Data from ward registers

Data regarding PRN medication, hospital stays, use of coercion, and violent situations will be collected from the participating wards' existing registers.

Semi-structured interviews

Both patients and staff will be individually interviewed by the researchers, using a semi-structured format.[53] During phase B, patients will be interviewed just before or shortly after their discharge from the ward and staff will be interviewed at the end of the phase. The participants will be asked to share their experience of TT's impact on the quality of the interactions. For staff there will also be questions about TT's impact on their daily work and organisational issues that facilitate and complicates TT. For this process evaluation component of the study, the sample will be selected purposively by the researchers. We will strive at describing variations in experience of the intervention. This will approximately

require 30 staff members and 30 patients (10 from each ward), however, interviews will be performed until saturation is acheived [54].

Participant observations

Participant observations will be used during phase B. This approach, aimed to describe patterns of behaviours among individuals and groups in a particular culture, gives researchers the opportunity to share certain experiences with both patients and staff on the wards. In this project, observations with a focused approach will allow researchers to describe activities and interactions between patients and staff during TT.[55]

Log

During phase B, the research assistant at each ward will keep a log recording the number of TT sessions, their duration, the kinds of activities engaged in, and reflections upon each session.

Analysis

Quantitative data

Demographic data for participants will be presented as means and proportions. To evaluate changes during the intervention, both visual and statistical methods will be used to analyse data.[56] The visual inspection of data in SSED studies is described as a viable and approved method to analyse and compare levels, trends, and variability between intervention phases.[38] For the statistical calculations, *percentage of non-overlapping data* statistics will be used. This is a calculation of the percentage of treatment data that overlaps with the most extreme data point exhibited at baseline.[38]

Qualitative data

Both the participant observations and the semi-structured interviews will be analysed using qualitative content analysis (QCA). In QCA the focus is on variations in participants' experiences and presenting the results in categories and/or themes.[57]

ETHICS AND DISSEMINATION

The study has been approved by the heads of the clinical departments of psychiatry involved and the regional Ethical Review Board in Umeå, Sweden (Dnr 2016/339-31). All participants will receive written and verbal information about the aim of the study. They will be informed that participation is voluntary, that they have the right to withdraw without specifying why, and that confidentiality will be assured. Informed consent will be assigned by all participants. The findings will be disseminated through conference presentations and peer-reviewed publications.

DISCUSSION

Introducing TT is not only an attempt to meet the needs described by patients and staff in psychiatric inpatient care, but also an attempt to come to terms with some of the shortcomings described in the evidence (i.e., lack of structure and unmanaged chaos).[14,15] To our knowledge, similar studies are sparse in the international evidence and no similar projects have been tested or implemented in the context of Swedish psychiatric inpatient care.

The project, including the SSED and the process evaluation, will provide a first description of TT in a Swedish context. It is significant because studies of this type are sparse both nationally and internationally. Research in mental health nursing has a responsibility to take

the next step since many of the problematic circumstances now are known. The development of interventions is a step in the right direction towards solving some of these problems.[58]

This study is performed at three hospital wards. Even though this may be considered a small sample with a limited generalizability, this study will still assess the effect of TT in this context. Such knowledge will provide a basis for further development and indications of what adjustments needs to be done to better suit psychiatric inpatient care nationally and possibly, even internationally in similar context.

Combining the SSED with a process evaluation has been described as highly valuable.[59] Collecting both quantitative and qualitative data will offer us opportunities to describe the introduction of TT from different viewpoints, enable us to capture a broad picture of the effects of TT, and enable us to evaluate the trustworthiness and quality of the introduction of the intervention.[59] This in turn could contribute to the development and dissemination of TT.

According to Craig et al.,[40] a distinct theoretical framework is the basis of sustainable interventions and allows for better evaluations. Barker and Buchanan-Barker's concept of engagement[2] is added as a theoretical framework for this project. This stance, combined with the introduction of TT to the Swedish context will provide opportunities for further development of the intervention.

The composition of the research team provides a mix of experience in the context and the methods used for evaluation. JM, BML, and UHG are experienced mental health nurses and

AR and UHG have use SSED, including the quantitative methods used during analysis. All authors are experienced in qualitative methods.

In the first descriptions, the PET intervention is described to have its roots in practice rather than in theory.[30] This pragmatic approach has been preserved in the design of TT which will be tailored to local circumstances at each participating ward. This has been done in collaboration with staff working on the wards and patients have also been asked about what joint activities they want to be offered during TT.[56] Such an approach, according to Storm and Edwards [60], is fundamental to promote user involvement. However, this could be seen as a study limitation as the intervention then is less standardised. Still, it has been key to introducing a feasible intervention that would be realistic to implement if it is proven to be effective. As described, we see the potential of the intervention because it does not require additional staff or costs, being in line with the wishes of the patients and the ideals of the staff.[14, 15]

DECLARATIONS

Competing interests

The authors report no conflict of interest.

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Data sharing

No additional data available.

Authors' contributions

Study design: JM, AR, BML, UHG. Manuscript preparation: JM, AR, BML, UHG. All authors read and approved the final manuscript.

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Table 1

Description of the three intervention wards

Ward no.	Sub-speciality	Number of beds	Total number of eligible staff
1	Substance and addictive syndroms	12	17
2	Substance and addictive syndroms	12	25
3	Acute mental health	13	19

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym P. 1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry P. 2
	2b	All items from the World Health Organization Trial Registration Data Set N/A
Protocol version	3	Date and version identifier
Funding	4	Sources and types of financial, material, and other support P. 14
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors P. 1
	5b	Name and contact information for the trial sponsor N/A (no sponsor)
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities N/A
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) N/A
Introduction		
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention P. 3 - 5
	6b	Explanation for choice of comparators N/A
Objectives	7	Specific objectives or hypotheses P. 5
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) P. 6

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained P. 7
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) P. 6
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered P. 7
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) P. 11
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended P. 9 - 10
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) P. 6
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations P. 6
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size P. 5

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions N/A - not randomized

Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned N/A
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions p. 8
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how N/A
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial N/A
Methods: Data collection, management, and analysis		
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol p. 8
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols —
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol N/A
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol p. 11
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses) —
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) N/A
Methods: Monitoring		
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed N/A

	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct P12
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor N/A
Ethics and dissemination		
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval P. 12
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) P12
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) P12, 8
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial P12
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site P14
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators -
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions P.12
	31b	Authorship eligibility guidelines and any intended use of professional writers N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code N/A