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## PSYCHIATRIC HOSPITAL REFORM IN LOW AND MIDDLE INCOME COUNTRIES STRUCTURED INDIVIDUALIZED INTERVENTION AND RECOVERY (SITAR); A TWO ARM PRAGMATIC RANDOMIZED CONTROL TRIAL-STUDY PROTOCOL.

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STRUCTURED INDIVIDUALIZED INTERVENTION AND RECOVERY (SITAR); A TWO ARM  
PRAGMATIC RANDOMIZED CONTROL TRIAL-STUDY PROTOCOL.**

**Tasneem Raja, Helena Tuomainen, Jason Madan, Sanjeev Jain, Swaran P Singh**

**Corresponding author**

Tasneem Raja,  
Tata Trusts (Udaan) office, Behind OPD Building, Regional Mental Hospital, Nelson Square,  
Chindwara Road, Nagpur 440013 Email [T.Raja@warwick.ac.uk](mailto:T.Raja@warwick.ac.uk) / [traja@tatatrusters.org](mailto:traja@tatatrusters.org) Mobile-  
+91 7506091860 ORCID ID [0000-0002-5821-8673](https://orcid.org/0000-0002-5821-8673)

Dr Helena Tuomainen, Senior Research Fellow, Mental Health and Wellbeing, Warwick Medical  
School, University of Warwick, UK, T: +44 (0)24 765 28205 [helena.tuomainen@warwick.ac.uk](mailto:helena.tuomainen@warwick.ac.uk)  
[ORCID: 0000-0003-1636-8187](https://orcid.org/0000-0003-1636-8187)

Jason Madan  
Professor in Health Economics | Director of Graduate Research Studies  
Centre for Health Economics at Warwick  
Warwick Medical School, University of Warwick ORCID ID 0000-0003-4316-1480

Prof. Sanjeev Jain DPM,MD, Molecular Genetics Laboratory  
Department of Psychiatry, National Institute of Mental Health and Neurosciences, Hosur Road  
Bangalore 560029, INDIA tel: \*\*91 80 26 99 52 62/63, fax: \*\* 91 80 26 56 48 30,  
email: [sjain.nimhans@nic.in](mailto:sjain.nimhans@nic.in); / [sjain.nimhans@gmail.com](mailto:sjain.nimhans@gmail.com)

Professor Swaran P Singh MBBS, MD, DM, FRCPsych  
Director, Centre for Mental Health and Wellbeing Research  
University of Warwick ORCID ID 0000-0003-3454-2089

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**ABSTRACT**

**Introduction**

Low and middle-income settings like India have large treatment gaps in mental health care. People with Severe Mental Disorders face impediments to their clinical and functional recovery, and have large unmet needs associated to poverty, human rights, social inclusion and participatory citizenship. Mental hospitals built during the colonial period play an important role in the care of the severely mentally ill in India. The infrastructure and standards of care are poor. There are no clear pathways to discharge and successful integration of recovered individuals into the community. Over 15% of patients stay in hospital for more than five years.

**Methods and analysis**

We aim to study the impact of psychiatric hospital reform on individual patient outcomes in a mental hospital in India. Structured Individualized Intervention and Recovery (SITAR) is a two-arm pragmatic randomized control trial, focusing on the long stay patient cohort. It tests the effectiveness of structural and process reform with and without an individually tailored recovery plan on patient outcomes of disability, symptom severity, social and occupational functioning and quality of life. A health economic analysis will determine the costing of implementing the individually tailored recovery plan for long stay individuals. SITAR is embedded in a larger mental health reform program with three other key elements: structural reform, process reform, and building capacity across all staff cadres.

**Ethics and dissemination**

The study will provide answers to important questions around the nature and process of reforms in institutional care that promote recovery while being cognizant of protecting human rights, and dignity. Ethical approval for SITAR was obtained from a registered ethics committee in India (Institutional Ethics Committee VikasAnvesh Foundation, VAF/2018-19/012 dated 6/12/2018) and the University of Warwick's Biomedical and Scientific Research Ethics Committee (REGO-2019-2332, dated 21 March 2019), and registered on the Central Trial Registry of India (CTRI/2019/01/017267).

**STRENGTHS AND LIMITATIONS OF THE STUDY**

- This is the first ever methodologically robust study to test the impact of reforms in a psychiatric hospital on important patient outcomes such as change in disability, symptoms, social and occupational functioning and quality of life.
- The study systematizes a set of feasible reforms in psychiatric hospital settings with potential applicability to similar institutions across the low and middle income world.
- The cost implication of the individual service package will be studied. This has relevance in influencing mental health care policy across the country.
- There is a strong component of government involvement that adds to the replicability potential of the study.
- It is not possible to blind the case managers to the group allocation due to the nature of the intervention, hence it is a single-blind study, with only researchers assessing outcomes being blind to allocation.

## INTRODUCTION

People living with Severe Mental Disorders (SMD) in low and middle-income countries (LMICs) face impediments to their clinical and functional recovery, and have large unmet needs associated to poverty, protection of human rights, social inclusion and participatory citizenship.(1-4) A range of cost-effective and evidence-based interventions are now available, however there are major barriers in access to appropriate care, increasing vulnerability and disadvantage along with stigma and discrimination. (1, 2, 5-8) Many languish in large hospitals, abandoned by family and forgotten by policy makers. India has 43 mental hospitals built during the colonial period that continue to function almost in the same way as they did when they were set up. (9-13) These hospitals constitute 80% of all available psychiatric beds. (14) At the end of 2015 there were 6,829 patients staying in 30 of the 43 mental hospitals; 16% had been inpatients for more than five years, some for 3-4 decades.(15) The infrastructure and standards of care are poor. There are no clear pathways to discharge and successfully integrate former patients into the community. (16) A complex mix of low priority for mental health care in India, lack of support from central and state governments and low autonomy and decision making power amongst professionals working in such institutions has impeded any meaningful reform.(13)

Mental hospitals in India have played an important role in the care of very vulnerable people and continues to remain a legitimate and relevant locus of care for people in need of services.(17) Given the lack of feasibility of closing down psychiatric institutions in most low and middle income countries, there is an urgent need for manageable and evidence based reform of these hospitals. The Udaan program seeks to address this need.

### The Udaan Program

Udaan is a partnership of Tata Trusts with government of Maharashtra, formalized through an MoU, to develop the Regional Mental Hospital Nagpur (RMHN) as a center of excellence through systematic reform of the hospital. Udaan comprises four key reform elements: structural (refurbishing old colonial infrastructure to meet current service user needs), process (standardizing clinical and non-clinical processes of the hospital), capacity building (standard training for different levels of hospital staff) and introduction of an individual need based, recovery oriented, service package for patients delivered through intensive case management. The Udaan elements are detailed in figure 1.

The Needs based Intensive case management (NB-ICM) for people living with SMD is based on a psychosocial rehabilitation model that takes a holistic approach to improving quality of life, reducing disability, improving role function, promoting independence and autonomy based on a hope for the future. It is a mix of working on individual competencies in the context of real everyday experiences and introducing environmental change propelled by individual choice.(18-25)

### Structured Individualized inTervention And Recovery (SITAR)

The Structured Individualized Intervention and Recovery (SITAR) study is embedded within the Udaan program. In a clinical trial we test whether NB-ICM improves patient outcomes amongst long stay inpatients, in comparison to care as usual in a psychiatric hospital undergoing reform in a low and middle-income country. The objectives of SITAR are

- a. To compare the effectiveness of structural and process reform with and without an individually tailored recovery plan on patient level outcomes of disability, symptom severity, social and occupational functioning and quality of life for the long stay patient cohort of the hospital

- b. To determine the costing of implementing an individually tailored recovery plan for long stay individuals in psychiatric hospitals

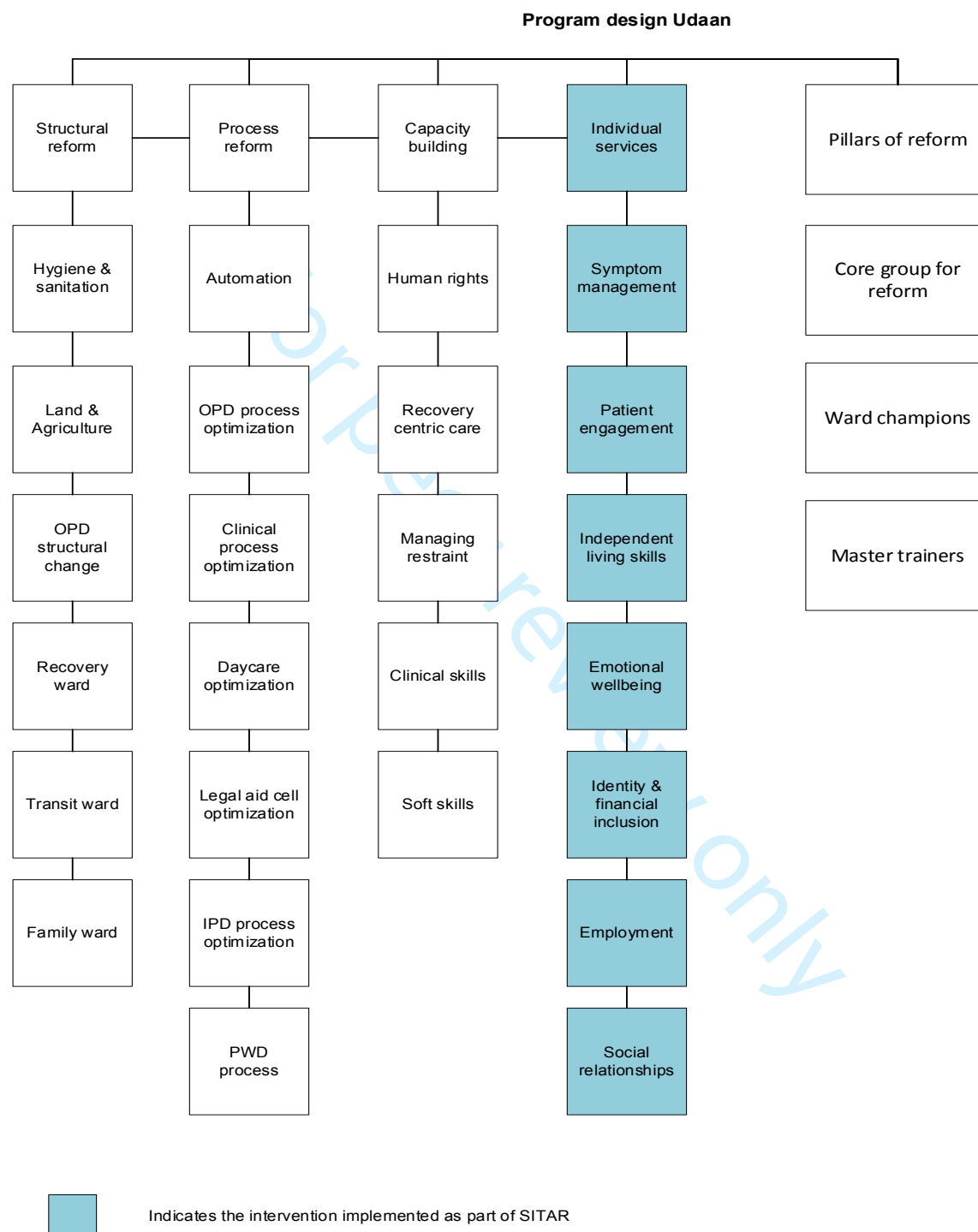
In the trial context, individual recovery plan constitutes a structured individual recovery plan based on individual needs assessment, patient outcomes refer to change in symptoms of illness, disability levels, social and occupational functioning and quality of life, long stay patients are patients having a continuous period of stay between 12 months and up to 10 years at RMHN and Care as usual refers to the structural and process reform in the hospital with a view to modernizing it.

The case managers are trained on a specially designed training module that comprises content around severe mental illness and intensive case management with a focus on the needs of people with high disabilities in psychiatric institutions.

Intensive case management calls for high resources and as such may not be feasible in low income settings. We thus seek to compare patient outcomes emerging from larger structural and process reform in old psychiatric hospitals as compared to patient outcomes when intensive case management is added along with the reform. This comparison has significant value in policy decision making on how meagre resources should be used in low resource settings where mental health care continues to be provided by psychiatric hospitals set up 100 to 200 years ago.

This paper presents the protocol of SITAR which aims to bridge a critical gap in scientific evidence by studying the impact of reform of psychiatric hospitals on individual patient outcomes. The findings will provide an evidence based package of reforms for psychiatric hospitals in transition in low and middle-income countries.

Figure 1 Graphic representation of Udaan and SITAR



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## METHODS AND ANALYSIS

### Study Design And Management

The study is a pragmatic parallel arm single blind randomised control trial at a single site, the Regional Mental Hospital Nagpur (RMHN). The mental hospital in Nagpur was started in 1864. The hospital has a capacity of 940 beds with an average occupancy of 600 patients at any given time.

Recruitment of patients for the study was initiated after completion of permissions, ethics approval and trial registry. We will continue recruitment till adequate sample size (85 in each arm) is reached. This is a changing population with a constant process of admission and discharge to the hospital. We assume a six months' time frame to complete full recruitment from the start of intervention.

The in-patient population of the hospital will be compiled on a database, mapping socio-demographic variables, history of illness and history of treatment as baseline data. Patients fitting the inclusion criteria will be identified and randomly assigned to the intervention and control arms of the study. Recruitment will be continued till desired numbers are reached. The intervention will be carried out for a six-month period. Post measures on all patients who have undergone pre-measures will be undertaken at completion of intervention (at six months) and at two follow-up intervals post intervention of nine months and 12 months (3 and 6 months after completion of intervention). The SITAR study design is presented graphically in figure 2.

Several steps are proposed to ensure *quality control and minimize the risk of bias*.

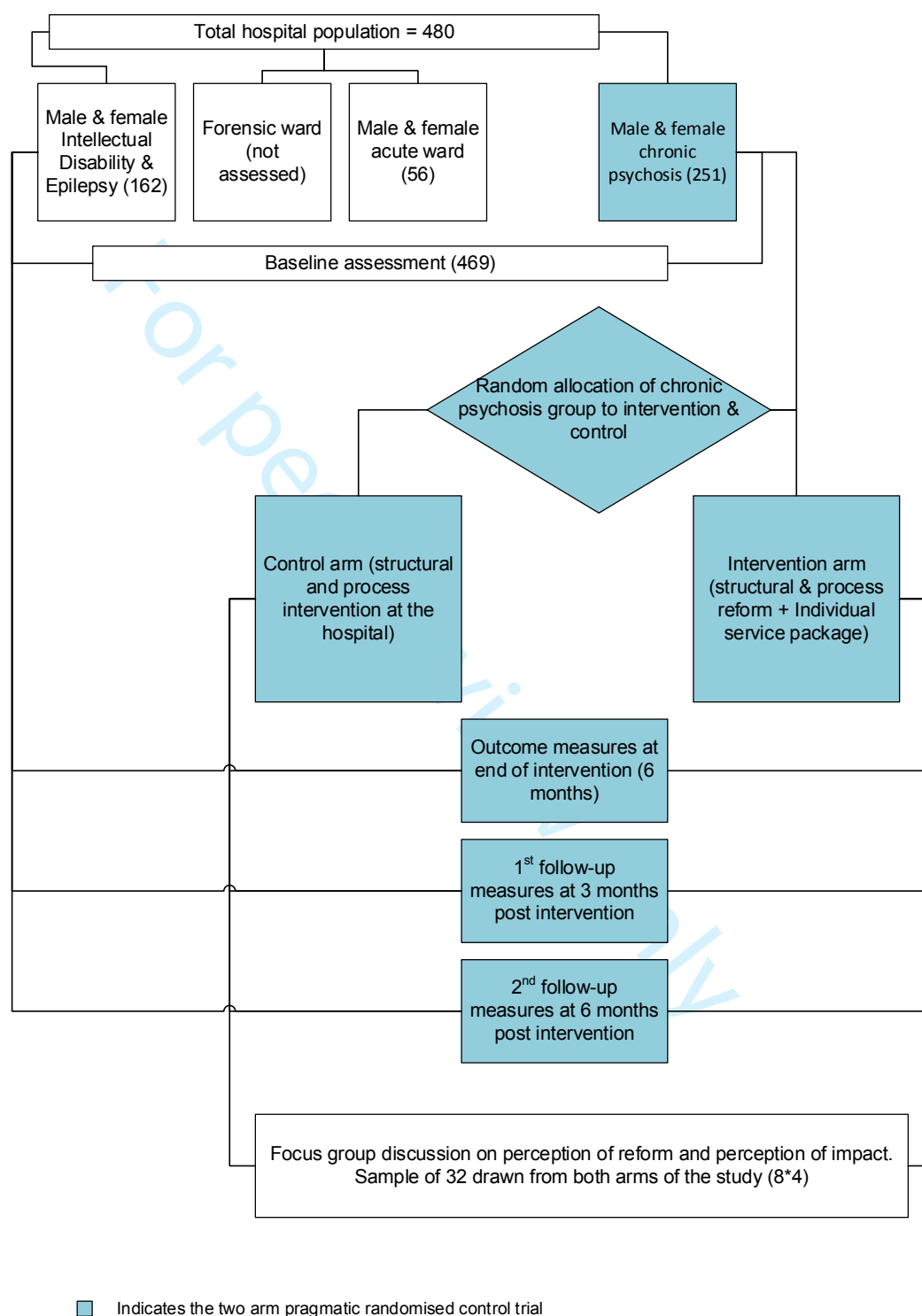
1. Use of a standard case management intervention (intervention manual developed for the study)
2. Randomization of the sample to intervention and care as usual arms of the study.
3. Outcome measurements will be undertaken by researchers independent of the case managers delivering the intervention. Inter-rater reliability for the researchers will be computed. The statistician drawing the randomization tables will be blinded to the allocation of the groups.

SITAR is part of the work done by the first author in fulfilment of the PhD program at the University of Warwick. The study will be coordinated by the UDAAN office located at RMHN. The study is managed by the PI with supervision from the supervisors and oversight by the Trial Management Committee (TMC). The TMC comprises of members from the University of Warwick and mental health experts from India.

### Ethical Approval

Ethical approval for SITAR has been obtained from a registered ethics committee in India (Institutional Ethics Committee VikasAnvesh Foundation, VAF/2018-19/012 dated 6/12/2018) and the University of Warwick's Biomedical and Scientific Research Ethics Committee (REGO-2019-2332, dated 21 March 2019), and registered on the Central Trial Registry of India (CTRI/2019/01/017267).

Figure 2 Graphic representation of SITAR

**SITAR- A graphic representation of the research design**

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3 **Participant Eligibility And Recruitment**

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5 In-patients at baseline will comprise all service users admitted to RMHN. Patients meeting the

6 inclusion criteria for the study will be randomized to the two arms of the study. For the study to be

7 powered at the 90% level with 5% significance level, the required sample is 170 people, 85 in

8 each arm. Assuming a 15% drop out we aim to recruit 100 people in each arm of the study. For

9 the power calculation, we have assumed a moderate effect size of 0.5 (26). With a minimum

10 clinical difference of a score of 10 points with a  $\sigma$  of 20. The effect size and variance was drawn

11 from an Indian study based in the community with non-intensive case management using

12 WHODAS scores as primary outcome measures (27). People with psychosis in institutional set-

13 ups might have higher disability levels as compared to people living in the community, however

14 most people in LMICs continue to remain in institutions due to the absence of viable pathways of

15 community reintegration. The intervention being offered is intensive with longer case

16 management time than what would be feasible in a dispersed community setting.

17

18 Service users will be eligible if they have a primary diagnosis of psychosis (based on diagnosis

19 given in their case files), a continued length of stay between 12 to 120 months in the hospital and

20 are over the age of 18 years. Service users will be excluded from the study if they are over the

21 age of 60 years, have a neuro-developmental disorder such as epilepsy, an intellectual disability

22 or are service users in acute and forensic wards.

23

24 **Informed Consent**

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26 The treating psychiatrist will assess the service users' ability to participate in the study as well as

27 ability to consent. The psychiatrist will provide consent for those patients unable to give consent

28 but deemed appropriate for the intervention. This is especially important in the case of this

29 intervention since it is a 'need based' psychosocial intervention. Based on inability to consent,

30 patients who may need the intervention most might actually be left out of the study. The consent

31 by the treating psychiatrist will ensure equitable inclusion. Additionally, the ward in charge also

32 signs off on the consent. The study will be explained pictorially to the service user with the aid of

33 a specially designed flip chart. Signatures and or thumb impressions will be taken on simple

34 consent forms drawn up in Hindi and Marathi.

35

36 **Randomization**

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38 The study will use a computer generated permuted block randomization schedule for the

39 allocation of recruited subjects to the two study arms. The researcher will create a list of service

40 users meeting the inclusion criteria and consenting to the study and give them a unique ID

41 number. This list will be handed over to the statistician who is independent to the research team.

42 Random allocation of eligible study subjects to two study arms (A and B) will be done by the

43 statistician using ralloc software (version 3.7.6) available in STATA (version 10.1, 2011) module.

44

45 **Intervention**

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47 Trained case managers will deliver the intervention through a clinical and intensive case

48 management approach that taps in to a functional network of a spectrum of services being created

49 at the hospital level through the reform process.

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51 The intervention components comprise 1) accommodation, safety and food (this is contextualized

52 to the hospital setting where all service users may not have access to clean living spaces and

53 enough food); 2) psychoeducation (about the illness and its symptoms); 3) symptom

54 management; 4) physical health; 5) emotional wellbeing; 6) self-care and other living skills; 7)

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social relationships; 8) connecting with family; 9) leisure activities; 10) occupational and financial inclusion; and 11) spiritual needs.

The intervention is based on an objective assessment of current needs of the service user and provides a comprehensive package of services to meet the range of individual needs. The case manager works collaboratively with the person in developing a personalized care plan drawing from the larger context of available opportunities within the hospital, created through the ongoing reform process. The care plan adjusts to the patient's cultural context. It draws on the strengths and potential of the individual and is focused on the reduction of personal distress and disability. Care provided through this approach is continuous and consistent for the defined period of the intervention. Case managers have the primary responsibility for planning, coordinating and delivering the care. Each case manager will have a caseload of 12-14 service users and spend at least eight sessions per case per month. The case manager will deliver the intervention face to face either in the ward complex or through calls and home visits in case the person is discharged from hospital as per protocol.

The intervention will aim

- To address unmet needs on symptomatology through appropriate pharmacological management and psychosocial support. It also includes diminishing and eliminating wherever possible the adverse physical and behavioral consequence of symptom management as well as those arising out of prolonged institutionalization.
- To address unmet basic needs of adequate accommodation and food
- To address unmet needs on personal functioning, improving activities of daily living both in terms of skills and access to opportunities
- To address unmet needs of social connectedness, engagement, leisure and social competence through individual competency building and access to environmental opportunities
- To address unmet needs for personal identity and citizenship
- To address the unmet needs of occupational functioning, employment and financial inclusion
- To address the unmet needs of connecting to family and community where feasible

Patients in the control arm will go through the same baseline and follow up measurements as the intervention arm. This group will however not receive the NB-ICM during the trial period, the control arm will continue receiving care as usual, in this case care being provided in a setting undergoing reform.

The intervention will be discontinued given the following conditions: 1) If the participant wants to discontinue participation; 2) An acute illness episode that significantly disrupts time in intervention (beyond four weeks); 3) When the participant is discharged from the hospital and community based intervention is not possible either due to distance beyond Nagpur district, unwillingness of participant or family for home based intervention; 4) In case of death of a participant.

### **Adverse Events- Recording And Reporting**

Given the nature of the study population and the chronicity of the illness certain events are expected. The study protocol classifies these events under 'adverse events' and 'serious adverse events'. Adverse events comprise of a) acute illness (psychosis) episodes as determined by transfer to acute ward; b) episodes of isolation and restraint; c) transfer for medical care outside the psychiatric hospital; d) absconding-from the facility. Serious adverse events comprise e) episode of self-harm and f) death.

To record and report adverse events, we will use the Warwick CTU's Clinical Trials Standard Operating Procedure 17 part 2 Safety Reporting for Clinical Trials other than those of Investigational Medicinal Products v1.5.

Any adverse event occurring with any participant will be first notified and discussed with the ward in charge. Based on routine hospital care processes, it is the responsibility of the ward in charge to initiate action of either directly providing any care, making a psychiatric referral or making a medical referral. All recorded adverse events will be reported to the core committee and the trial supervisor through monthly reports. These reports will also be submitted to the TMC. Any unexpected adverse event will be reported to Tata Trusts (as the sponsor) along with the India ethics committee, the Central Trial Registry of India as well as the university ethics committee (BSREC) within 15 days of the event.

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## Measurements

The study comprises outcome measures and process measures. Other baseline measurements include sociodemographic details, illness history and treatment history.

### *Outcome measures*

Assessment of level of disability will form the primary outcome for the study. *WHO Disability Assessment Scale 2.0 (WHODAS 2.0)*, a generic assessment instrument for health and disability that produces standardized disability levels and profiles applicable across cultures and diseases.(28) SITAR will use the simple scoring format sufficient to describe the degree of functional limitation.(28) Secondary outcome measures include an assessment of severity of symptoms, assessment of social and occupational functioning and assessment of quality of life. The scales used for these measurements include *The symptom measure- The Clinical Global Improvement Scale (Schizophrenia) (CGI-S)*, a brief, stand-alone assessment of the clinician's view of the patient's global functioning prior to and after initiating a study medication or intervention.(29) The CGI comprises two one-item measures evaluating (a) severity of psychopathology from 1 to 7 and (b) change from the initiation of treatment on a similar seven-point scale.(30) *Social and Occupational Functioning Scale (SOFS)* assesses individual's level of social and occupational functioning and is not directly influenced by the overall severity of the individual's psychological symptoms.(31, 32) *Health related quality of life measure EuroQol-5D (EQ-5D)* is a widely used generic patient reported outcome (PRO) questionnaire designed specifically for cost-utility economic evaluation internationally. The EQ- 5D asks patients to indicate whether they have no, some or extreme problems on each of five dimensions of health: mobility; self-care; usual activities; pain/discomfort, anxiety/depression.(33, 34)

Process (intervention) measurements include the *assessment of need* through a standard form based on Camberwell Assessment of Need (CANSAS).(35) The adaptation draws from prior use of this measure in India through the formative study of needs(36) and need assessment formats used in community setting.(37) This will be carried out by the allocated case managers five times during the study period and will be an indicator of the number of met and unmet needs of the service user at different points during the study. *The Intervention plan*, case managers will draw up a personal care plan collaboratively with the service user and the ward in charge on a monthly basis. Case managers will record the plan on a standard form developed for the intervention and reviewed monthly by the researcher. *The symptoms checklist* has been adapted from ones used in other Indian settings and will record the change in symptoms over the study period and serve as an adjunct to the symptom measure (CGI). The case manager will carry out the measure five times during the study period. *Self-care and other living skills checklist* is adapted to an institutional setting from scales for assessing activities of daily living.(38, 39) Its purpose is to aid the case manager in assessing progress on the intervention plan.

### *Baseline and Follow-up Measurements schedule*

Baseline measurements will be initiated at the start of the study and completed for all in-patients over a three-month period. Inter rater reliability will be established for all the research assistants conducting the measurements.

The intervention will be initiated after completion of the baseline measurements and carried out for a period of six months. At the end of the six-month intervention period, the first outcome measurement will be initiated and completed over a two-month period. The first and second follow-up outcome measurements will be initiated at three and six months post intervention, respectively, and completed over a two-month period.

The patient sequence will be kept standard for the measurements to ensure uniformity in time between measures. In case of an adverse event where the patient may not be available for measurement as per sequence, accommodation will be made to complete the measure any time during the two-month period of that measurement cycle. In case this is not possible, the patient will be considered as Lost to Follow-up (LFU). Sequence and time frame of measures are summarized in table 1.

Table 1 List and time frame for assessments (six months considered from date of first intervention)

Assessment	Type	By	Months													
			0	1	2	3	4	5	6	7	8	9	10	11	12	
WHODAS (Disability)	OM	RA	●							●			●			●
SOFS (Social &Occupational functioning)	OM	RA	●							●			●			●
CGI (Symptoms)	OM	RA	●							●			●			●
EQ-5D (Quality of life)	OM	RA	●							●			●			●
Episodes of seclusion & restraint	OM	CM	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Discharge / adverse events	OM	CM	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Needs Assessment	PM	CM	●			●				●			●			●
Intervention plan	PM	CM	●	●	●	●	●	●	●	●						
Symptoms checklist	PM	CM	●			●				●			●			●
Self-care and other living skills checklist	PM	CM	●	●	●	●	●	●	●	●						
Case management record form	PM	CM	●	●	●	●	●	●	●	●						
(OM) Outcome Measure (PM) Process Measure (RA) Research Assistant (CM) Case Manager																

Data Management During The Trial

Data collection

Quantitative data will be collected by trained Research Assistants (RAs) using pre-designed; pre-tested tools as included in the protocol. Senior RA will check completeness and accuracy of data gathered on daily basis before electronic data entry.

Data storage

The paper data will be stored in secure cabinets, in the PI's cabin at the Tata Trust office in the hospital campus. The office is under CCTV surveillance. The data will be held for ten years post completion of the study.

Data entry and coding

Data will coded and entered in an efficient database using MS Excel. Data will be kept confidential and anonymous on password-protected files. The master sheet will be kept separately on MS excel with password protection. Built in validity, checks will be incorporated in data entry software with flash/ warning alerts for incorrect or out of range values.

Data screening, data validation and data editing

Data will be screened at every stage i.e. pre-randomization, post randomization and closing stage of the trial. This will be done for each and every item of the individual record.by student researcher (trial PI) Accuracy of electronic data will be checked through comparison with questionnaire data on a sample basis.

### *Data processing*

Data will be processed by the Udaan program at baseline (pre-randomization), during trial (post randomization) and closing stage (outcome assessment) to monitor conduct, progress and process of the trial. Raw data from the master file will be coded and processed into a data file. The data file will include both original variables as well as some newly derived variables or transformed variables specific to the study objectives. Statistical Package of Social Sciences (SPSS) will be used for data analysis. The data analyst will be blinded to treatment assignment.

### *Anonymizing data*

Direct identifiers that allow the identification and communication with an individual participant will be removed. The names of all participants will be replaced with a master list identity (ID) number. The master list containing the ID number will be kept with the PI on a password-protected file, which will be housed in a password, protected firewalled system. The data set for analysis will not include any email address, telephone numbers or home address of patients (where available). Quasi identifiers such as ward numbers will be removed from and variables such as date of admission and date of discharge will be generalized into length of stay.

### *Sharing of data*

Analyzed data will be shared with the co-authors of the study through a password-protected process. The password for the file will be shared through a phone call made for this purpose. No personal or primary data will be shared.

### **Patient and public involvement**

Focus Group Discussions (FGDs) are built into the design of the program to incorporate the patient experience of intervention. No patients were involved in the study design.

### **COSTING AND POTENTIAL ECONOMIC GAINS OF THE INTERVENTION**

The SITAR study will also include a retrospective bottom-up cost analysis of the individualized intervention in terms of resource or input requirement along with costing of resources for care as usual. Cost elements will include all the resources used in development of the intervention and training material, costs of training, costs of intervention delivery which will include staff time and costs of supervision (people, facilities, equipment and supplies). The costing will be based on actual expenditure incurred through the Udaan program as well as costs components derived through collaboration this will include costs of items received in kind such as clothes, soaps and shampoos and such directly linked to patient care. Actual government spending on patient care will also be done. Costing will be appropriately apportioned to the SITAR study in terms of time allocation of staff based on an analysis of case management records. The study will compare the costs with benefit in terms of disability and health related quality of life. Given the scope of the study, this will be presented as a cost-consequence analysis/ (40)

### **DISSEMINATION**

Findings of the study will be presented through scientific publications as well as through a national level dissemination in India along with presentations in different conferences. We also intend to do a policy paper recommending a feasible reform process for psychiatric hospitals in India.

### **AUTHOR CONTRIBUTIONS**

Tasneem Raja- Principal Investigator, design and implementation of the trial. Wrote first draft of protocol paper.

Helena Tuomainen- Supported the design, protocol development, ethics application and continued supervision, review and editing of manuscript

Jason Madan- Supported the design of economic elements of the protocol.

Swaran Singh- primary supervisor on the trial, supported the design, protocol development, ethics application for India and UK, Trial registry, ongoing supervision on the trial.

All Co-authors reviewed and edited the manuscript and accepted the final version of the paper.

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**COMPETING INTERESTS STATEMENT**

This trial is part of the PhD program undertaken by the PI Tasneem Raja. She is an employee of the Tata Trusts and the Tata Trusts External Individual educational grants program funds the PhD won on basis of merit.

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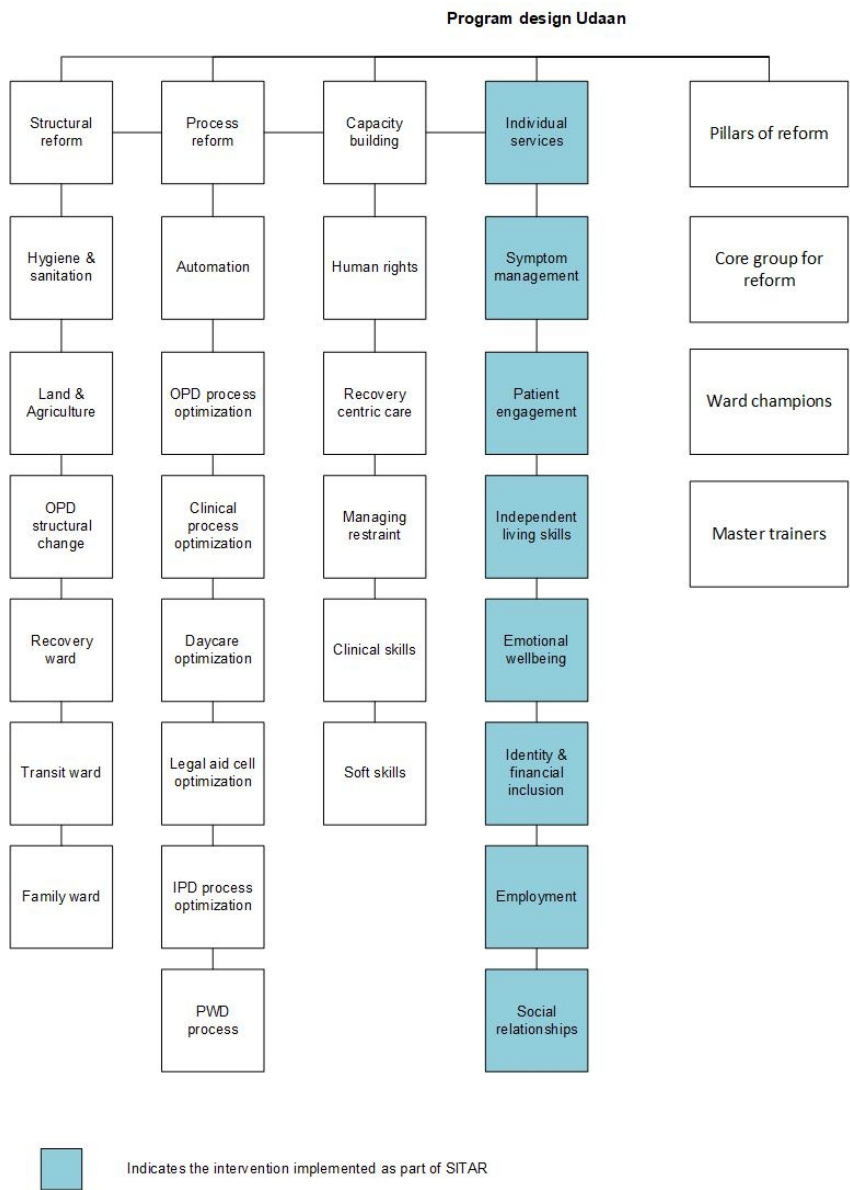


Figure 1 Graphic representation of Udaan and SITAR

72x92mm (300 x 300 DPI)

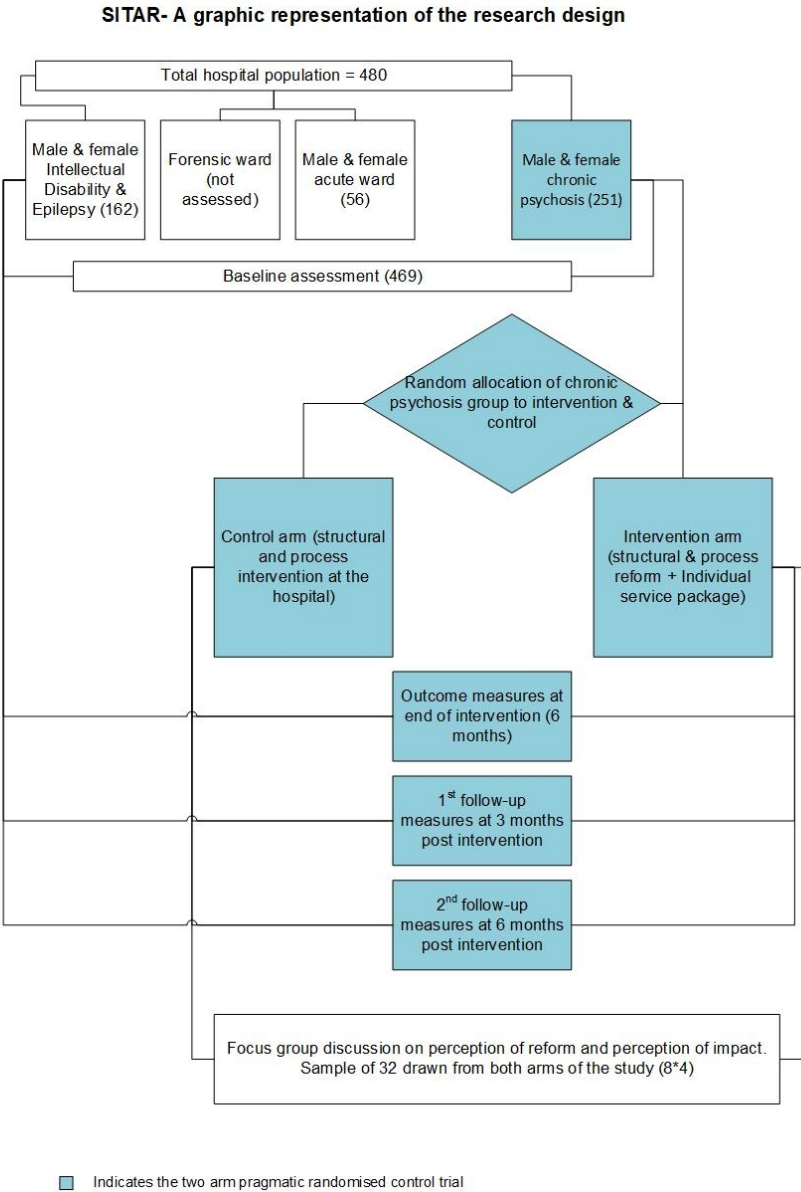


Figure 2 Graphic representation of SITAR  
81x102mm (300 x 300 DPI)

# BMJ Open

## PSYCHIATRIC HOSPITAL REFORM IN LOW AND MIDDLE INCOME COUNTRIES STRUCTURED INDIVIDUALIZED INTERVENTION AND RECOVERY (SITAR); A TWO ARM PRAGMATIC RANDOMIZED CONTROL TRIAL-STUDY PROTOCOL.

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Keywords:	Adult psychiatry < PSYCHIATRY, Change management < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Schizophrenia & psychotic disorders < PSYCHIATRY

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**PSYCHIATRIC HOSPITAL REFORM IN LOW AND MIDDLE INCOME COUNTRIES  
STRUCTURED INDIVIDUALIZED INTERVENTION AND RECOVERY (SITAR); A TWO ARM  
PRAGMATIC RANDOMIZED CONTROL TRIAL-STUDY PROTOCOL.**

**Tasneem Raja, Helena Tuomainen, Jason Madan, Sanjeev Jain, Swaran P Singh**

**Corresponding author**

Tasneem Raja,  
Tata Trusts (Udaan) office, Behind OPD Building, Regional Mental Hospital, Nelson Square,  
Chindwara Road, Nagpur 440013 Email [T.Raja@warwick.ac.uk](mailto:T.Raja@warwick.ac.uk) / [traja@tatatrusters.org](mailto:traja@tatatrusters.org) Mobile-  
+91 7506091860 ORCID ID [0000-0002-5821-8673](https://orcid.org/0000-0002-5821-8673)

Dr Helena Tuomainen, Senior Research Fellow, Mental Health and Wellbeing, Warwick Medical  
School, University of Warwick, UK, T: +44 (0)24 765 28205 [helena.tuomainen@warwick.ac.uk](mailto:helena.tuomainen@warwick.ac.uk)  
[ORCID: 0000-0003-1636-8187](https://orcid.org/0000-0003-1636-8187)

Jason Madan  
Professor in Health Economics | Director of Graduate Research Studies  
Centre for Health Economics at Warwick  
Warwick Medical School, University of Warwick ORCID ID 0000-0003-4316-1480

Prof. Sanjeev Jain DPM,MD, Molecular Genetics Laboratory  
Department of Psychiatry, National Institute of Mental Health and Neurosciences, Hosur Road  
Bangalore 560029, INDIA tel: \*\*91 80 26 99 52 62/63, fax: \*\* 91 80 26 56 48 30,  
email: [sjain.nimhans@nic.in](mailto:sjain.nimhans@nic.in); / [sjain.nimhans@gmail.com](mailto:sjain.nimhans@gmail.com)

Professor Swaran P Singh MBBS, MD, DM, FRCPsych  
Director, Centre for Mental Health and Wellbeing Research  
University of Warwick ORCID ID 0000-0003-3454-2089

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**ABSTRACT**

**Introduction**

Low and middle-income settings like India have large treatment gaps in mental health care. People with Severe Mental Disorders face impediments to their clinical and functional recovery, and have large unmet needs. The infrastructure and standards of care are poor in colonial-period mental hospitals, with no clear pathways to discharge and successfully integrate recovered individuals into the community. Our aim is to study the impact of psychiatric hospital reform on individual patient outcomes in a mental hospital in India.

**Methods and analysis**

Structured Individualized Intervention and Recovery (SITAR) is a two-arm pragmatic randomized control trial, focusing on patients aged 18 to 60 years with a hospital stay of 12 to 120 months and a primary diagnosis of psychosis. It tests the effectiveness of structural and process reform with and without an individually tailored recovery plan on patient outcomes of disability (primary outcome WHODAS), symptom severity, social and occupational functioning and quality of life. A computer generated permuted block randomization schedule will allocate recruited subjects to the two study arms. We aim to recruit 100 people into each trial arm. Baseline and outcome measures will be undertaken by trained researchers independent to the case managers providing the individual intervention. A health economic analysis will determine the costing of implementing the individually tailored recovery plan.

**Ethics and dissemination**

The study will provide answers to important questions around the nature and process of reforms in institutional care that promote recovery while being cognizant of protecting human rights, and dignity. Ethical approval for SITAR was obtained from a registered ethics committee in India (Institutional Ethics Committee VikasAnvesh Foundation, VAF/2018-19/012 dated 6/12/2018) and the University of Warwick's Biomedical and Scientific Research Ethics Committee (REGO-2019-2332, dated 21 March 2019), and registered on the Central Trial Registry of India (CTRI/2019/01/017267).

**STRENGTHS AND LIMITATIONS OF THE STUDY**

- This is the first ever methodologically robust study in low and middle income countries to test the impact of reforms in a psychiatric hospital on important patient outcomes such as change in disability, symptoms, social and occupational functioning and quality of life.
- The study offers an individual recovery plan for a psychiatric hospital setting in low resource settings
- The cost implication of the individual service package will be studied. This has relevance in influencing mental health care policy across the country.
- There is a strong component of government involvement that adds to the potential of sustainability and scaling up across other mental hospitals in the country.
- It is not possible to blind the case managers to the group allocation due to the nature of the intervention, hence it is a single-blind study, with only researchers assessing outcomes being blind to allocation. Given the nature of the setting, there is also a risk of contamination across both trial arms.

## INTRODUCTION

People living with Severe Mental Disorders (SMD) (psychosis, bipolar and affective disorders and severe-moderate depression) in low and middle-income countries (LMICs) face impediments to their clinical and functional recovery, and have large unmet needs associated to poverty, protection of human rights, social inclusion and participatory citizenship.(1-5) A range of cost-effective and evidence-based interventions are now available, however there are major barriers in access to appropriate care, increasing vulnerability and disadvantage along with stigma and discrimination. (1, 2, 6-9) Many languish in large hospitals, abandoned by family and forgotten by policy makers. India has 43 mental hospitals built during the colonial period that continue to function almost in the same way as they did when they were set up. (10-14) These hospitals constitute 80% of all available psychiatric beds. (15) At the end of 2015 there were 6,829 patients staying in 30 of the 43 mental hospitals; 16% had been inpatients for more than five years, some for 3-4 decades.(5) The infrastructure and standards of care are poor.(14) There are no clear pathways to discharge and successfully integrate former patients into the community. (16) A complex mix of low priority for mental health care in India, lack of support from central and state governments and low autonomy and decision making power amongst professionals working in such institutions has impeded any meaningful reform.(14)

Mental hospitals in India have played an important role in the care of very vulnerable people and continues to remain a legitimate and relevant locus of care for people in need of services.(17) Given the lack of feasibility of closing down psychiatric institutions in most low and middle income countries, there is an urgent need for manageable and evidence based reform of these hospitals. The Udaan program seeks to address this need.

### The Udaan Program

Udaan is a partnership of Tata Trusts with government of Maharashtra, formalized through an MoU, to develop the Regional Mental Hospital Nagpur (RMHN) as a center of excellence through systematic reform of the hospital. Maharashtra is a state in the Western peninsular region of India with Nagpur being right in the center of the country. Udaan comprises four key reform elements: structural (refurbishing old colonial infrastructure to meet current service user needs), process (standardizing clinical and non-clinical processes of the hospital), capacity building (standard training for different levels of hospital staff) and introduction of the Needs Based Intensive Case Management (NB-ICM), an individual need based, recovery oriented, service package for patients delivered through intensive case management. The Udaan elements are detailed in figure 1.

### Structured Individualized inTervention And Recovery (SITAR)

The Structured Individualized Intervention and Recovery (SITAR) study is embedded within the Udaan program. In a clinical trial we test whether NB-ICM improves patient outcomes amongst long stay inpatients, in comparison to care as usual in a psychiatric hospital undergoing reform in a low and middle-income country. The objectives of SITAR are

- a. To compare the effectiveness of structural and process reform with and without an individually tailored recovery plan on patient level outcomes of disability (primary Outcome), symptom severity, social and occupational functioning and quality of life for the long stay patient cohort of the hospital
- b. To determine the costing of implementing an individually tailored recovery plan for long stay individuals in psychiatric hospitals

Intensive case management calls for high resources and as such may not be feasible in low income settings. We thus seek to compare patient outcomes emerging from larger structural

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and process reform in old psychiatric hospitals as compared to patient outcomes when intensive case management is added along with the reform. This comparison has significant value in policy decision making on how meagre resources should be used in low resource settings where mental health care continues to be provided by psychiatric hospitals set up 100 to 200 years ago.

This paper presents the protocol of SITAR which aims to bridge a critical gap in scientific evidence by studying the impact of reform of psychiatric hospitals on individual patient outcomes. The findings will provide an evidence based package of reforms for psychiatric hospitals in transition in low and middle-income countries.

For peer review only

Figure 1 Graphic representation of Udaan and SITAR

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3 **METHODS AND ANALYSIS**

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5 **Study Design And Management**

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7 The study is a pragmatic parallel arm single blind randomised control trial at a single site, the

8 Regional Mental Hospital Nagpur (RMHN). The mental hospital in Nagpur was started in 1864

9 The hospital has a capacity of 940 beds with an average occupancy of 600 patients at any given

10 time.

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12 Recruitment of patients for the study was initiated after completion of permissions, ethics approval

13 and trial registry. We will continue recruitment till adequate sample size (85 in each arm) is

14 reached. This is a changing population with a constant process of admission and discharge to the

15 hospital. We assume a six months' time frame to complete full recruitment from the start of

16 intervention.

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18 The in-patient population of the hospital will be compiled on a database, mapping socio-

19 demographic variables, history of illness and history of treatment as baseline data. Patients fitting

20 the inclusion criteria will be identified and randomly assigned to the intervention and control arms

21 of the study. Recruitment will be continued till desired numbers are reached. The intervention will

22 be carried out for a six-month period. Post measures on all patients who have undergone pre-

23 measures will be undertaken at completion of intervention (at six months) and at two follow-up

24 intervals post intervention of nine months and 12 months (3 and 6 months after completion of

25 intervention). The SITAR study design is presented graphically in figure 2.

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27 Several steps are proposed to ensure *quality control and minimize the risk of bias*.

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1. Use of a standard case management intervention (intervention manual developed for the study)
  2. Randomization of the sample to intervention and care as usual arms of the study.
  3. Outcome measurements will be undertaken by researchers independent of the case managers delivering the intervention. Inter-rater reliability for the researchers will be computed. The statistician drawing the randomization tables will be blinded to the allocation of the groups

36 Given the nature of the setting, there is a risk of contamination across arms especially since the

37 hospital staff providing care in both arms are the same. We believe this is a minimal possibility

38 given the meagerness of engagement of hospital staff with the patients.

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40 SITAR is part of the work done by the first author in fulfilment of the PhD program at the University

41 of Warwick. The study will be coordinated by the UDAAN office located at RMHN. The study is

42 managed by the PI with supervision from the supervisors and oversight by the Trial Management

43 Committee (TMC). The TMC comprises of members from the University of Warwick and mental

44 health experts from India.

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46 *Figure 2 Graphic representation of SITAR*

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## Participant Eligibility And Recruitment

In-patients at baseline will comprise all service users admitted to RMHN. Patients meeting the inclusion criteria for the study will be randomized to the two arms of the study. Service users will be eligible if they have a primary diagnosis of psychosis (schizophrenia, bipolar affective disorders and psychosis NOS) based on diagnosis given in their case files, a continued length of hospital stay between 12 to 120 months and are over the age of 18 years. Service users will be excluded from the study if they are over the age of 60 years, have a neuro-developmental disorder such as epilepsy, an intellectual disability or are service users in acute and forensic wards.

## Sample Size

For the study to be powered at the 90% level with 5% significance level, the required sample is 170 people, 85 in each arm. Assuming a 15% drop out we aim to recruit 100 people in each arm of the study. For the power calculation, we have assumed a moderate effect size of 0.5 (18). With a minimum clinical difference of a score of 10 points with a  $\sigma$  of 20. The effect size and variance was drawn from an Indian study based in the community with non-intensive case management using WHODAS scores as primary outcome measures (19). People with psychosis in institutional set-ups might have higher disability levels as compared to people living in the community, however most people in LMICs continue to remain in institutions due to the absence of viable pathways of community reintegration. The intervention being offered is intensive with longer case management time than what would be feasible in a dispersed community setting.

## Informed Consent

The treating psychiatrist will assess the service users' ability to participate in the study as well as ability to consent. The psychiatrist will provide consent for those patients unable to give consent but deemed appropriate for the intervention. This is especially important in the case of this intervention since it is a 'need based' psychosocial intervention. Based on inability to consent, patients who may need the intervention most might actually be left out of the study. The consent by the treating psychiatrist will ensure equitable inclusion. Additionally, the ward in charge also signs off on the consent. The study will be explained pictorially to the service user with the aid of a specially designed flip chart. Signatures and or thumb impressions will be taken on simple consent forms drawn up in Hindi and Marathi.

## Randomization

The study will use a computer generated permuted block randomization schedule for the allocation of recruited subjects to the two study arms. The researcher will create a list of service users meeting the inclusion criteria and consenting to the study and give them a unique ID number. This list will be handed over to the statistician who is independent to the research team. Random allocation of eligible study subjects to two study arms (A and B) will be done by the statistician using ralloc software (version 3.7.6) available in STATA (version 10.1, 2011) module.

## Intervention

The Needs based Intensive case management (NB-ICM) for people living with SMD is based on a psychosocial rehabilitation model that takes a holistic approach to improving quality of life, reducing disability, improving role function, promoting independence and autonomy based on a hope for the future. It is a mix of working on individual competencies in the context of real everyday experiences and introducing environmental change propelled by individual choice.(20-27)

Trained case managers will deliver the intervention through a clinical and intensive case management approach that taps into a functional network of a spectrum of services being created at the hospital level through the reform process.

The case managers are trained on a specially designed training module that comprises content around severe mental illness and intensive case management with a focus on the needs of people with high disabilities in psychiatric institutions. The 60 hour training module was delivered through seven days of offsite training for the purpose of this study.

The intervention components comprise 1) accommodation, safety and food (this is contextualized to the hospital setting where all service users may not have access to clean living spaces and enough food); 2) psychoeducation (about the illness and its symptoms); 3) symptom management; 4) physical health; 5) emotional wellbeing; 6) self-care and other living skills; 7) social relationships; 8) connecting with family; 9) leisure activities; 10) occupational and financial inclusion; and 11) spiritual needs.

The intervention is based on an objective assessment of current needs of the service user and provides a comprehensive package of services to meet the range of individual needs. The case manager works collaboratively with the person in developing a personalized care plan drawing from the larger context of available opportunities within the hospital, created through the ongoing reform process. The care plan adjusts to the patient’s cultural context. It draws on the strengths and potential of the individual and is focused on the reduction of personal distress and disability. Care provided through this approach is continuous and consistent for the defined period of the intervention. Case managers have the primary responsibility for planning, coordinating and delivering the care. Each case manager will have a caseload of 12-14 service users and spend at least eight sessions per case per month. The case manager will deliver the intervention face to face either in the ward complex or through calls and home visits in case the person is discharged from hospital as per protocol.

The intervention will aim

- To address unmet needs on symptomatology through appropriate pharmacological management and psychosocial support. It also includes diminishing and eliminating wherever possible the adverse physical and behavioral consequence of symptom management as well as those arising out of prolonged institutionalization.
- To address unmet basic needs of adequate accommodation and food
- To address unmet needs on personal functioning, improving activities of daily living both in terms of skills and access to opportunities
- To address unmet needs of social connectedness, engagement, leisure and social competence through individual competency building and access to environmental opportunities
- To address unmet needs for personal identity and citizenship
- To address the unmet needs of occupational functioning, employment and financial inclusion
- To address the unmet needs of connecting to family and community where feasible

Patients in the control arm will go through the same baseline and follow up measurements as the intervention arm. This group will however not receive the NB-ICM during the trial period, the control arm will continue receiving care as usual, in this case care being provided in a setting undergoing reform.

The intervention will be discontinued given the following conditions: 1) If the participant wants to discontinue participation; 2) An acute illness episode that significantly disrupts time in intervention (beyond four weeks); 3) When the participant is discharged from the hospital and community

based intervention is not possible either due to distance beyond Nagpur district, unwillingness of participant or family for home based intervention;4) In case of death of a participant.

### Adverse Events- Recording And Reporting

Given the nature of the study population and the chronicity of the illness certain events are expected. The study protocol classifies these events under 'adverse events' and 'serious adverse events'. Adverse events comprise of a) acute illness (psychosis) episodes as determined by transfer to acute ward; b) episodes of isolation and restraint; c) transfer for medical care outside the psychiatric hospital; d) absconding-from the facility. Serious adverse events comprise e) episode of self-harm and f) death.

To record and report adverse events, we will use the Warwick CTU's Clinical Trials Standard Operating Procedure 17 part 2 Safety Reporting for Clinical Trials other than those of Investigational Medicinal Products v1.5.

Any adverse event occurring with any participant will be first notified and discussed with the ward in charge. Based on routine hospital care processes, it is the responsibility of the ward in charge to initiate action of either directly providing any care, making a psychiatric referral or making a medical referral. All recorded adverse events will be reported to the core committee and the trial supervisor through monthly reports. These reports will also be submitted to the TMC. Any unexpected adverse event will be reported to Tata Trusts (as the sponsor) along with the India ethics committee, the Central Trial Registry of India as well as the university ethics committee (BSREC) within 15 days of the event.

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3 **Measurements**

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5 The study comprises outcome measures and process measures. Other baseline measurements

6 include sociodemographic details, illness history and treatment history.

7

8 *Outcome measures*

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10 Assessment of level of disability will form *the primary outcome for the study*. *WHO Disability*

11 *Assessment Scale 2.0 (WHODAS 2.0)*, a generic assessment instrument for health and disability

12 that produces standardized disability levels and profiles applicable across cultures and

13 diseases.(28) SITAR will use the simple scoring format sufficient to describe the degree of

14 functional limitation.(28)Secondary outcome measures include an assessment of severity of

15 symptoms, assessment of social and occupational functioning and assessment of quality of life.

16 The scales used for these measurements include *The symptom measure- The Clinical Global*

17 *Improvement Scale (Schizophrenia) (CGI-S)*, a brief, stand-alone assessment of the clinician's

18 view of the patient's global functioning prior to and after initiating a study medication or

19 intervention.(29) The CGI comprises two one-item measures evaluating (a) severity of

20 psychopathology from 1 to 7 and (b) change from the initiation of treatment on a similar seven-

21 point scale.(30) *Social and Occupational Functioning Scale (SOFS)* assesses individual's level of

22 social and occupational functioning and is not directly influenced by the overall severity of the

23 individual's psychological symptoms.(31, 32) *Health related quality of life measure EuroQol-5D*

24 *(EQ-5D)* is a widely used generic patient reported outcome (PRO) questionnaire designed

25 specifically for cost-utility economic evaluation internationally. The EQ- 5D asks patients to

26 indicate whether they have no, some or extreme problems on each of five dimensions of health:

27 mobility; self-care; usual activities; pain/discomfort, anxiety/depression.(33, 34)

28

29 Process (intervention) measurements include the *assessment of need* through a standard form

30 based on Camberwell Assessment of Need (CANSAS).(35) The adaptation draws from prior use

31 of this measure in India through the formative study of needs(36) and need assessment formats

32 used in community setting.(37) This will be carried out by the allocated case managers five times

33 during the study period and will be an indicator of the number of met and unmet needs of the

34 service user at different points during the study. *The Intervention plan*, case managers will draw

35 up a personal care plan collaboratively with the service user and the ward in charge on a monthly

36 basis. Case managers will record the plan on a standard form developed for the intervention and

37 reviewed monthly by the researcher. *The symptoms checklist* has been adapted from ones used

38 in other Indian settings and will record the change in symptoms over the study period and serve

39 as an adjunct to the symptom measure (CGI). The case manager will carry out the measure five

40 times during the study period. *Self-care and other living skills checklist* is adapted to an

41 institutional setting from scales for assessing activities of daily living.(38, 39) Its purpose is to aid

42 the case manager in assessing progress on the intervention plan.

43

44 *Baseline and Follow-up Measurements schedule*

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47 Baseline measurements will be initiated at the start of the study and completed for all in-patients

48 over a three-month period. Inter rater reliability will be established for all the research assistants

49 conducting the measurements.

50

51 The intervention will be initiated after completion of the baseline measurements and carried out

52 for a period of six months. At the end of the six-month intervention period, the first outcome

53 measurement will be initiated and completed over a two-month period. The first and second

54 follow-up outcome measurements will be initiated at three and six months post intervention,

55 respectively, and completed over a two-month period.

56

The patient sequence will be kept standard for the measurements to ensure uniformity in time between measures. In case of an adverse event where the patient may not be available for measurement as per sequence, accommodation will be made to complete the measure any time during the two-month period of that measurement cycle. In case this is not possible, the patient will be considered as Lost to Follow-up (LFU). Sequence and time frame of measures are summarized in table 1.

**Table 1 List and time frame for assessments (six months considered from date of first intervention)**

Assessment	Type	By	Months													
			0	1	2	3	4	5	6	7	8	9	10	11	12	
WHODAS (Disability)	OM	RA	●							●			●			●
SOFS (Social &Occupational functioning)	OM	RA	●							●			●			●
CGI (Symptoms)	OM	RA	●							●			●			●
EQ-5D (Quality of life)	OM	RA	●							●			●			●
Episodes of seclusion & restraint	OM	CM	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Discharge / adverse events	OM	CM	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Needs Assessment	PM	CM	●				●			●			●			●
Intervention plan	PM	CM	●	●	●	●	●	●	●	●						
Symptoms checklist	PM	CM	●				●			●			●			●
Self-care and other living skills checklist	PM	CM	●	●	●	●	●	●	●	●						
Case management record form	PM	CM	●	●	●	●	●	●	●	●						
(OM) Outcome Measure (PM) Process Measure (RA) Research Assistant (CM) Case Manager																

## Qualitative element of the study

The qualitative component of the study comprises patient perceptions on the overall reform process and the individual intervention and its felt impact. The SITAR study will use Focus Group Discussions (FGDs) to elicit this. Four FGDs of 8 patients each (16 patients from each study arm) will be conducted in the last quarter of the study period. Since we seek to understand the lived experience of the service user, a phenomenological epistemological perspective is proposed. A basic thematic analysis will be done using the Scissor and sort technique (Krzyzanowski, 2008). Verbatim quotes will also be used to highlight findings from quantitative components of the study.

## Data management and analysis

### Data collection

Quantitative data will be collected by trained Research Assistants (RAs) using pre-designed; pre-tested tools as included in the protocol. Senior RA will check completeness and accuracy of data gathered on daily basis before electronic data entry.

### Data storage

The paper data will be stored in secure cabinets, in the PI's cabin at the Tata Trust office in the hospital campus. The office is under CCTV surveillance. The data will be held for ten years post completion of the study.

### Data entry and coding

Data will be coded and entered in an efficient database using MS Excel. Data will be kept confidential and anonymous on password-protected files. The master sheet will be kept separately on MS Excel with password protection. Built-in validity checks will be incorporated in data entry software with flash/warning alerts for incorrect or out of range values.

*Data screening, data validation and data editing*

Data will be screened at every stage i.e. pre-randomization, post randomization and closing stage of the trial. This will be done for each and every item of the individual record by student researcher (trial PI). Accuracy of electronic data will be checked through comparison with questionnaire data on a sample basis.

*Data analysis*

Analysis will focus on assessing between-the-group differences in effectiveness of interventions, and thereafter finding associations between the outcome and a set of predictors or explanatory variables of the respondents. Inferential statistics: 95% Confidence Intervals will be obtained for all the descriptive measures, especially for efficacy parameters. Between-the-group differences in means of two groups (Study versus Control) will be tested by independent samples t-test assuming equal variance. Relevant covariates such as gender and age will be adjusted for using linear regression. Within-the-group differences in means (Baseline to End line) will be tested with Paired t-test for each group separately. Difference in proportions in two study arms will be tested by Pearson's Chi-square test, while within-the-group (before-after) comparisons will be assessed by McNemar's Chi square test. In a scenario where the assumption of normality is not valid, equivalent non-parametric alternatives (e.g. Rank-based statistics) shall be used especially for score data. The study will consider a P value less than 0.05 as significant for all variables.

We will handle missing data in the following manner-

Imputation method will be used in conjunction with an estimation technique (e.g. regression) for coping with missing values of one or more variables. For instance, if value of a dependent variable (or outcome) is missing it will be replaced by the predicted value from the best available subset of otherwise present data. For quantitative outcome variable (like score or measurement value) estimated median value will be used to replace missing values. For categorical outcome variable (like scale or scoring system) estimated factor scores will be used to predict missing values based on the factor loadings obtained from factor analysis.

*Data processing*

Data will be processed by the Udaan program at baseline (pre-randomization), during trial (post randomization) and closing stage (outcome assessment). Raw data from the master file will be coded and processed into a data file. The data file will include both original variables as well as some newly derived variables or transformed variables specific to the study objectives. Statistical Package of Social Sciences (SPSS) will be used for data analysis. The data analyst will be blinded to treatment assignment.

*Anonymizing data*

Direct identifiers that allow the identification and communication with an individual participant will be removed. The names of all participants will be replaced with a master list identity (ID) number. The master list containing the ID number will be kept with the PI on a password-protected file, which will be housed in a password, protected firewalled system. The data set for analysis will not include any email address, telephone numbers or home address of patients (where available). Quasi identifiers such as ward numbers will be removed from and variables such as date of admission and date of discharge will be generalized into length of stay.

### *Sharing of data*

Analyzed data will be shared with the co-authors of the study through a password-protected process. The password for the file will be shared through a phone call made for this purpose. No personal or primary data will be shared. The completely anonymized data set will be made available on request, with due permissions, in keeping with Indian legislation, once primary data analysis is published.

## **PATIENT AND PUBLIC INVOLVEMENT**

Focus Group Discussions (FGDs) are built into the design of the program to incorporate the patient experience of intervention. No patients were involved in the study design.

## **COSTING AND POTENTIAL ECONOMIC GAINS OF THE INTERVENTION**

The SITAR study will also include a retrospective bottom-up cost analysis of the individualized intervention in terms of resource or input requirement along with costing of resources for care as usual. Cost elements will include all the resources used in development of the intervention and training material, costs of training, costs of intervention delivery which will include staff time and costs of supervision (people, facilities, equipment and supplies). The costing will be based on actual expenditure incurred through the Udaan program as well as costs components derived through collaboration this will include costs of items received in kind such as clothes, soaps and shampoos and such directly linked to patient care. Actual government spending on patient care will also be done. Costing will be appropriately apportioned to the SITAR study in terms of time allocation of staff based on an analysis of case management records. The study will compare the costs with benefit in terms of disability and health related quality of life. Given the scope of the study, this will be presented as a cost-consequence analysis/ (40)

## **Ethical Approval**

Ethical approval for SITAR has been obtained from a registered ethics committee in India (Institutional Ethics Committee VikasAnvesh Foundation, VAF/2018-19/012 dated 6/12/2018) and the University of Warwick's Biomedical and Scientific Research Ethics Committee (REGO-2019-2332, dated 21 March 2019), and registered on the Central Trial Registry of India (CTRI/2019/01/017267).

## **DISSEMINATION**

Findings of the study will be presented through scientific publications as well as through a national level dissemination in India along with presentations in different conferences. We also intend to do a policy paper recommending a feasible reform process for psychiatric hospitals in India. Trial results will be published in accordance to CONSORT guidelines.

## **CURRENT TRIAL STATUS**

Recruitment of patients was initiated in April 2019. Recruitment was closed in December 2019. The final patient recruited will reach end-point follow-up in December 2020.

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**AUTHOR CONTRIBUTIONS**

Tasneem Raja- Principal Investigator, design and implementation of the trial. Wrote first draft of protocol paper.

Helena Tuomainen- Supported the design, protocol development, ethics application and continued supervision, review and editing of manuscript

Jason Madan- Supported the design of economic elements of the protocol.

Sanjeev Jain reviewed and edited the manuscript

Swaran Singh- primary supervisor on the trial, supported the design, protocol development, ethics application for India and UK, Trial registry, ongoing supervision on the trial.

All Co-authors reviewed, edited the manuscript and accepted the final version of the paper.

**FUNDING STATEMENT**

This work is supported by Tata Education and Development Trust (TEDT) (DI Regional mental hospital Nagpur, circular number 130) and R G Manudhane Foundation for Excellence (MoU with TEDT dated 10<sup>th</sup> Aug 2016).

**COMPETING INTERESTS STATEMENT**

This trial is part of the PhD program undertaken by the PI Tasneem Raja. She is an employee of the Tata Trusts and the Tata Trusts External Individual educational grants program funds the PhD won on basis of merit.

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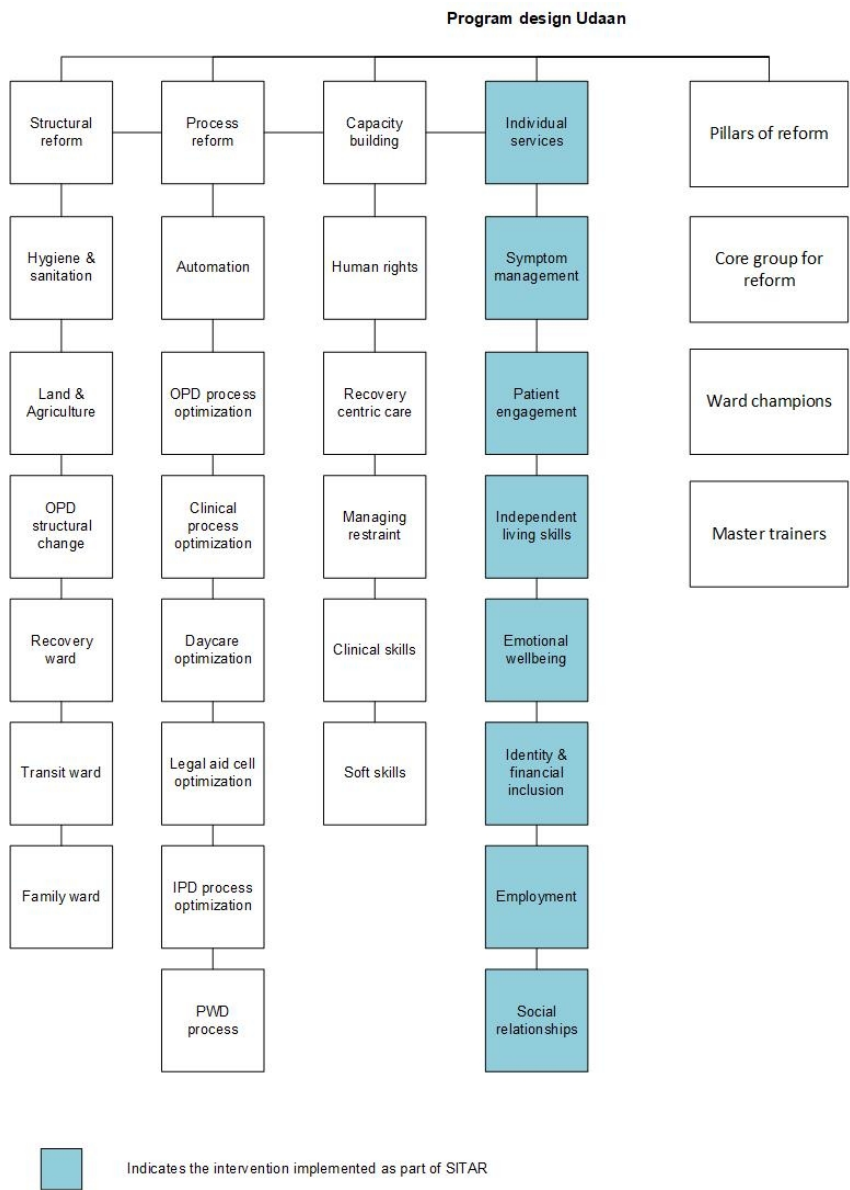


Figure 1 Graphic representation of Udaan and SITAR

72x92mm (300 x 300 DPI)

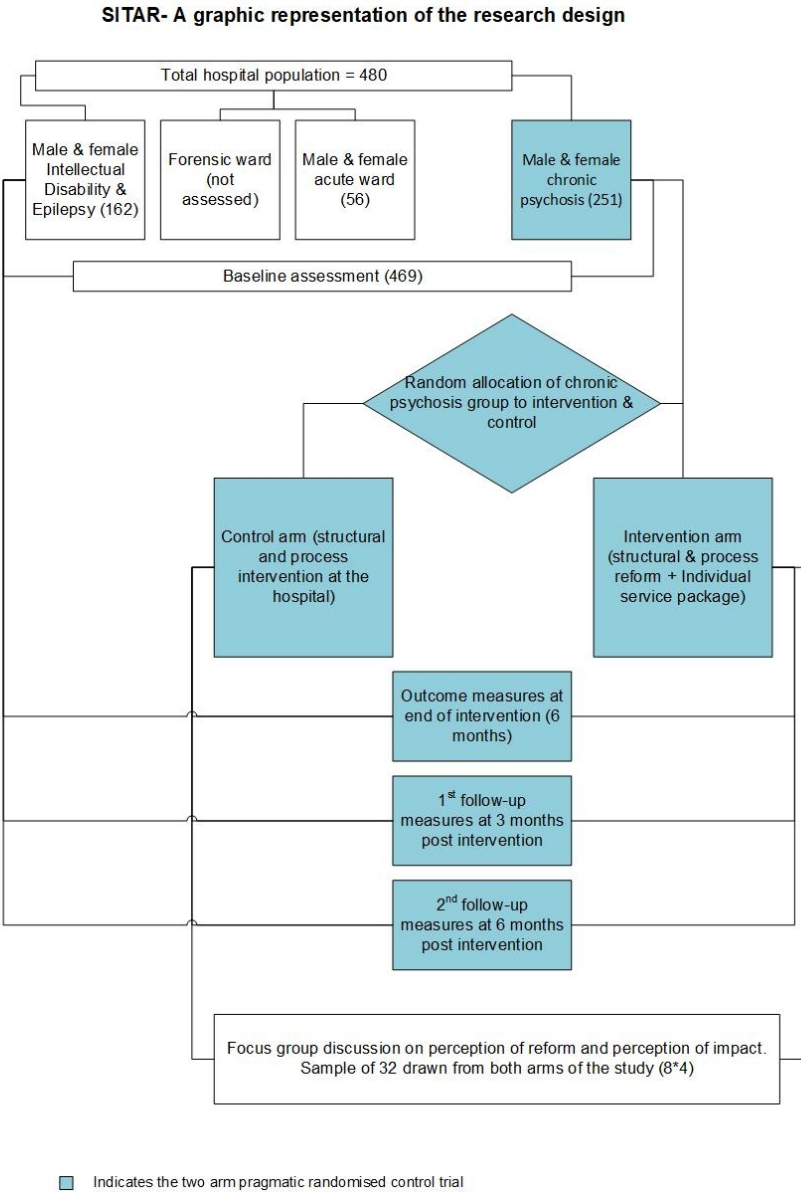


Figure 2 Graphic representation of SITAR

81x102mm (300 x 300 DPI)

## SPIRIT PROTOCOL FOR SITAR

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

Section/item	Item No	Description
<b>Administrative information</b>		
Title	1	Psychiatric Hospital Reform in Low and Middle-income Countries Structured Individualized Intervention and Recovery – SITAR Trial Acronym – SITAR (Pg 1)
Trial registration	2a	Central Trial Registry (CTR – ICMR) (CTRI/2019/01/017267).
	2b	All items from the World Health Organization Trial Registration Data Set included below the complete SPIRIT protocol
Protocol version	3	Version – 2 <i>31<sup>st</sup> Dec 2018</i>
Funding	4	Tata Trusts
Roles and responsibilities	5a	Tasneem Raja
	5b	Tata Trusts World Trade Centre -1, 26 <sup>th</sup> Floor, Cuffe Parade, Mumbai – 400 005 Tel: +91 - 22 - 6665 8282

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5c    *Funder-* (pg 15)

- *MoU with the Government of Maharashtra for the Psychiatric hospital reform (Tata Trusts)*
- *Part funding of the program with other donors (R.G Marudhane Motivation for Excellence Foundation and part funding by the Government of Maharashtra)*
- *The Donors do not have a direct say in the design, data analysis and interpretation / publication of the study findings*

5d    *Overall steering committee for Udaan is as per the MoU and is formed by the Government of Maharashtra*

*Coordinating center- Udaan office located on site*

*Data collection- A team of research assistants hired for the purpose and supervised directly by the PI*

*Data management- PI along with M&E manager and senior research assistant to ensure quality check on collection and entry of data.*

*Supervisors- Professor Swaran Preet Singh, Professor Jason Madan and Dr Helena Tuomainen from University of Warwick & Dr Sanjeev Jain from NIMHANS India- will oversee the design and execution of the trial. (Pg12-14)*

Introduction                      (pg 3 to 6)

Background and 6a  
rationale

SITAR aims to bridge a critical gap in scientific evidence by studying the impact of reform of psychiatric hospitals on individual patient outcomes. It will offer an evidence based package of reforms for psychiatric hospitals in transition in low and middle-income countries.

The SITAR study is embedded within a larger program called **Udaan**. Udaan is a collaboration of the Tata Trusts (a leading philanthropic foundation in India) with the Government of Maharashtra. The goal of Udaan is to develop the Regional Mental Hospital Nagpur (RMHN) into a center of excellence through a series of structural and process reforms. This is intended as a model that will inform policy change for transition of other psychiatric hospitals in the state of Maharashtra and India.

The key research question is: Do individual recovery plans\* improve patient outcomes, \*\* amongst long stay inpatients\*\*\*, in comparison to care as usual\*\*\*\* in a psychiatric hospital undergoing reform in a low and middle-income country?

\*Individual recovery plan- A structured individual recovery plan based on individual needs assessment

\*\*Patient outcomes refer to change in symptoms of illness, disability levels, social and occupational functioning and quality of life.

\*\*\*Long stay patients- Patients having a continuous period of stay between 12 months and up to 10 years in the Nagpur Regional Mental Hospital in India.

\*\*\*\*Care as usual- For the purpose of this study, care as usual, refers to the structural and process reform in the hospital with a view to modernizing it. This does not include individual recovery plans for patients.

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6b Explanation for choice of comparators

The study compares patient outcomes with care as usual in a psychiatric hospital in India undergoing reform to those with an addition of needs based intensive case management.

The premise of this comparison is that Needs based intensive case management, used in most high resource countries, is a resource intensive intervention. In such a scenario, can individual patient outcomes be modified significantly with larger structural and process reforms in old psychiatric hospitals to meet the needs of current day service users? This comparison has significant value in policy decision making on how meagre resources should be used in low resource settings where mental health care is predominantly provided by psychiatric hospitals set up 100 to 200 years ago.

Objectives  
Hypothesis

& 7

The objectives of SITAR are: (Pg 3-4)  
To determine the effectiveness of structural and process reform of psychiatric institutions on patient level outcomes for in-patients of the hospital.

- a. To compare the effectiveness of structural and process reform with and without an individually tailored recovery plan on patient level outcomes of disability (primary Outcome), symptom severity, social and occupational functioning and quality of life for the long stay patient cohort of the hospital
- b. To determine the costing of implementing an individually tailored recovery plan for long stay individuals in psychiatric hospitals

Primary hypothesis- there is no difference in WHODAS (disability levels) scores between study participants receiving the individual (active) intervention and those receiving usual care (control arm).

Secondary hypothesis- there is no difference in disability outcomes before and after structural and process reform and individual treatment for in-patient service users of the hospital.

## Trial design

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(pg 7 &amp; 8)

SITAR is a real world implementation study. The trial design is a pragmatic two arm RCT as it is not pragmatically possible to create the ideal study situation of a Randomized Control Trial. The entire in-patient population of the hospital is compiled on a database, for the purpose of this study, mapping socio-demographic variables, history of illness and history of treatment as baseline data (No electronic database of this nature existed prior to this).

The hospital population is divided into four major units, comprising the intellectual disabilities and epilepsy patients' ward forensic ward, acute care ward and the chronic psychosis wards.

Patients fitting the inclusion criteria for the long stay patient cohort (chronic psychosis wards) will be compiled from the larger dataset and randomly assigned to the intervention and control groups.

Intervention – Intensive needs based case management will be carried out for a six-month period. Post measures on all patients who have undergone pre measures will be compiled at completion of intervention (at six months) and at two follow-up intervals post intervention of nine months and 12 months (3 and 6 months after completion of intervention).

The researcher will track fidelity indicators for the intervention as well as process indicators. Loss of sample and the reasons for that will be documented.

The trial also has a qualitative component which brings in the experience of the user and their perception of reform and or intensive case management. This will be done by the researcher through Focused Group Discussions (FGDs) in the last quarter of the one-year study period. People from both arms of the study will be included for this component.

Several steps are proposed to ensure quality control and minimize the risk of bias.

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1. Standardizing the intervention program through an intervention manual comprising of all the intervention protocols. The intervention manual is presented as appendix.
  2. Development of a standard training manual for training of all case managers delivering the individual intervention. The training manual is included in the appendix.
  3. Randomization of the sample to intervention and care as usual arms of the study.
  4. Blinding will be done at two levels. Outcome measurements will be undertaken by researchers independent of the case managers delivering the intervention. Inter-rater reliability for the researchers will be computed. The statistician drawing the randomization tables will be blinded to the allocation of the groups.
- This being a real world setting, it is not possible to mask the case managers to the group allocation. Though the researchers and case managers are independent, masking may not be completely feasible due to the nature of the setting. Episodes of unmasking will be recorded.

Methods: Participants, interventions, and outcomes (Pg 7 to 12)

Study setting	9	Regional Mental Hospital, Nagpur. Country – India. This is a psychiatric hospital set up in 1884 and a major care provider in the central region of India.
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## Eligibility criteria 10

Key Inclusion	Exclusion Criteria
A primary diagnosis of psychosis**	Service users over the age of 60 years*
Continuous length of stay in the hospital $\geq 12$ to 120 months	Service users with neuro-developmental disorders such as epilepsy**
Over the age of 18 years	Service users with Intellectual Disability**
	Service users in Acute Wards***
	Service users in forensic wards****

\*Older people with a longer duration of stay in institutions are not likely to benefit greatly from intensive intervention.

\*\*Based on diagnosis given in case files of the hospital

\*\*\*Service users in acute wards are acutely ill and unable to participate effectively

\*\*\*\*Legal access issues in Forensic ward

The individual needs based intervention will be provided by case managers trained to deliver a standard intervention for the study through the standard training manual of the study.

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Interventions

(Pg 8-9)

- 11a This intervention package is based on the premise of contemporary understanding of psychosocial rehabilitation that takes a holistic approach to improving quality of life for a person living with mental illness, reducing disability, improving role function, promoting independence and autonomy based on a hope for the future. Trained case managers will deliver the intervention through a clinical and intensive case management approach that taps in to a functional network of a spectrum of services being created at the hospital level through the reform process. Case managers will draw up a personal care plan collaboratively with the service user and in discussion with the ward in charge, and checked and revised on a monthly basis. Case managers will record the plan on a standard form developed for the intervention and reviewed monthly by the researcher. Each case manager will have a case load of 12-14 service users and will spend at least 8 sessions per case per month of at least 60 minutes each.
- 11b Intervention will be discontinued under the following circumstances-
- If the participant wants to discontinue participation
  - An acute illness episode that significantly disrupts time in intervention (beyond four weeks)
  - When the participant is discharged from the hospital and community based intervention is not possible either due to distance beyond Nagpur district, unwillingness of participant or family for home based intervention.
  - In case of death of a participant

11c This is a psycho-social rehabilitation intervention and as such does not involve intervention adherence. One component of the intervention is symptom management. Adherence to medication within this component will be managed in the following manner

- Medication administered under observation while the participant is in hospital
- Psychoeducation on importance of medication to participant and family (where available)
- Addressing side effects in discussion with psychiatrists
- Ensuring medication stock availability when participant is discharged from hospital

11d Relevant concomitant care and interventions that are permitted or prohibited during the trial

All routine interventions available in the hospital (in this case a hospital undergoing structural and process reform) will be available to the participant as concomitant intervention.

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Outcomes	12	<p>The outcome measures comprise assessment of disability levels, symptom measure, assessment of social and occupation functioning and assessment of quality of life. These four measures are described in detail below-</p> <p>The primary measure is disability levels</p> <p><b>Disability Measure- WHO Disability Assessment Scale 2.0 (WHODAS 2.0)</b> (primary outcome) is a generic assessment instrument for health and disability and produces standardized disability levels and profiles and is applicable across cultures, in all adult populations and is used across all diseases, including mental, neurological and addictive disorders. SITAR will use the simple scoring format, which is the recommended one for a busy clinical setting and constitutes a statistic that is sufficient to describe the degree of functional limitation.</p> <p><b>Symptom measure- The Clinical Global Improvement Scale (CGI)</b> is a brief, stand-alone assessment of the clinician's view of the patient's global functioning prior to and after initiating a study medication or intervention (Haro <i>et al.</i>, 2003). The CGI comprises two one-item measures evaluating (a) severity of psychopathology from 1 to 7 and (b) change from the initiation of treatment on a similar seven-point scale.(JOAN BUSNER &amp; and STEVEN D. TARGUM, July 2007)</p> <p><b>Social and Occupational Functioning Scale (SOFS)</b></p> <p>The SOFS focuses exclusively on the individual's level of social and occupational functioning and is not directly influenced by the overall severity of the individual's psychological symptoms (Morosini <i>et al.</i>, 2000). In study it will used to rate functionality over a three month period.</p> <p><b>Health related quality of life measure EuroQol-5D (EQ-5D)</b> is a</p> <p>The EQ-5D is the most widely used generic Patient reported outcome (PRO) questionnaire internationally. The EQ- 5D asks patients to indicate whether they have no, some or extreme problems on each of five dimensions of health: mobility; self-care; usual activities; pain/discomfort, anxiety/depression</p>
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## Episodes of seclusion and restraint

For the purpose of this study, seclusion and restraint are defined as follows:-

Seclusion means the placement and retention of an inpatient service user in a bare room in order to contain a clinical situation that may result in a state of emergency.

Physical restraint refers to the manual holding and restriction of the service user by staff or under their instruction.

Mechanical restraint refers to the use of belts, handcuffs and the like, which restrict the service user's movements or totally prevent the person from moving.

These episodes will be recorded as they occur on the case manager's record form included in (Appendix 5.2.6).

Process/ intervention measures include the following-

- Assessment of need
- The intervention plan
- Symptoms checklist
- Self-care and other living skills checklist

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Participant 13  
timeline (PG 14-15)

We aim to recruit 100 participants in each arm of the trial. Recruitment will continue up to the point we achieve the number based on inclusion and exclusion criteria of the protocol. Intervention time frame will start as soon as a participant is recruited since this is an individual intervention. We anticipate a two month time frame in completion of recruitment from the time of initiation. This means intervention will run maximum for a period of 8 months to complete the intervention time frame of six month for those recruited last.

Time line of the trial														
Time (Months)	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Enrolment														
Eligibility screen														
Informed consent														
Baseline assessment														
Allocation														
Intervention														
Outcome measurement														
1st Follow-up measure														
2nd Follow-up measure														
Month 1 starts post ethics approval														

Sample size	14	<p>Study population – 469</p> <p>Sample will be in-patient service user population of the hospital (600 <math>\pm</math> 50 <i>n</i>) excluding the in-patients of the forensic ward and acute ward. This brings the study population to about 515. Service users meeting the inclusion criteria for the study will be randomized on a 1: 1 basis to the two arms of the study post informed consent. For the study to be powered at the 90% level with 5% significance level, the required sample is 170 people, 85 in each arm. Assuming a 15% drop out we aim to recruit 100 people in each arm of the study. For the power calculation, we have assumed a moderate effect size of 0.5. With a minimum clinical difference of a score of 10 points with a <math>\sigma</math> of 20.</p> <p>The effect size and variance was drawn from an Indian study based in the community with non-intensive case management using WHODAS scores as primary outcome measures (Murthy <i>et al.</i>, 2005).</p> <p>People with psychosis in institutional set-ups might have higher disability levels as compared to people living in the community, however most people in LMICs continue to remain in institutions due to the absence of viable pathways of community reintegration. The intervention being offered is intensive with longer case management time than what would be feasible in a dispersed community setting. This forms the basis for assuming a moderate effect size.</p>
Recruitment	15	<p>The sample will be recruited from the hospital's in-patient service user population based on the inclusion and exclusion criteria. The sample recruitment will be continued until such time the required numbers are fulfilled. Almost 58% of service users are under 1 year of stay at the RMHN with the median length of stay being 15 months. Service users who have crossed the 1-year mark will be put through the recruitment and randomization process as per the study protocol.</p> <p>If a service user is discharged from the hospital during the study period, the case manager will continue to provide intervention as per protocol in the service users' setting to the extent feasible. Dropouts and reasons for lack of end measures will be captured.</p>

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**Methods: Assignment of interventions (for controlled trials) (Pg 8)**

Allocation:

Sequence generation	16a	The study will use a computer generated permuted block randomization schedule
Allocation concealment mechanism	16b	The researcher will create a list of service users meeting the inclusion criteria and consenting to the study and give them a unique ID number. This list will be handed over to the statistician who is independent to the research team
Implementation	16c	. Random allocation of eligible study subjects to two study arms (A and B) will be done by the statistician using ralloc software (version 3.7.6) available in STATA (version 10.1, 2011) module.
Blinding (masking)	17a	Statistician drawing the randomization tables will be blinded to the allocation of the groups and Case Managers delivering the intervention will be blinded to the baseline and outcome measurements.
	17b	Un-blinding post intervention, at the time of the three outcome measures may occur with research assistants conducting measurements. These instances will be recorded and reported.

**Methods: Data collection, management, and analysis (Pg 12-14)**



# Data collection 18a methods

Baseline measurements will be initiated at the start of the study and will be completed for the entire in-patient population over a three-month period. Research assistants trained in using all instruments will carry out assessments.

The intervention will be initiated after completion of the baseline measurements and carried out for a period of six months based on structured protocols. At the end of the six-month intervention period, the first outcome measurement will be initiated and completed over a two-month period. The first and second follow-up outcome measurements will be initiated at three and six months post intervention, respectively, and completed over a two-month period.

All the four outcome measures will be done using standardised instruments as described in the protocol.

Table 4-3 List and time frame for assessments

Assessment	Type	By	0	1	2	3	4	5	6	7	8	9	10	11	12
WHODAS (Disability)	OM	RA	•						•			•			•
SOFs (Social & Occupational functioning)	OM	RA	•						•			•			•
CGI (Symptoms)	OM	RA	•						•			•			•
EQ-5D (Quality of life)	OM	RA	•						•			•			•
Episodes of seclusion & restraint	OM	CM	•	•	•	•	•	•	•	•	•	•	•	•	•
Discharge / adverse events	OM	CM	•	•	•	•	•	•	•	•	•	•	•	•	•
Needs Assessment	PM	CM	•			•			•			•			•
Intervention plan	PM	CM	•	•	•	•	•	•	•						
Symptoms checklist	PM	CM	•			•						•			•
Self-care and other living skills checklist	PM	CM	•	•	•	•	•	•	•						
Case management record form	PM	CM	•	•	•	•	•	•	•						

(OM) Outcome Measure (PM) Process Measure (RA) Research Assistant (CM) Case Manager

*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*

- 18b In the case of an adverse event where the patient may not be available for measurement as per sequence, accommodation will be made to complete the measure any time during the two-month period of that measurement cycle. In case this is not possible, the patient will be considered as Lost to Follow-up (LFU).

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Data  
management

19      Questionnaire data will be collected using paper pencil formats; hand scored, and entered on computer. Quality checks will be done on 20% of the data randomly. Focus group notes and recordings will be transcribed in English as Word files. The Excel Word and SPSS files will be stored on password-protected computers and hosted on secure servers.

Physical data files will be stored in a secure place in locked filing cabinets within the Tata Trusts office. Only the researcher, study statistician and the supervisors will access baseline, outcome measurement and focus group data. Data will be shared with supervisors at the University of Warwick using standard good practice. Password protected data files will be sent over email and the password sent in a separate email. The shared data files will be completely anonymized

review only

## Statistical methods

20a Data analysis will mainly focus on assessing between-the-group differences in effectiveness of interventions, and thereafter finding associations between the outcome and a set of predictors or explanatory variables of the respondents.

The researcher will use descriptive statistics like Mean/Standard Deviation, or Median/Quartile Deviation depending on the distribution of data for describing variables such as scores and other measures while frequency and proportions or percentages will summarize count data.

Inferential statistics: 95% Confidence Intervals will be obtained for all the descriptive measures, especially for efficacy parameters.

Between-the-group differences in means of two groups (Study versus Control) will be tested by independent samples t-test assuming equal variance. Relevant covariates such as gender and age will be adjusted for using linear regression.

Within-the-group differences in means (Baseline to End line) will be tested with Paired t-test for each group separately.

Difference in proportions in two independent groups (Study versus Control) will be tested by Pearson's Chi-square test, while within-the group (before-after) comparisons will be assessed by Mc Nemar's Chi square test.

20b *Additional analysis may be focused on age group based sub grouping and gender based sub grouping of findings.*

20c In a scenario where in the assumption of normality is not valid, equivalent non-parametric alternatives (e.g. Rank-based statistics) shall be used especially for score data. The study will consider a P value less than 0.05 as significant for all variables.

## Methods: Monitoring

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Data monitoring	21a	<p>Adverse events are defined in the protocol and are not considered an outcome or related to the trial but as events that occur whilst the trial is on. This is specifically so given that this is a psychosocial rehabilitation intervention. Adverse events will be recorded and reported.</p> <p>Harm arising out of the intervention to key stakeholders has been considered along with mitigation strategies and is part of the protocol.</p> <p>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</p>
	21b	<p>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- NA</p>
Harms	22	<p>Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct- included in 21a</p>
Auditing	23	<p>Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor- through the process of supervision</p>
Ethics and dissemination		

Research ethics approval (Pg 14)	24	<p><i>The following has been done</i></p> <ul style="list-style-type: none"> <li>• <i>Memorandum of understanding between Tata Trusts and Government of Maharashtra to undertake a reform program of which the individual intervention (under study) is a part (completed).</i></li> <li>• <i>Permission sought from Hospital administration to initiate the individual intervention package, baseline and outcome measures as defined in the protocol (completed).</i></li> <li>• <i>Ethics clearance sought from a registered ethics committee in India</i></li> <li>• <i>Ethics clearance sought from the University of Warwick ethics committee.</i></li> <li>• <i>Trial registry on the Central Trials Registry of India</i></li> </ul>
Protocol amendments	25	<i>Any modification in protocol will be informed in writing along with reasons to all the parties involved in permission and ethics clearance as stated in section 24 of SPIRIT protocol.</i>
Consent or assent (Pg 8)	26a	<p><i>The PI will obtain all informed consent using the pictorial information sheet and set of cards attached with the protocol.</i></p> <p><i>Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)</i></p>
	26b	<i>Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable</i>
Confidentiality (Pg 12- 14)	27	<p><i>Data will be collected in hard copies which will be stored in locked cabinets in the Tata Trusts office. The data will be entered into excel sheets which will be password protected on password protected computes. All data will be anonymised before sharing with the supervisor at University of Warwick. The file sent over email will be password protected and password will be shared in a separate email. A similar process will be used with the statistician analysing the data. These are the only two entities with whom data will be shared.</i></p>

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Declaration of interests	28	<i>The PI is an employee of the Tata Trusts. Tata Trusts is a non-sectarian philanthropic organization based in India. It is also one of the funders of the Udaan program within which this PhD study is nested.</i>
(Pg 15)		
Access to data	29	<i>The PI, statistician and university supervisor will have access to the data</i>
(Pg 14)		
Ancillary and post-trial care	30	<i>This being a psychosocial intervention study, continuing services is an important consideration. Tata Trusts will train the Government hospital staff in case management based psychosocial intervention with the training material developed for this study.</i>
Dissemination policy	31a	<i>The following modalities will be used for dissemination of results-</i> <ul style="list-style-type: none"><li><i>• Part of the yearly process dissemination of the larger Udaan program</i></li><li><i>• Scientific publications as part of the PhD</i></li><li><i>• PhD thesis made available in the public domain</i></li><li><i>• Policy brief for the Government based on the findings of the study</i></li><li><i>• Tool kit of the final tools and manuals used for the study made available in the public domain</i></li></ul>
	31b	<i>Primary authorship will be with the PI. Supervisors will be invited to be co-authors on all publications. No professional writers will be used.</i>
	31c	<i>NA</i>
Appendices		
Informed consent materials	32	<i>Informed Consent and Participant Information Sheet in pictorial format enclosed with the protocol.</i>  <i>Model consent form and other related documentation given to participants and authorised surrogates</i>

Biological  
specimens

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For peer review only

# BMJ Open

## PSYCHIATRIC HOSPITAL REFORM IN LOW AND MIDDLE INCOME COUNTRIES STRUCTURED INDIVIDUALIZED INTERVENTION AND RECOVERY (SITAR); A TWO ARM PRAGMATIC RANDOMIZED CONTROL TRIAL-STUDY PROTOCOL.

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Manuscript ID	bmjopen-2019-035753.R2
Article Type:	Protocol
Date Submitted by the Author:	12-Mar-2020
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<b>Primary Subject Heading</b>:	Mental health
Secondary Subject Heading:	Health services research
Keywords:	Adult psychiatry < PSYCHIATRY, Change management < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Schizophrenia & psychotic disorders < PSYCHIATRY

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**PSYCHIATRIC HOSPITAL REFORM IN LOW AND MIDDLE INCOME COUNTRIES  
STRUCTURED INDIVIDUALIZED INTERVENTION AND RECOVERY (SITAR); A TWO ARM  
PRAGMATIC RANDOMIZED CONTROL TRIAL-STUDY PROTOCOL.**

**Tasneem Raja, Helena Tuomainen, Jason Madan, Dipesh Mistry, Sanjeev Jain, Swaran P  
Singh**

**Corresponding author**

Tasneem Raja,  
Tata Trusts (Udaan) office, Behind OPD Building, Regional Mental Hospital, Nelson Square,  
Chindwara Road, Nagpur 440013 Email [T.Raja@warwick.ac.uk](mailto:T.Raja@warwick.ac.uk) / [traja@tatatrusters.org](mailto:traja@tatatrusters.org) Mobile-  
+91 7506091860 ORCID ID [0000-0002-5821-8673](https://orcid.org/0000-0002-5821-8673)

Dr Helena Tuomainen, Senior Research Fellow, Mental Health and Wellbeing, Warwick Medical  
School, University of Warwick, UK, T: +44 (0)24 765 28205 [helena.tuomainen@warwick.ac.uk](mailto:helena.tuomainen@warwick.ac.uk)  
[ORCID: 0000-0003-1636-8187](https://orcid.org/0000-0003-1636-8187)

Jason Madan  
Professor in Health Economics | Director of Graduate Research Studies  
Centre for Health Economics at Warwick  
Warwick Medical School, University of Warwick ORCID ID 0000-0003-4316-1480

Dr Dipesh Mistry  
Senior Research Fellow Statistician, Warwick Clinical Trials Unit, University of Warwick ORCID  
0000-0002-0875-9260

Prof. Sanjeev Jain DPM,MD, Molecular Genetics Laboratory  
Department of Psychiatry, National Institute of Mental Health and Neurosciences, Hosur Road  
Bangalore 560029, INDIA tel: \*\*91 80 26 99 52 62/63, fax: \*\* 91 80 26 56 48 30,  
email: [sjain.nimhans@nic.in](mailto:sjain.nimhans@nic.in); / [sjain.nimhans@gmail.com](mailto:sjain.nimhans@gmail.com)

Professor Swaran P Singh MBBS, MD, DM, FRCPsych  
Director, Centre for Mental Health and Wellbeing Research  
University of Warwick ORCID ID 0000-0003-3454-2089

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**ABSTRACT**

Introduction

Low and middle-income settings like India have large treatment gaps in mental health care. People with Severe Mental Disorders face impediments to their clinical and functional recovery, and have large unmet needs. The infrastructure and standards of care are poor in colonial-period mental hospitals, with no clear pathways to discharge and successfully integrate recovered individuals into the community. Our aim is to study the impact of psychiatric hospital reform on individual patient outcomes in a mental hospital in India.

Methods and analysis

Structured Individualized Intervention and Recovery (SITAR) is a two-arm pragmatic randomized control trial, focusing on patients aged 18 to 60 years with a hospital stay of 12 to 120 months and a primary diagnosis of psychosis. It tests the effectiveness of structural and process reform with and without an individually tailored recovery plan on patient outcomes of disability (primary outcome WHODAS), symptom severity, social and occupational functioning and quality of life. A computer generated permuted block randomization schedule will allocate recruited subjects to the two study arms. We aim to recruit 100 people into each trial arm. Baseline and outcome measures will be undertaken by trained researchers independent to the case managers providing the individual intervention. A health economic analysis will determine the costing of implementing the individually tailored recovery plan.

Ethics and dissemination

The study will provide answers to important questions around the nature and process of reforms in institutional care that promote recovery while being cognizant of protecting human rights, and dignity. Ethical approval for SITAR was obtained from a registered ethics committee in India (Institutional Ethics Committee VikasAnvesh Foundation, VAF/2018-19/012 dated 6/12/2018) and the University of Warwick's Biomedical and Scientific Research Ethics Committee (REGO-2019-2332, dated 21 March 2019), and registered on the Central Trial Registry of India (CTRI/2019/01/017267).

**STRENGTHS AND LIMITATIONS OF THE STUDY**

- This is the first ever methodologically robust study in low and middle income countries to test the impact of reforms in a psychiatric hospital on important patient outcomes such as change in disability, symptoms, social and occupational functioning and quality of life.
- The study offers an individual recovery plan for a psychiatric hospital setting in low resource settings
- The cost implication of the individual service package will be studied. This has relevance in influencing mental health care policy across the country.
- There is a strong component of government involvement that adds to the potential of sustainability and scaling up across other mental hospitals in the country.
- It is not possible to blind the case managers to the group allocation due to the nature of the intervention, hence it is a single-blind study, with only researchers assessing outcomes being blind to allocation. Given the nature of the setting, there is also a risk of contamination across both trial arms.

## INTRODUCTION

People living with Severe Mental Disorders (SMD) (psychosis, bipolar and affective disorders and severe-moderate depression) in low and middle-income countries (LMICs) face impediments to their clinical and functional recovery, and have large unmet needs associated to poverty, protection of human rights, social inclusion and participatory citizenship.(1-5) A range of cost-effective and evidence-based interventions are now available, however there are major barriers in access to appropriate care, increasing vulnerability and disadvantage along with stigma and discrimination. (1, 2, 6-9) Many languish in large hospitals, abandoned by family and forgotten by policy makers. India has 43 mental hospitals built during the colonial period that continue to function almost in the same way as they did when they were set up. (10-14) These hospitals constitute 80% of all available psychiatric beds. (15) At the end of 2015 there were 6,829 patients staying in 30 of the 43 mental hospitals; 16% had been inpatients for more than five years, some for 3-4 decades.(5) The infrastructure and standards of care are poor.(14) There are no clear pathways to discharge and successfully integrate former patients into the community. (16) A complex mix of low priority for mental health care in India, lack of support from central and state governments and low autonomy and decision making power amongst professionals working in such institutions has impeded any meaningful reform.(14)

Mental hospitals in India have played an important role in the care of very vulnerable people and continues to remain a legitimate and relevant locus of care for people in need of services.(17) Given the lack of feasibility of closing down psychiatric institutions in most low and middle income countries, there is an urgent need for manageable and evidence based reform of these hospitals. The Udaan program seeks to address this need.

### The Udaan Program

Udaan is a partnership of Tata Trusts with government of Maharashtra, formalized through an MoU, to develop the Regional Mental Hospital Nagpur (RMHN) as a center of excellence through systematic reform of the hospital. Maharashtra is a state in the Western peninsular region of India with Nagpur being right in the center of the country. Udaan (which in Hindi mean 'to soar') comprises four key reform elements: structural (refurbishing old colonial infrastructure to meet current service user needs), process (standardizing clinical and non-clinical processes of the hospital), capacity building (standard training for different levels of hospital staff) and introduction of the Needs Based Intensive Case Management (NB-ICM), an individual need based, recovery oriented, service package for patients delivered through intensive case management. The Udaan elements are detailed in figure 1.

### Structured Individualized inTervention And Recovery (SITAR)

The Structured Individualized Intervention and Recovery (SITAR) study is embedded within the Udaan program. In a clinical trial we test whether NB-ICM improves patient outcomes amongst long stay inpatients, in comparison to care as usual in a psychiatric hospital undergoing reform in a low and middle-income country. The objectives of SITAR are

- a. To compare the effectiveness of structural and process reform with and without an individually tailored recovery plan on patient level outcomes of disability (primary Outcome), symptom severity, social and occupational functioning and quality of life for the long stay patient cohort of the hospital
- b. To determine the costing of implementing an individually tailored recovery plan for long stay individuals in psychiatric hospitals

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Intensive case management calls for high resources and as such may not be feasible in low income settings. We thus seek to compare patient outcomes emerging from larger structural and process reform in old psychiatric hospitals as compared to patient outcomes when intensive case management is added along with the reform. This comparison has significant value in policy decision making on how meagre resources should be used in low resource settings where mental health care continues to be provided by psychiatric hospitals set up 100 to 200 years ago.

This paper presents the protocol of SITAR which aims to bridge a critical gap in scientific evidence by studying the impact of reform of psychiatric hospitals on individual patient outcomes. The findings will provide an evidence based package of reforms for psychiatric hospitals in transition in low and middle-income countries.

For peer review only

## METHODS AND ANALYSIS

### Study Design And Management

The study is a pragmatic parallel arm single blind randomised control trial at a single site, the Regional Mental Hospital Nagpur (RMHN). The mental hospital in Nagpur was started in 1864. The hospital has a capacity of 940 beds with an average occupancy of 600 patients at any given time.

Recruitment of patients for the study was initiated after completion of permissions, ethics approval and trial registry. We will continue recruitment till adequate sample size (85 in each arm) is reached. This is a changing population with a constant process of admission and discharge to the hospital. We assume a six months' time frame to complete full recruitment from the start of intervention.

The in-patient population of the hospital will be compiled on a database, mapping socio-demographic variables, history of illness and history of treatment as baseline data. Patients fitting the inclusion criteria will be identified and randomly assigned to the intervention and control arms of the study. Recruitment will be continued till desired numbers are reached. The intervention will be carried out for a six-month period. Post measures on all patients who have undergone pre-measures will be undertaken at completion of intervention (at six months) and at two follow-up intervals post intervention of nine months and 12 months (3 and 6 months after completion of intervention). The SITAR study design is presented graphically in figure 2.

Several steps are proposed to ensure *quality control and minimize the risk of bias*.

1. Use of a standard case management intervention (intervention manual developed for the study)
2. Randomization of the sample to intervention and care as usual arms of the study.
3. Outcome measurements will be undertaken by researchers independent of the case managers delivering the intervention. Inter-rater reliability for the researchers will be computed. The statistician drawing the randomization tables will be blinded to the allocation of the groups
4. Each case manager will be supervised at least once every month on at least 20% of the cases undertaken by them. Joint monthly meetings of all case managers will be held for case reviews and sharing of experiences and discussion on overcoming barriers.
5. The primary supervisor will conduct a site visit and meet the case managers to assess fidelity of intervention.

Given the nature of the setting, there is a risk of contamination across arms especially since the hospital staff providing care in both arms are the same. We believe this is a minimal possibility given the meagerness of engagement of hospital staff with the patients.

SITAR is part of the work done by the first author in fulfilment of the PhD program at the University of Warwick. The study will be coordinated by the UDAAN office located at RMHN. The study is managed by the PI with supervision from the supervisors and oversight by the Trial Management Committee (TMC). The TMC comprises of members from the University of Warwick and mental health experts from India.

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**Participant Eligibility And Recruitment**

In-patients at baseline will comprise all service users admitted to RMHN. Patients meeting the inclusion criteria for the study will be randomized to the two arms of the study. Service users will be eligible if they have a primary diagnosis of psychosis (schizophrenia, bipolar affective disorders and psychosis NOS) based on diagnosis given in their case files, a continued length of hospital stay between 12 to 120 months and are over the age of 18 years. Service users will be excluded from the study if they are over the age of 60 years, have a neuro-developmental disorder such as epilepsy, an intellectual disability or are service users in acute and forensic wards.

**Sample Size**

For the study to be powered at the 90% level with 5% significance level, the required sample is 170 people, 85 in each arm. Assuming a 15% drop out we aim to recruit 100 people in each arm of the study. For the power calculation, the estimated sample size allows us to detect a minimum clinical difference of 10 points in the primary outcome (WHODAS) at 6 months with a standard deviation of 20. This equates to a moderate effect size of 0.5. (18) The parameter estimates to inform the sample size were drawn from an Indian study based in the community with non-intensive case management using the WHODAS score as the primary outcome measure. (19) People with psychosis in institutional set-ups might have higher disability levels as compared to people living in the community, however most people in LMICs continue to remain in institutions due to the absence of viable pathways of community reintegration. The intervention being offered is intensive with longer case management time than what would be feasible in a dispersed community setting.

**Informed Consent**

The treating psychiatrist will assess the service users’ ability to participate in the study as well as ability to consent. The psychiatrist will provide consent for those patients unable to give consent but deemed appropriate for the intervention. This is especially important in the case of this intervention since it is a ‘need based’ psychosocial intervention. Based on inability to consent, patients who may need the intervention most might actually be left out of the study. The consent by the treating psychiatrist will ensure equitable inclusion. Additionally, the ward in charge also signs off on the consent. The study will be explained pictorially to the service user with the aid of a specially designed flip chart. Signatures and or thumb impressions will be taken on simple consent forms drawn up in Hindi and Marathi. Service users will be assured that their refusal to participate / consent to the study will have no impact on the care they receive.

**Randomization**

The study will use a computer generated permuted block randomization schedule for the allocation of recruited subjects to the two study arms. The researcher will create a list of service users meeting the inclusion criteria and consenting to the study and give them a unique ID number. This list will be handed over to the statistician who is independent to the research team. Random allocation of eligible study subjects to two study arms (A and B) will be done by the statistician using ralloc software (version 3.7.6) available in STATA (version 10.1, 2011) module.

**Intervention**

The Needs based Intensive case management (NB-ICM) for people living with SMD is based on a psychosocial rehabilitation model that takes a holistic approach to improving quality of life, reducing disability, improving role function, promoting independence and autonomy based on a

hope for the future. It is a mix of working on individual competencies in the context of real everyday experiences and introducing environmental change propelled by individual choice.(20-27)

Trained case managers will deliver the intervention through a clinical and intensive case management approach that taps into a functional network of a spectrum of services being created at the hospital level through the reform process.

The case managers are trained on a specially designed training module that comprises content around severe mental illness and intensive case management with a focus on the needs of people with high disabilities in psychiatric institutions. The 60-hour training module was delivered through seven days of offsite training for the purpose of this study.

The intervention components comprise 1) accommodation, safety and food (this is contextualized to the hospital setting where all service users may not have access to clean living spaces and enough food); 2) psychoeducation (about the illness and its symptoms); 3) symptom management; 4) physical health; 5) emotional wellbeing; 6) self-care and other living skills; 7) social relationships; 8) connecting with family; 9) leisure activities; 10) occupational and financial inclusion; and 11) spiritual needs.

The intervention is based on an objective assessment of current needs of the service user and provides a comprehensive package of services to meet the range of individual needs. The case manager works collaboratively with the person in developing a personalized care plan drawing from the larger context of available opportunities within the hospital, created through the ongoing reform process. The care plan adjusts to the patient's cultural context. It draws on the strengths and potential of the individual and is focused on the reduction of personal distress and disability. Care provided through this approach is continuous and consistent for the defined period of the intervention. Case managers have the primary responsibility for planning, coordinating and delivering the care. Each case manager will have a caseload of 12-14 service users and spend at least eight sessions per case per month. The case manager will deliver the intervention face to face either in the ward complex or through calls and home visits in case the person is discharged from hospital as per protocol.

The intervention will aim

- To address unmet needs on symptomatology through appropriate pharmacological management and psychosocial support. It also includes diminishing and eliminating wherever possible the adverse physical and behavioral consequence of symptom management as well as those arising out of prolonged institutionalization.
- To address unmet basic needs of adequate accommodation and food
- To address unmet needs on personal functioning, improving activities of daily living both in terms of skills and access to opportunities
- To address unmet needs of social connectedness, engagement, leisure and social competence through individual competency building and access to environmental opportunities
- To address unmet needs for personal identity and citizenship
- To address the unmet needs of occupational functioning, employment and financial inclusion
- To address the unmet needs of connecting to family and community where feasible

Patients in the control arm will go through the same baseline and follow up measurements as the intervention arm. This group will however not receive the NB-ICM during the trial period, the control arm will continue receiving care as usual, in this case care being provided in a setting

undergoing reform. In most mental hospitals in India care as usual largely comprises biomedical management. (14, 28)

The intervention will be discontinued given the following conditions: 1) If the participant wants to discontinue participation; 2) An acute illness episode that significantly disrupts time in intervention (beyond four weeks); 3) When the participant is discharged from the hospital and community based intervention is not possible either due to distance beyond Nagpur district, unwillingness of participant or family for home based intervention;4) In case of death of a participant.

**Adverse Events- Recording And Reporting**

Given the nature of the study population and the chronicity of the illness certain events are expected. The study protocol classifies these events under ‘adverse events’ and ‘serious adverse events’. Adverse events comprise of a) acute illness (psychosis) episodes as determined by transfer to acute ward; b) episodes of isolation and restraint; c) transfer for medical care outside the psychiatric hospital; d) absconding-from the facility. Serious adverse events comprise e) episode of self-harm and f) death.

To record and report adverse events, we will use the Warwick CTU’s Clinical Trials Standard Operating Procedure 17 part 2 Safety Reporting for Clinical Trials other than those of Investigational Medicinal Products v1.5.

Any adverse event occurring with any participant will be first notified and discussed with the ward in charge. Based on routine hospital care processes, it is the responsibility of the ward in charge to initiate action of either directly providing any care, making a psychiatric referral or making a medical referral. All recorded adverse events will be reported to the core committee and the trial supervisor through monthly reports. These reports will also be submitted to the TMC. Any unexpected adverse event will be reported to Tata Trusts (as the sponsor) along with the India ethics committee, the Central Trial Registry of India as well as the university ethics committee (BSREC) within 15 days of the event.

## Measurements

The study comprises outcome measures and process measures. Other baseline measurements include sociodemographic details, illness history and treatment history.

### *Outcome measures*

Assessment of level of disability will form *the primary outcome for the study*. *WHO Disability Assessment Scale 2.0 (WHODAS 2.0)*, a generic assessment instrument for health and disability that produces standardized disability levels and profiles applicable across cultures and diseases.(29) SITAR will use the simple scoring format sufficient to describe the degree of functional limitation.(29) Three items of WHODAS are not applicable for scoring due to the nature of the setting. These are items 3.4, 4.5 and 6.6. Secondary outcome measures include an assessment of severity of symptoms, assessment of social and occupational functioning and assessment of quality of life. The scales used for these measurements include *The symptom measure- The Clinical Global Improvement Scale (Schizophrenia) (CGI-S)*, a brief, stand-alone assessment of the clinician's view of the patient's global functioning prior to and after initiating a study medication or intervention.(30) The CGI comprises two one-item measures evaluating (a) severity of psychopathology from 1 to 7 and (b) change from the initiation of treatment on a similar seven-point scale.(31) *Social and Occupational Functioning Scale (SOFs)* assesses individual's level of social and occupational functioning and is not directly influenced by the overall severity of the individual's psychological symptoms.(32, 33) *Health related quality of life measure EuroQol-5D (EQ-5D)* is a widely used generic patient reported outcome (PRO) questionnaire designed specifically for cost-utility economic evaluation internationally. The EQ- 5D asks patients to indicate whether they have no, some or extreme problems on each of five dimensions of health: mobility; self-care; usual activities; pain/discomfort, anxiety/depression.(34, 35)

Process (intervention) measurements include the *assessment of need* through a standard form based on Camberwell Assessment of Need (CANSAS).(36) The adaptation draws from prior use of this measure in India through the formative study of needs(37) and need assessment formats used in community setting.(38) This will be carried out by the allocated case managers five times during the study period and will be an indicator of the number of met and unmet needs of the service user at different points during the study. *The Intervention plan*, case managers will draw up a personal care plan collaboratively with the service user and the ward in charge on a monthly basis. Case managers will record the plan on a standard form developed for the intervention and reviewed monthly by the researcher. *The symptoms checklist* has been adapted from ones used in other Indian settings and will record the change in symptoms over the study period and serve as an adjunct to the symptom measure (CGI). The case manager will carry out the measure five times during the study period. *Self-care and other living skills checklist* is adapted to an institutional setting from scales for assessing activities of daily living.(39, 40) Its purpose is to aid the case manager in assessing progress on the intervention plan.

### *Baseline and Follow-up Measurements schedule*

Baseline measurements will be initiated at the start of the study and completed for all in-patients over a three-month period by trained research assistants (RA) who have a Masters' degree in Psychology or Social Work RAs are not involved in the hospital setting, however unmasking is possible and we will record all episodes of unmasking. Inter rater reliability will be established for all the research assistants conducting the measurements.

The intervention will be initiated after completion of the baseline measurements and carried out for a period of six months. At the end of the six-month intervention period, the first outcome measurement will be initiated and completed over a two-month period. The first and second

follow-up outcome measurements will be initiated at three and six months post intervention, respectively, and completed over a two-month period.

The patient sequence will be kept standard for the measurements to ensure uniformity in time between measures. In case of an adverse event where the patient may not be available for measurement as per sequence, accommodation will be made to complete the measure any time during the two-month period of that measurement cycle. In case this is not possible, the patient will be considered as Lost to Follow-up (LFU). Sequence and time frame of measures are summarized in table 1. All patients (except drop-outs as per criteria) will be followed up as per protocol either within the hospital or in the community.

**Table 1 List and time frame for assessments (six months considered from date of first intervention**

			Months												
Assessment	Type	By	0	1	2	3	4	5	6	7	8	9	10	11	12
WHODAS (Disability)	OM	RA	●						●			●			●
SOFS (Social &Occupational functioning)	OM	RA	●						●			●			●
CGI (Symptoms)	OM	RA	●						●			●			●
EQ-5D (Quality of life)	OM	RA	●						●			●			●
Episodes of seclusion & restraint	OM	CM	●	●	●	●	●	●	●	●	●	●	●	●	●
Discharge / adverse events	OM	CM	●	●	●	●	●	●	●	●	●	●	●	●	●
Needs Assessment	PM	CM	●			●			●			●			●
Intervention plan	PM	CM	●	●	●	●	●	●	●						
Symptoms checklist	PM	CM	●			●			●			●			●
Self-care and other living skills checklist	PM	CM	●	●	●	●	●	●	●						
Case management record form	PM	CM	●	●	●	●	●	●	●						
(OM) Outcome Measure (PM) Process Measure (RA) Research Assistant (CM) Case Manager □ intervention time frame															

**Qualitative element of the study**

The qualitative component of the study comprises patient perceptions on the overall reform process and the individual intervention and its felt impact. The SITAR study will use Focus Group Discussions (FGDs) to elicit this. Four FGDs of 8 patients each (16 patients from each study arm) will be conducted in the last quarter of the study period. Since we seek to understand the lived experience of the service user, a phenomenological epistemological perspective is proposed. A basic thematic analysis will be done using NVivo .(41) Verbatim quotes will also be used to highlight findings from quantitative components of the study.

**Data management and analysis**

*Data collection*

Quantitative data will be collected by trained Research Assistants (RAs) using pre-designed; pre-tested tools as included in the protocol. Senior RA will check completeness and accuracy of data gathered on daily basis before electronic data entry.

*Data storage*

The paper data will be stored in secure cabinets, in the PI's cabin at the Tata Trust office in the hospital campus. The office is under CCTV surveillance. The data will be held for ten years post completion of the study.

#### *Data entry and coding*

Data will be coded and entered in an efficient database using MS Excel. Data will be kept confidential and anonymous on password-protected files. The master sheet will be kept separately on MS Excel with password protection. Built-in validity checks will be incorporated in data entry software with flash/warning alerts for incorrect or out of range values.

#### *Data screening, data validation and data editing*

Data will be screened at every stage i.e. pre-randomization, post randomization and closing stage of the trial. This will be done for each and every item of the individual record by student researcher (trial PI). Accuracy of electronic data will be checked through comparison with questionnaire data on a sample basis.

#### *Data analysis*

All results from the trial will be reported according to the Consolidation Standards of Reporting Trials (CONSORT) guideline for randomized controlled trials.<sup>(42)</sup> Descriptive statistics will be presented for participant characteristics and outcomes collected in the trial summarized by treatment arm. Continuous outcomes will be summarized as mean and standard deviation, categorical data will be summarized using frequency and percentage. If data are non-normal, the median and inter-quartile range will be presented.

All of the analyses will be based on the Intention To Treat (ITT) principal where a P value less than 0.05 will be considered as statistically significant. The primary analysis will estimate the treatment effect and 95% confidence interval for the primary outcome (WHODAS) at the 6-month time point using a linear regression model having adjusted for clinically important baseline variables. For all secondary analyses, treatment effects will be estimated using adjusted linear regression models for continuous outcomes and adjusted logistic regression models for binary outcomes. The analyses will be undertaken at each of the follow-up time points (i.e. 6 months, 9 months and 12 months). Where the assumption of normality is not valid, equivalent non-parametric alternatives (e.g. rank-based statistics) will be used.

Every effort will be made to ensure that missing data is kept to a bare minimum in the trial. The level or extent of missingness in data will be assessed at the end of the trial, and if required, additional sensitivity analyses will be undertaken using multiple imputation techniques to impute the missing values.

#### *Data processing*

Data will be processed by the Udaan program at baseline (pre-randomization), during trial (post randomization) and closing stage (outcome assessment). Raw data from the master file will be coded and processed into a data file. The entire data set will be put through an Excel-based double entry process by two independent people. Formula-based comparison of the two sets will be undertaken and discrepancies will be resolved by rechecking with the hard copy of the questionnaire on file. The data file will include both original variables as well as some newly derived variables or transformed variables specific to the study objectives. Statistical Package of Social Sciences (SPSS) will be used for data analysis. The data analyst will be blinded to treatment assignment.

#### *Anonymizing data*

Direct identifiers that allow the identification and communication with an individual participant will be removed. The names of all participants will be replaced with a master list identity (ID) number. The master list containing the ID number will be kept with the PI on a password-protected file, which will be housed in a password, protected firewalled system. The data set for analysis will not include any email address, telephone numbers or home address of patients (where available). Quasi identifiers such as ward numbers will be removed from and variables such as date of admission and date of discharge will be generalized into length of stay.

**PATIENT AND PUBLIC INVOLVEMENT**

Focus Group Discussions (FGDs) are built into the design of the program to incorporate the patient experience of intervention. No patients were involved in the study design.

**COSTING AND POTENTIAL ECONOMIC GAINS OF THE INTERVENTION**

The SITAR study will also include a retrospective bottom-up cost analysis of the individualized intervention in terms of resource or input requirement along with costing of resources for care as usual. Cost elements will include all the resources used in development of the intervention and training material, costs of training, costs of intervention delivery which will include staff time and costs of supervision (people, facilities, equipment and supplies). The costing will be based on actual expenditure incurred through the Udaan program as well as costs components derived through collaboration this will include costs of items received in kind such as clothes, soaps and shampoos and such directly linked to patient care. Actual government spending on patient care will also be done. Costing will be appropriately apportioned to the SITAR study in terms of time allocation of staff based on an analysis of case management records. Given the scope of the study, costs will primarily be presented alongside measures of benefit listed in table one in the form of a cost-consequence analysis. (43) A secondary cost-effectiveness analysis will additionally be performed in which the trial primary outcome will be the measure of effectiveness. (44)

**Ethical Approval and Dissemination**

Ethical approval for SITAR has been obtained from a registered ethics committee in India (Institutional Ethics Committee VikasAnvesh Foundation, VAF/2018-19/012 dated 6/12/2018) and the University of Warwick’s Biomedical and Scientific Research Ethics Committee (REGO-2019-2332, dated 21 March 2019), and registered on the Central Trial Registry of India (CTRI/2019/01/017267).

Findings of the study will be presented through scientific publications as well as through a national level dissemination in India along with presentations in different conferences. We also intend to do a policy paper recommending a feasible reform process for psychiatric hospitals in India. Trial results will be published in accordance to CONSORT guidelines.

**CURRENT TRIAL STATUS**

Recruitment of patients was initiated in April 2019. Recruitment was closed in December 2019. The final patient recruited will reach end-point follow-up in December 2020.

**AUTHOR CONTRIBUTIONS**

Tasneem Raja- Principal Investigator, design and implementation of the trial. Wrote first draft of protocol paper.

Helena Tuomainen- Supported the design, protocol development, ethics application and continued supervision, review and editing of manuscript

Jason Madan- Supported the design of economic elements of the protocol.

Dipesh Mistry Supported the development of the data recording and analysis plan

Sanjeev Jain- reviewed and edited the manuscript.

Swaran Singh- primary supervisor on the trial, supported the design, protocol development, ethics application for India and UK, Trial registry, ongoing supervision on the trial.

All Co-authors accepted the final version of the paper.

## **FUNDING STATEMENT**

This work is supported by Tata Education and Development Trust (TEDT) (DI Regional mental hospital Nagpur, circular number 130) and R G Manudhane Foundation for Excellence (MoU with TEDT dated 10<sup>th</sup> Aug 2016).

## **COMPETING INTERESTS STATEMENT**

This trial is part of the PhD program undertaken by the PI Tasneem Raja. She is an employee of the Tata Trusts and the Tata Trusts External Individual educational grants program funds the PhD won on basis of merit.

## **DATA SHARING STATEMENT**

Analyzed data will be shared with the co-authors of the study through a password-protected process. The password for the file will be shared through a phone call made for this purpose. No personal or primary data will be shared. The completely anonymized data set will be made available on request, with due permissions, in keeping with Indian legislation, once primary data analysis is published.

## **Legends**

Figure 1. Graphic representation of Udaan and SITAR

Figure 2. Graphic representation of SITAR

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For peer review only

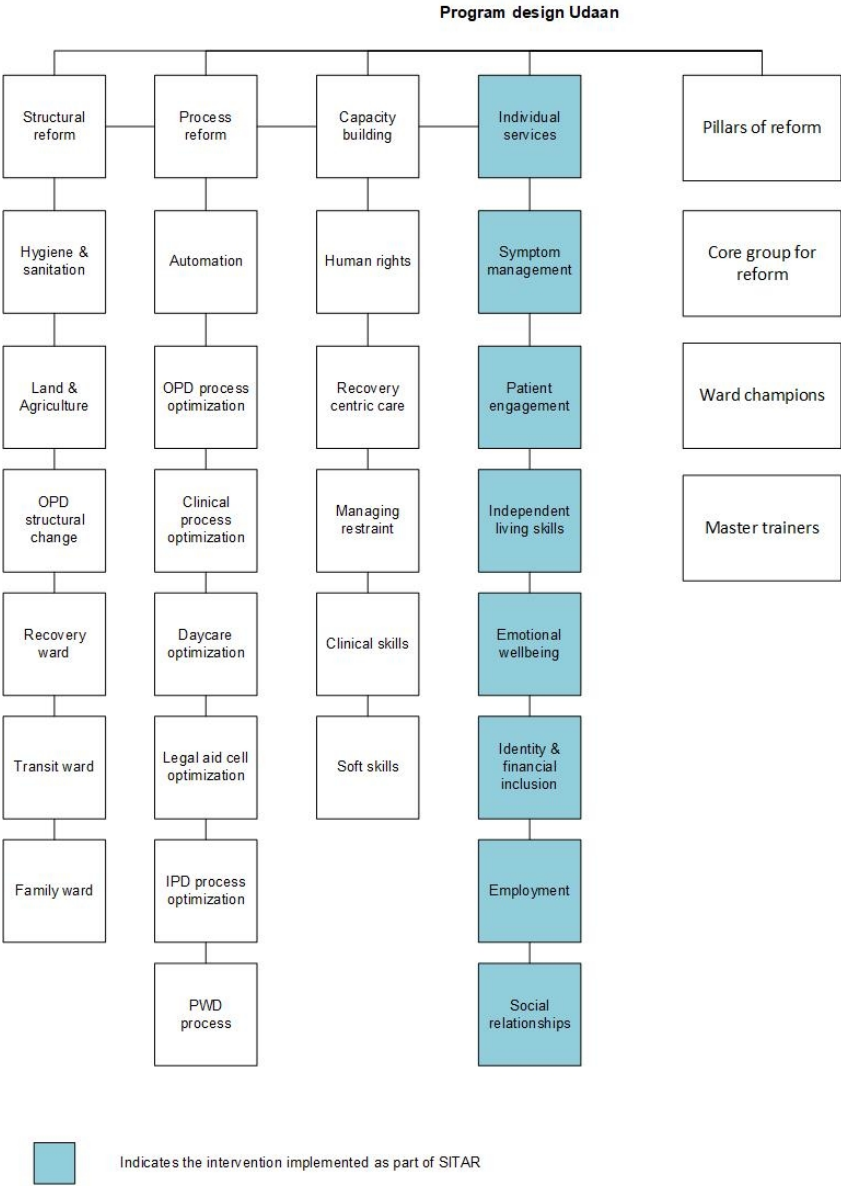


Figure 1 Graphic representation of Udaan and SITAR

72x92mm (300 x 300 DPI)

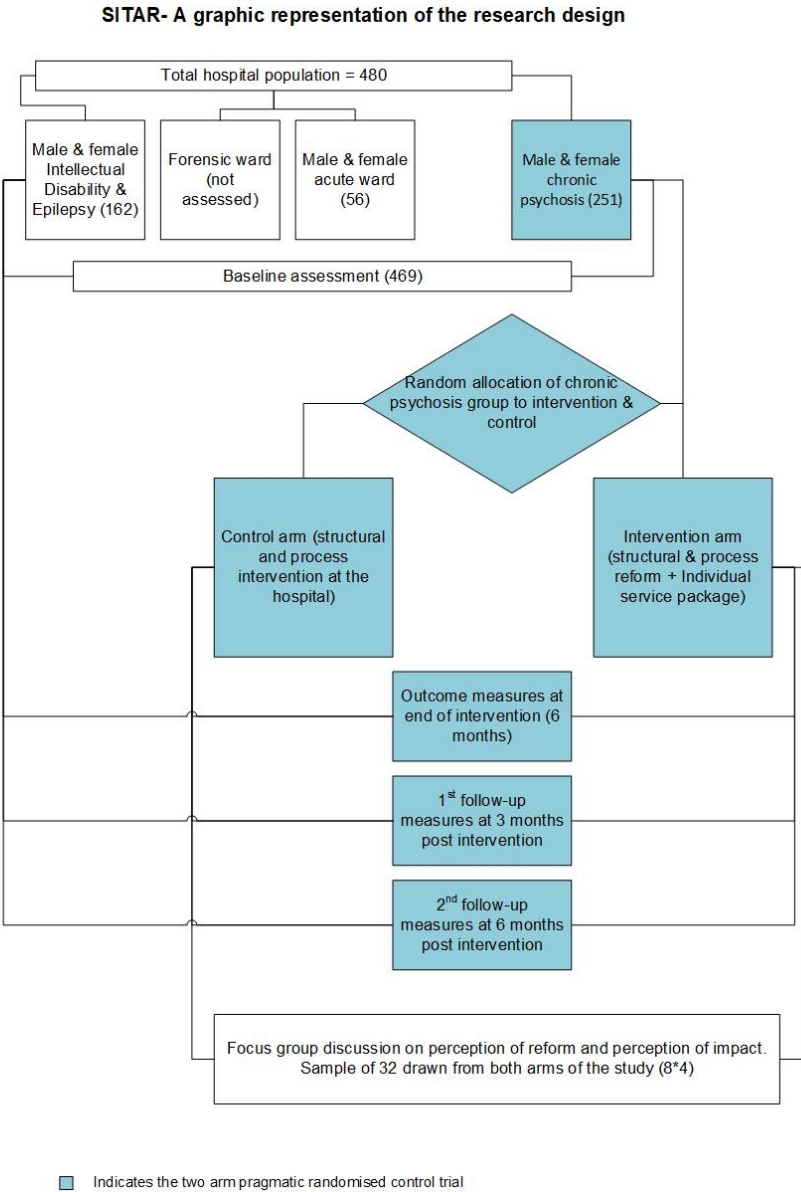


Figure 2 Graphic representation of SITAR  
81x102mm (300 x 300 DPI)

## SPIRIT PROTOCOL FOR SITAR

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

Section/item	Item No	Description
<b>Administrative information</b>		
Title	1	Psychiatric Hospital Reform in Low and Middle-income Countries Structured Individualized Intervention and Recovery – SITAR Trial Acronym – SITAR (Pg 1)
Trial registration	2a	Central Trial Registry (CTR – ICMR) (CTRI/2019/01/017267).
	2b	All items from the World Health Organization Trial Registration Data Set included below the complete SPIRIT protocol
Protocol version	3	Version – 2 <i>31<sup>st</sup> Dec 2018</i>
Funding	4	Tata Trusts
Roles and responsibilities	5a	Tasneem Raja
	5b	Tata Trusts World Trade Centre -1, 26 <sup>th</sup> Floor, Cuffe Parade, Mumbai – 400 005 Tel: +91 - 22 - 6665 8282

5c *Funder-* (pq 15)

- *MoU with the Government of Maharashtra for the Psychiatric hospital reform (Tata Trusts)*
- *Part funding of the program with other donors (R.G Marudhane Motivation for Excellence Foundation and part funding by the Government of Maharashtra)*
- *The Donors do not have a direct say in the design, data analysis and interpretation / publication of the study findings*

5d Overall steering committee for Udaan is as per the MoU and is formed by the Government of Maharashtra

*Coordinating center- Udaan office located on site*

*Data collection- A team of research assistants hired for the purpose and supervised directly by the PI*

*Data management- PI along with M&E manager and senior research assistant to ensure quality check on collection and entry of data.*

*Supervisors- Professor Swaran Preet Singh, Professor Jason Madan and Dr Helena Tuomainen from University of Warwick & Dr Sanjeev Jain from NIMHANS India- will oversee the design and execution of the trial. (Pg12-14)*

## Introduction

(pg 3 to 6)

Background and 6a  
rationale

SITAR aims to bridge a critical gap in scientific evidence by studying the impact of reform of psychiatric hospitals on individual patient outcomes. It will offer an evidence based package of reforms for psychiatric hospitals in transition in low and middle-income countries.

The SITAR study is embedded within a larger program called **Udaan**. Udaan is a collaboration of the Tata Trusts (a leading philanthropic foundation in India) with the Government of Maharashtra. The goal of Udaan is to develop the Regional Mental Hospital Nagpur (RMHN) into a center of excellence through a series of structural and process reforms. This is intended as a model that will inform policy change for transition of other psychiatric hospitals in the state of Maharashtra and India.

The key research question is: Do individual recovery plans\* improve patient outcomes, \*\* amongst long stay inpatients\*\*\*, in comparison to care as usual\*\*\*\* in a psychiatric hospital undergoing reform in a low and middle-income country?

\*Individual recovery plan- A structured individual recovery plan based on individual needs assessment

\*\*Patient outcomes refer to change in symptoms of illness, disability levels, social and occupational functioning and quality of life.

\*\*\*Long stay patients- Patients having a continuous period of stay between 12 months and up to 10 years in the Nagpur Regional Mental Hospital in India.

\*\*\*\*Care as usual- For the purpose of this study, care as usual, refers to the structural and process reform in the hospital with a view to modernizing it. This does not include individual recovery plans for patients.

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6b Explanation for choice of comparators

The study compares patient outcomes with care as usual in a psychiatric hospital in India undergoing reform to those with an addition of needs based intensive case management.

The premise of this comparison is that Needs based intensive case management, used in most high resource countries, is a resource intensive intervention. In such a scenario, can individual patient outcomes be modified significantly with larger structural and process reforms in old psychiatric hospitals to meet the needs of current day service users? This comparison has significant value in policy decision making on how meagre resources should be used in low resource settings where mental health care is predominantly provided by psychiatric hospitals set up 100 to 200 years ago.

Objectives  
Hypothesis

& 7

The objectives of SITAR are: (Pg 3-4)  
To determine the effectiveness of structural and process reform of psychiatric institutions on patient level outcomes for in-patients of the hospital.

- a. To compare the effectiveness of structural and process reform with and without an individually tailored recovery plan on patient level outcomes of disability (primary Outcome), symptom severity, social and occupational functioning and quality of life for the long stay patient cohort of the hospital
- b. To determine the costing of implementing an individually tailored recovery plan for long stay individuals in psychiatric hospitals

Primary hypothesis- there is no difference in WHODAS (disability levels) scores between study participants receiving the individual (active) intervention and those receiving usual care (control arm).  
Secondary hypothesis- there is no difference in disability outcomes before and after structural and process reform and individual treatment for in-patient service users of the hospital.

Trial design  
(pg 7 & 8)

8 SITAR is a real world implementation study. The trial design is a pragmatic two arm RCT as it is not pragmatically possible to create the ideal study situation of a Randomized Control Trial. The entire in-patient population of the hospital is compiled on a database, for the purpose of this study, mapping socio-demographic variables, history of illness and history of treatment as baseline data (No electronic database of this nature existed prior to this).

The hospital population is divided into four major units, comprising the intellectual disabilities and epilepsy patients' ward forensic ward, acute care ward and the chronic psychosis wards.

Patients fitting the inclusion criteria for the long stay patient cohort (chronic psychosis wards) will be compiled from the larger dataset and randomly assigned to the intervention and control groups.

Intervention – Intensive needs based case management will be carried out for a six-month period. Post measures on all patients who have undergone pre measures will be compiled at completion of intervention (at six months) and at two follow-up intervals post intervention of nine months and 12 months (3 and 6 months after completion of intervention).

The researcher will track fidelity indicators for the intervention as well as process indicators. Loss of sample and the reasons for that will be documented.

The trial also has a qualitative component which brings in the experience of the user and their perception of reform and or intensive case management. This will be done by the researcher through Focused Group Discussions (FGDs) in the last quarter of the one-year study period. People from both arms of the study will be included for this component.

Several steps are proposed to ensure quality control and minimize the risk of bias.

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1. Standardizing the intervention program through an intervention manual comprising of all the intervention protocols. The intervention manual is presented as appendix.
  2. Development of a standard training manual for training of all case managers delivering the individual intervention. The training manual is included in the appendix.
  3. Randomization of the sample to intervention and care as usual arms of the study.
  4. Blinding will be done at two levels. Outcome measurements will be undertaken by researchers independent of the case managers delivering the intervention. Inter-rater reliability for the researchers will be computed. The statistician drawing the randomization tables will be blinded to the allocation of the groups.
- This being a real world setting, it is not possible to mask the case managers to the group allocation. Though the researchers and case managers are independent, masking may not be completely feasible due to the nature of the setting. Episodes of unmasking will be recorded.

Methods: Participants, interventions, and outcomes (Pg 7 to 12)

Study setting	9	Regional Mental Hospital, Nagpur. Country – India. This is a psychiatric hospital set up in 1884 and a major care provider in the central region of India.
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## Eligibility criteria 10

Key Inclusion	Exclusion Criteria
A primary diagnosis of psychosis**	Service users over the age of 60 years*
Continuous length of stay in the hospital $\geq 12$ to 120 months	Service users with neuro-developmental disorders such as epilepsy**
Over the age of 18 years	Service users with Intellectual Disability**
	Service users in Acute Wards***
	Service users in forensic wards****

\*Older people with a longer duration of stay in institutions are not likely to benefit greatly from intensive intervention.

\*\*Based on diagnosis given in case files of the hospital

\*\*\*Service users in acute wards are acutely ill and unable to participate effectively

\*\*\*\*Legal access issues in Forensic ward

The individual needs based intervention will be provided by case managers trained to deliver a standard intervention for the study through the standard training manual of the study.

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- Interventions  
  
(Pg 8-9)
- 11a

This intervention package is based on the premise of contemporary understanding of psychosocial rehabilitation that takes a holistic approach to improving quality of life for a person living with mental illness, reducing disability, improving role function, promoting independence and autonomy based on a hope for the future. Trained case managers will deliver the intervention through a clinical and intensive case management approach that taps in to a functional network of a spectrum of services being created at the hospital level through the reform process. Case managers will draw up a personal care plan collaboratively with the service user and in discussion with the ward in charge, and checked and revised on a monthly basis. Case managers will record the plan on a standard form developed for the intervention and reviewed monthly by the researcher. Each case manager will have a case load of 12-14 service users and will spend at least 8 sessions per case per month of at least 60 minutes each.
- 11b

Intervention will be discontinued under the following circumstances-

  - If the participant wants to discontinue participation
  - An acute illness episode that significantly disrupts time in intervention (beyond four weeks)
  - When the participant is discharged from the hospital and community based intervention is not possible either due to distance beyond Nagpur district, unwillingness of participant or family for home based intervention.
  - In case of death of a participant



11c This is a psycho-social rehabilitation intervention and as such does not involve intervention adherence. One component of the intervention is symptom management. Adherence to medication within this component will be managed in the following manner

- Medication administered under observation while the participant is in hospital
- Psychoeducation on importance of medication to participant and family (where available)
- Addressing side effects in discussion with psychiatrists
- Ensuring medication stock availability when participant is discharged from hospital

11d Relevant concomitant care and interventions that are permitted or prohibited during the trial

All routine interventions available in the hospital (in this case a hospital undergoing structural and process reform) will be available to the participant as concomitant intervention.

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Outcomes  (Pg 11-12)	12	<p>The outcome measures comprise assessment of disability levels, symptom measure, assessment of social and occupation functioning and assessment of quality of life. These four measures are described in detail below-</p> <p>The primary measure is disability levels</p> <p><b>Disability Measure- WHO Disability Assessment Scale 2.0 (WHODAS 2.0)</b> (primary outcome) is a generic assessment instrument for health and disability and produces standardized disability levels and profiles and is applicable across cultures, in all adult populations and is used across all diseases, including mental, neurological and addictive disorders. SITAR will use the simple scoring format, which is the recommended one for a busy clinical setting and constitutes a statistic that is sufficient to describe the degree of functional limitation.</p> <p><b>Symptom measure- The Clinical Global Improvement Scale (CGI)</b> is a brief, stand-alone assessment of the clinician's view of the patient's global functioning prior to and after initiating a study medication or intervention (Haro <i>et al.</i>, 2003). The CGI comprises two one-item measures evaluating (a) severity of psychopathology from 1 to 7 and (b) change from the initiation of</p> <p>treatment on a similar seven-point scale.(JOAN BUSNER &amp; and STEVEN D. TARGUM, July 2007)</p> <p><b>Social and Occupational Functioning Scale (SOFS)</b></p> <p>The SOFS focuses exclusively on the individual's level of social and occupational functioning and is not directly influenced by the overall severity of the individual's psychological symptoms (Morosini <i>et al.</i>, 2000). In study it will used to rate functionality over a three month period.</p> <p><b>Health related quality of life measure EuroQol-5D (EQ-5D)</b> is a</p> <p>The EQ-5D is the most widely used generic Patient reported outcome (PRO) questionnaire internationally. The EQ- 5D asks patients to indicate whether they have no, some or extreme problems on each of five dimensions of health: mobility; self-care; usual activities; pain/discomfort, anxiety/depression</p>
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## Episodes of seclusion and restraint

For the purpose of this study, seclusion and restraint are defined as follows:-

Seclusion means the placement and retention of an inpatient service user in a bare room in order to contain a clinical situation that may result in a state of emergency.

Physical restraint refers to the manual holding and restriction of the service user by staff or under their instruction.

Mechanical restraint refers to the use of belts, handcuffs and the like, which restrict the service user's movements or totally prevent the person from moving.

These episodes will be recorded as they occur on the case manager's record form included in (Appendix 5.2.6).

Process/ intervention measures include the following-

- Assessment of need
- The intervention plan
- Symptoms checklist
- Self-care and other living skills checklist

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Participant 13  
timeline (PG 14-15)

We aim to recruit 100 participants in each arm of the trial. Recruitment will continue up to the point we achieve the number based on inclusion and exclusion criteria of the protocol. Intervention time frame will start as soon as a participant is recruited since this is an individual intervention. We anticipate a two month time frame in completion of recruitment from the time of initiation. This means intervention will run maximum for a period of 8 months to complete the intervention time frame of six month for those recruited last.

Time line of the trial														
Time (Months)	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Enrolment														
Eligibility screen														
Informed consent														
Baseline assessment														
Allocation														
Intervention														
Outcome measurement														
1st Follow-up measure														
2nd Follow-up measure														
Month 1 starts post ethics approval														

Sample size	14	Study population – 469
(pg 8)		<p>Sample will be in-patient service user population of the hospital (600 <math>\pm</math>50 <i>n</i>) excluding the in-patients of the forensic ward and acute ward. This brings the study population to about 515. Service users meeting the inclusion criteria for the study will be randomized on a 1: 1 basis to the two arms of the study post informed consent. For the study to be powered at the 90% level with 5% significance level, the required sample is 170 people, 85 in each arm. Assuming a 15% drop out we aim to recruit 100 people in each arm of the study. For the power calculation, we have assumed a moderate effect size of 0.5. With a minimum clinical difference of a score of 10 points with a <math>\sigma</math> of 20.</p> <p>The effect size and variance was drawn from an Indian study based in the community with non-intensive case management using WHODAS scores as primary outcome measures (Murthy <i>et al.</i>, 2005).</p> <p>People with psychosis in institutional set-ups might have higher disability levels as compared to people living in the community, however most people in LMICs continue to remain in institutions due to the absence of viable pathways of community reintegration. The intervention being offered is intensive with longer case management time than what would be feasible in a dispersed community setting. This forms the basis for assuming a moderate effect size.</p>
Recruitment	15	<p>The sample will be recruited from the hospital's in-patient service user population based on the inclusion and exclusion criteria. The sample recruitment will be continued until such time the required numbers are fulfilled. Almost 58% of service users are under 1 year of stay at the RMHN with the median length of stay being 15 months. Service users who have crossed the 1-year mark will be put through the recruitment and randomization process as per the study protocol.</p> <p>If a service user is discharged from the hospital during the study period, the case manager will continue to provide intervention as per protocol in the service users' setting to the extent feasible. Dropouts and reasons for lack of end measures will be captured.</p>
(Pg 8)		

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**Methods: Assignment of interventions (for controlled trials) (Pg 8)**

Allocation:

Sequence generation	16a	The study will use a computer generated permuted block randomization schedule
Allocation concealment mechanism	16b	The researcher will create a list of service users meeting the inclusion criteria and consenting to the study and give them a unique ID number. This list will be handed over to the statistician who is independent to the research team
Implementation	16c	. Random allocation of eligible study subjects to two study arms (A and B) will be done by the statistician using ralloc software (version 3.7.6) available in STATA (version 10.1, 2011) module.
Blinding (masking)	17a	Statistician drawing the randomization tables will be blinded to the allocation of the groups and Case Managers delivering the intervention will be blinded to the baseline and outcome measurements.
	17b	Un-blinding post intervention, at the time of the three outcome measures may occur with research assistants conducting measurements. These instances will be recorded and reported.

**Methods: Data collection, management, and analysis (Pg 12-14)**



# Data collection 18a methods

Baseline measurements will be initiated at the start of the study and will be completed for the entire in-patient population over a three-month period. Research assistants trained in using all instruments will carry out assessments.

The intervention will be initiated after completion of the baseline measurements and carried out for a period of six months based on structured protocols. At the end of the six-month intervention period, the first outcome measurement will be initiated and completed over a two-month period. The first and second follow-up outcome measurements will be initiated at three and six months post intervention, respectively, and completed over a two-month period.

All the four outcome measures will be done using standardised instruments as described in the protocol.

Table 4-3 List and time frame for assessments

Assessment	Type	By	0	1	2	3	4	5	6	7	8	9	10	11	12
WHODAS (Disability)	OM	RA	•						•			•			•
SOFs (Social & Occupational functioning)	OM	RA	•						•			•			•
CGI (Symptoms)	OM	RA	•						•			•			•
EQ-5D (Quality of life)	OM	RA	•						•			•			•
Episodes of seclusion & restraint	OM	CM	•	•	•	•	•	•	•	•	•	•	•	•	•
Discharge / adverse events	OM	CM	•	•	•	•	•	•	•	•	•	•	•	•	•
Needs Assessment	PM	CM	•			•			•			•			•
Intervention plan	PM	CM	•	•	•	•	•	•	•						
Symptoms checklist	PM	CM	•			•						•			•
Self-care and other living skills checklist	PM	CM	•	•	•	•	•	•	•						
Case management record form	PM	CM	•	•	•	•	•	•	•						

(OM) Outcome Measure (PM) Process Measure (RA) Research Assistant (CM) Case Manager

*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*

- 18b In the case of an adverse event where the patient may not be available for measurement as per sequence, accommodation will be made to complete the measure any time during the two-month period of that measurement cycle. In case this is not possible, the patient will be considered as Lost to Follow-up (LFU).

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Data management

19      Questionnaire data will be collected using paper pencil formats; hand scored, and entered on computer. Quality checks will be done on 20% of the data randomly. Focus group notes and recordings will be transcribed in English as Word files. The Excel Word and SPSS files will be stored on password-protected computers and hosted on secure servers.

Physical data files will be stored in a secure place in locked filing cabinets within the Tata Trusts office. Only the researcher, study statistician and the supervisors will access baseline, outcome measurement and focus group data. Data will be shared with supervisors at the University of Warwick using standard good practice. Password protected data files will be sent over email and the password sent in a separate email. The shared data files will be completely anonymized

review only

## Statistical methods

20a Data analysis will mainly focus on assessing between-the-group differences in effectiveness of interventions, and thereafter finding associations between the outcome and a set of predictors or explanatory variables of the respondents.

The researcher will use descriptive statistics like Mean/Standard Deviation, or Median/Quartile Deviation depending on the distribution of data for describing variables such as scores and other measures while frequency and proportions or percentages will summarize count data.

Inferential statistics: 95% Confidence Intervals will be obtained for all the descriptive measures, especially for efficacy parameters.

Between-the-group differences in means of two groups (Study versus Control) will be tested by independent samples t-test assuming equal variance. Relevant covariates such as gender and age will be adjusted for using linear regression.

Within-the-group differences in means (Baseline to End line) will be tested with Paired t-test for each group separately.

Difference in proportions in two independent groups (Study versus Control) will be tested by Pearson's Chi-square test, while within-the group (before-after) comparisons will be assessed by Mc Nemar's Chi square test.

20b *Additional analysis may be focused on age group based sub grouping and gender based sub grouping of findings.*

20c In a scenario where in the assumption of normality is not valid, equivalent non-parametric alternatives (e.g. Rank-based statistics) shall be used especially for score data. The study will consider a P value less than 0.05 as significant for all variables.

## Methods: Monitoring

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Data monitoring (Pg 10)	21a	<p>Adverse events are defined in the protocol and are not considered an outcome or related to the trial but as events that occur whilst the trial is on. This is specifically so given that this is a psychosocial rehabilitation intervention. Adverse events will be recorded and reported.</p> <p>Harm arising out of the intervention to key stakeholders has been considered along with mitigation strategies and is part of the protocol.</p> <p>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</p>
	21b	<p>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- NA</p>
Harms	22	<p>Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct- included in 21a</p>
Auditing	23	<p>Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor- through the process of supervision</p>
Ethics and dissemination		

Research ethics approval (Pg 14)	24	<p><i>The following has been done</i></p> <ul style="list-style-type: none"> <li>• <i>Memorandum of understanding between Tata Trusts and Government of Maharashtra to undertake a reform program of which the individual intervention (under study) is a part (completed).</i></li> <li>• <i>Permission sought from Hospital administration to initiate the individual intervention package, baseline and outcome measures as defined in the protocol (completed).</i></li> <li>• <i>Ethics clearance sought from a registered ethics committee in India</i></li> <li>• <i>Ethics clearance sought from the University of Warwick ethics committee.</i></li> <li>• <i>Trial registry on the Central Trials Registry of India</i></li> </ul>
Protocol amendments	25	<i>Any modification in protocol will be informed in writing along with reasons to all the parties involved in permission and ethics clearance as stated in section 24 of SPIRIT protocol.</i>
Consent or assent (Pg 8)	26a	<p><i>The PI will obtain all informed consent using the pictorial information sheet and set of cards attached with the protocol.</i></p> <p><i>Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)</i></p>
	26b	<i>Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable</i>
Confidentiality (Pg 12- 14)	27	<p><i>Data will be collected in hard copies which will be stored in locked cabinets in the Tata Trusts office. The data will be entered into excel sheets which will be password protected on password protected computes. All data will be anonymised before sharing with the supervisor at University of Warwick. The file sent over email will be password protected and password will be shared in a separate email. A similar process will be used with the statistician analysing the data. These are the only two entities with whom data will be shared.</i></p>

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Declaration of interests	28	<i>The PI is an employee of the Tata Trusts. Tata Trusts is a non-sectarian philanthropic organization based in India. It is also one of the funders of the Udaan program within which this PhD study is nested.</i>
(Pg 15)		
Access to data	29	<i>The PI, statistician and university supervisor will have access to the data</i>
(Pg 14)		
Ancillary and post-trial care	30	<i>This being a psychosocial intervention study, continuing services is an important consideration. Tata Trusts will train the Government hospital staff in case management based psychosocial intervention with the training material developed for this study.</i>
Dissemination policy	31a	<i>The following modalities will be used for dissemination of results-</i> <ul style="list-style-type: none"><li><i>• Part of the yearly process dissemination of the larger Udaan program</i></li><li><i>• Scientific publications as part of the PhD</i></li><li><i>• PhD thesis made available in the public domain</i></li><li><i>• Policy brief for the Government based on the findings of the study</i></li><li><i>• Tool kit of the final tools and manuals used for the study made available in the public domain</i></li></ul>
(Pg 14)		
	31b	<i>Primary authorship will be with the PI. Supervisors will be invited to be co-authors on all publications. No professional writers will be used.</i>
	31c	<i>NA</i>
Appendices		
Informed consent materials	32	<i>Informed Consent and Participant Information Sheet in pictorial format enclosed with the protocol.</i>  <i>Model consent form and other related documentation given to participants and authorised surrogates</i>

Biological  
specimens

33 NA

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## PSYCHIATRIC HOSPITAL REFORM IN LOW AND MIDDLE INCOME COUNTRIES STRUCTURED INDIVIDUALIZED INTERVENTION AND RECOVERY (SITAR); A TWO ARM PRAGMATIC RANDOMIZED CONTROL TRIAL-STUDY PROTOCOL.

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**PSYCHIATRIC HOSPITAL REFORM IN LOW AND MIDDLE INCOME COUNTRIES  
STRUCTURED INDIVIDUALIZED INTERVENTION AND RECOVERY (SITAR); A TWO ARM  
PRAGMATIC RANDOMIZED CONTROL TRIAL-STUDY PROTOCOL.**

**Tasneem Raja, Helena Tuomainen, Jason Madan, Dipesh Mistry, Sanjeev Jain, Swaran P  
Singh**

**Corresponding author**

Tasneem Raja,  
Tata Trusts (Udaan) office, Behind OPD Building, Regional Mental Hospital, Nelson Square,  
Chindwara Road, Nagpur 440013 Email [T.Raja@warwick.ac.uk](mailto:T.Raja@warwick.ac.uk) / [traja@tatatrusters.org](mailto:traja@tatatrusters.org) Mobile-  
+91 7506091860 ORCID ID [0000-0002-5821-8673](https://orcid.org/0000-0002-5821-8673)

Dr Helena Tuomainen, Senior Research Fellow, Mental Health and Wellbeing, Warwick Medical  
School, University of Warwick, UK, T: +44 (0)24 765 28205 [helena.tuomainen@warwick.ac.uk](mailto:helena.tuomainen@warwick.ac.uk)  
[ORCID: 0000-0003-1636-8187](https://orcid.org/0000-0003-1636-8187)

Jason Madan  
Professor in Health Economics | Director of Graduate Research Studies  
Centre for Health Economics at Warwick  
Warwick Medical School, University of Warwick ORCID ID 0000-0003-4316-1480

Dr Dipesh Mistry  
Senior Research Fellow Statistician, Warwick Clinical Trials Unit, University of Warwick ORCID  
0000-0002-0875-9260

Prof. Sanjeev Jain DPM,MD, Molecular Genetics Laboratory  
Department of Psychiatry, National Institute of Mental Health and Neurosciences, Hosur Road  
Bangalore 560029, INDIA tel: \*\*91 80 26 99 52 62/63, fax: \*\* 91 80 26 56 48 30,  
email: [sjain.nimhans@nic.in](mailto:sjain.nimhans@nic.in); / [sjain.nimhans@gmail.com](mailto:sjain.nimhans@gmail.com)

Professor Swaran P Singh MBBS, MD, DM, FRCPsych  
Director, Centre for Mental Health and Wellbeing Research  
University of Warwick ORCID ID 0000-0003-3454-2089

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**ABSTRACT**

Introduction

Low and middle-income settings like India have large treatment gaps in mental health care. People with Severe Mental Disorders face impediments to their clinical and functional recovery, and have large unmet needs. The infrastructure and standards of care are poor in colonial-period mental hospitals, with no clear pathways to discharge and successfully integrate recovered individuals into the community. Our aim is to study the impact of psychiatric hospital reform on individual patient outcomes in a mental hospital in India.

Methods and analysis

Structured Individualized Intervention and Recovery (SITAR) is a two-arm pragmatic randomized control trial, focusing on patients aged 18 to 60 years with a hospital stay of 12 to 120 months and a primary diagnosis of psychosis. It tests the effectiveness of structural and process reform with and without an individually tailored recovery plan on patient outcomes of disability (primary outcome WHODAS), symptom severity, social and occupational functioning and quality of life. A computer generated permuted block randomization schedule will allocate recruited subjects to the two study arms. We aim to recruit 100 people into each trial arm. Baseline and outcome measures will be undertaken by trained researchers independent to the case managers providing the individual intervention. A health economic analysis will determine the costing of implementing the individually tailored recovery plan.

Ethics and dissemination

The study will provide answers to important questions around the nature and process of reforms in institutional care that promote recovery while being cognizant of protecting human rights, and dignity. Ethical approval for SITAR was obtained from a registered ethics committee in India (Institutional Ethics Committee VikasAnvesh Foundation, VAF/2018-19/012 dated 6/12/2018) and the University of Warwick's Biomedical and Scientific Research Ethics Committee (REGO-2019-2332, dated 21 March 2019), and registered on the Central Trial Registry of India (CTRI/2019/01/017267).

**STRENGTHS AND LIMITATIONS OF THE STUDY**

- This is the first ever methodologically robust study in low and middle income countries to test the impact of reforms in a psychiatric hospital on important patient outcomes such as change in disability, symptoms, social and occupational functioning and quality of life.
- The study offers an individual recovery plan for a psychiatric hospital setting in low resource settings
- The cost implication of the individual service package will be studied. This has relevance in influencing mental health care policy across the country.
- There is a strong component of government involvement that adds to the potential of sustainability and scaling up across other mental hospitals in the country.
- It is not possible to blind the case managers to the group allocation due to the nature of the intervention, hence it is a single-blind study, with only researchers assessing outcomes being blind to allocation. Given the nature of the setting, there is also a risk of contamination across both trial arms.

## INTRODUCTION

People living with Severe Mental Disorders (SMD) (psychosis, bipolar and affective disorders and severe-moderate depression) in low and middle-income countries (LMICs) face impediments to their clinical and functional recovery, and have large unmet needs associated to poverty, protection of human rights, social inclusion and participatory citizenship.(1-5) A range of cost-effective and evidence-based interventions are now available, however there are major barriers in access to appropriate care, increasing vulnerability and disadvantage along with stigma and discrimination. (1, 2, 6-9) Many languish in large hospitals, abandoned by family and forgotten by policy makers. India has 43 mental hospitals built during the colonial period that continue to function almost in the same way as they did when they were set up. (10-14) These hospitals constitute 80% of all available psychiatric beds. (15) At the end of 2015 there were 6,829 patients staying in 30 of the 43 mental hospitals; 16% had been inpatients for more than five years, some for 3-4 decades.(5) The infrastructure and standards of care are poor.(14) There are no clear pathways to discharge and successfully integrate former patients into the community. (16) A complex mix of low priority for mental health care in India, lack of support from central and state governments and low autonomy and decision making power amongst professionals working in such institutions has impeded any meaningful reform.(14)

Mental hospitals in India have played an important role in the care of very vulnerable people and continues to remain a legitimate and relevant locus of care for people in need of services.(17) Given the lack of feasibility of closing down psychiatric institutions in most low and middle income countries, there is an urgent need for manageable and evidence based reform of these hospitals. The Udaan program seeks to address this need.

### The Udaan Program

Udaan is a partnership of Tata Trusts with government of Maharashtra, formalized through an MoU, to develop the Regional Mental Hospital Nagpur (RMHN) as a center of excellence through systematic reform of the hospital. Maharashtra is a state in the Western peninsular region of India with Nagpur being right in the center of the country. Udaan (which in Hindi mean 'to soar') comprises four key reform elements: structural (refurbishing old colonial infrastructure to meet current service user needs), process (standardizing clinical and non-clinical processes of the hospital), capacity building (standard training for different levels of hospital staff) and introduction of the Needs Based Intensive Case Management (NB-ICM), an individual need based, recovery oriented, service package for patients delivered through intensive case management. The Udaan elements are detailed in figure 1.

### Structured Individualized inTervention And Recovery (SITAR)

The Structured Individualized Intervention and Recovery (SITAR) study is embedded within the Udaan program. In a clinical trial we test whether NB-ICM improves patient outcomes amongst long stay inpatients, in comparison to care as usual in a psychiatric hospital undergoing reform in a low and middle-income country. The objectives of SITAR are

- a. To compare the effectiveness of structural and process reform with and without an individually tailored recovery plan on patient level outcomes of disability (primary Outcome), symptom severity, social and occupational functioning and quality of life for the long stay patient cohort of the hospital
- b. To determine the costing of implementing an individually tailored recovery plan for long stay individuals in psychiatric hospitals

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Intensive case management calls for high resources and as such may not be feasible in low income settings. We thus seek to compare patient outcomes emerging from larger structural and process reform in old psychiatric hospitals as compared to patient outcomes when intensive case management is added along with the reform. This comparison has significant value in policy decision making on how meagre resources should be used in low resource settings where mental health care continues to be provided by psychiatric hospitals set up 100 to 200 years ago.

This paper presents the protocol of SITAR which aims to bridge a critical gap in scientific evidence by studying the impact of reform of psychiatric hospitals on individual patient outcomes. The findings will provide an evidence based package of reforms for psychiatric hospitals in transition in low and middle-income countries.

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## METHODS AND ANALYSIS

### Study Design And Management

The study is a pragmatic parallel arm single blind randomised control trial at a single site, the Regional Mental Hospital Nagpur (RMHN). The mental hospital in Nagpur was started in 1864. The hospital has a capacity of 940 beds with an average occupancy of 600 patients at any given time.

Recruitment of patients for the study was initiated after completion of permissions, ethics approval and trial registry. We will continue recruitment till adequate sample size (85 in each arm) is reached. This is a changing population with a constant process of admission and discharge to the hospital. We assume a six months' time frame to complete full recruitment from the start of intervention.

The in-patient population of the hospital will be compiled on a database, mapping socio-demographic variables, history of illness and history of treatment as baseline data. Patients fitting the inclusion criteria will be identified and randomly assigned to the intervention and control arms of the study. Recruitment will be continued till desired numbers are reached. The intervention will be carried out for a six-month period. Post measures on all patients who have undergone pre-measures will be undertaken at completion of intervention (at six months) and at two follow-up intervals post intervention of nine months and 12 months (3 and 6 months after completion of intervention). The SITAR study design is presented graphically in figure 2.

Several steps are proposed to ensure *quality control and minimize the risk of bias*.

1. Use of a standard case management intervention (intervention manual developed for the study)
2. Randomization of the sample to intervention and care as usual arms of the study.
3. Outcome measurements will be undertaken by researchers independent of the case managers delivering the intervention. Inter-rater reliability for the researchers will be computed. The statistician drawing the randomization tables will be blinded to the allocation of the groups
4. Each case manager will be supervised at least once every month on at least 20% of the cases undertaken by them. Joint monthly meetings of all case managers will be held for case reviews and sharing of experiences and discussion on overcoming barriers.
5. The primary supervisor will conduct a site visit and meet the case managers to assess fidelity of intervention.

Given the nature of the setting, there is a risk of contamination across arms especially since the hospital staff providing care in both arms are the same. We believe this is a minimal possibility given the meagerness of engagement of hospital staff with the patients.

SITAR is part of the work done by the first author in fulfilment of the PhD program at the University of Warwick. The study will be coordinated by the UDAAN office located at RMHN. The study is managed by the PI with supervision from the supervisors and oversight by the Trial Management Committee (TMC). The TMC comprises of members from the University of Warwick and mental health experts from India.

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## Participant Eligibility And Recruitment

In-patients at baseline will comprise all service users admitted to RMHN. Patients meeting the inclusion criteria for the study will be randomized to the two arms of the study. Service users will be eligible if they have a primary diagnosis of psychosis (schizophrenia, bipolar affective disorders and psychosis NOS) based on diagnosis given in their case files, a continued length of hospital stay between 12 to 120 months and are over the age of 18 years. Service users will be excluded from the study if they are over the age of 60 years, have a neuro-developmental disorder such as epilepsy, an intellectual disability or are service users in acute and forensic wards.

### Sample Size

For the study to be powered at the 90% level with 5% significance level, the required sample is 170 people, 85 in each arm. Assuming a 15% drop out we aim to recruit 100 people in each arm of the study. For the power calculation, the estimated sample size allows us to detect a minimum clinical difference of 10 points in the primary outcome (WHODAS) at 6 months with a standard deviation of 20. This equates to a moderate effect size of 0.5. (18) The parameter estimates to inform the sample size were drawn from an Indian study based in the community with non-intensive case management using the WHODAS score as the primary outcome measure. (19) People with psychosis in institutional set-ups might have higher disability levels as compared to people living in the community, however most people in LMICs continue to remain in institutions due to the absence of viable pathways of community reintegration. The intervention being offered is intensive with longer case management time than what would be feasible in a dispersed community setting.

### Informed Consent

The treating psychiatrist will assess the service users' ability to participate in the study as well as ability to consent. The psychiatrist will provide consent for those patients unable to give consent but deemed appropriate for the intervention. This is especially important in the case of this intervention since it is a 'need based' psychosocial intervention. Based on inability to consent, patients who may need the intervention most might actually be left out of the study. The consent by the treating psychiatrist will ensure equitable inclusion. Additionally, the ward in charge also signs off on the consent. The study will be explained pictorially to the service user with the aid of a specially designed flip chart. Signatures and or thumb impressions will be taken on simple consent forms drawn up in Hindi and Marathi. Service users will be assured that their refusal to participate / consent to the study will have no impact on the care they receive.

### Randomization

The study will use a computer generated permuted block randomization schedule for the allocation of recruited subjects to the two study arms. The researcher will create a list of service users meeting the inclusion criteria and consenting to the study and give them a unique ID number. This list will be handed over to the statistician who is independent to the research team. Random allocation of eligible study subjects to two study arms (A and B) will be done by the statistician using ralloc software (version 3.7.6) available in STATA (version 10.1, 2011) module.

### Intervention

The Needs based Intensive case management (NB-ICM) for people living with SMD is based on a psychosocial rehabilitation model that takes a holistic approach to improving quality of life, reducing disability, improving role function, promoting independence and autonomy based on a

hope for the future. It is a mix of working on individual competencies in the context of real everyday experiences and introducing environmental change propelled by individual choice.(20-27)

Trained case managers will deliver the intervention through a clinical and intensive case management approach that taps into a functional network of a spectrum of services being created at the hospital level through the reform process.

The case managers are trained on a specially designed training module that comprises content around severe mental illness and intensive case management with a focus on the needs of people with high disabilities in psychiatric institutions. The 60-hour training module was delivered through seven days of offsite training for the purpose of this study.

The intervention components comprise 1) accommodation, safety and food (this is contextualized to the hospital setting where all service users may not have access to clean living spaces and enough food); 2) psychoeducation (about the illness and its symptoms); 3) symptom management; 4) physical health; 5) emotional wellbeing; 6) self-care and other living skills; 7) social relationships; 8) connecting with family; 9) leisure activities; 10) occupational and financial inclusion; and 11) spiritual needs.

The intervention is based on an objective assessment of current needs of the service user and provides a comprehensive package of services to meet the range of individual needs. The case manager works collaboratively with the person in developing a personalized care plan drawing from the larger context of available opportunities within the hospital, created through the ongoing reform process. The care plan adjusts to the patient's cultural context. It draws on the strengths and potential of the individual and is focused on the reduction of personal distress and disability. Care provided through this approach is continuous and consistent for the defined period of the intervention. Case managers have the primary responsibility for planning, coordinating and delivering the care. Each case manager will have a caseload of 12-14 service users and spend at least eight sessions per case per month. The case manager will deliver the intervention face to face either in the ward complex or through calls and home visits in case the person is discharged from hospital as per protocol.

The intervention will aim

- To address unmet needs on symptomatology through appropriate pharmacological management and psychosocial support. It also includes diminishing and eliminating wherever possible the adverse physical and behavioral consequence of symptom management as well as those arising out of prolonged institutionalization.
- To address unmet basic needs of adequate accommodation and food
- To address unmet needs on personal functioning, improving activities of daily living both in terms of skills and access to opportunities
- To address unmet needs of social connectedness, engagement, leisure and social competence through individual competency building and access to environmental opportunities
- To address unmet needs for personal identity and citizenship
- To address the unmet needs of occupational functioning, employment and financial inclusion
- To address the unmet needs of connecting to family and community where feasible

Patients in the control arm will go through the same baseline and follow up measurements as the intervention arm. This group will however not receive the NB-ICM during the trial period, the control arm will continue receiving care as usual, in this case care being provided in a setting

undergoing reform. In most mental hospitals in India care as usual largely comprises biomedical management. (14, 28)

The intervention will be discontinued given the following conditions: 1) If the participant wants to discontinue participation; 2) An acute illness episode that significantly disrupts time in intervention (beyond four weeks); 3) When the participant is discharged from the hospital and community based intervention is not possible either due to distance beyond Nagpur district, unwillingness of participant or family for home based intervention;4) In case of death of a participant.

**Adverse Events- Recording And Reporting**

Given the nature of the study population and the chronicity of the illness certain events are expected. The study protocol classifies these events under ‘adverse events’ and ‘serious adverse events’. Adverse events comprise of a) acute illness (psychosis) episodes as determined by transfer to acute ward; b) episodes of isolation and restraint; c) transfer for medical care outside the psychiatric hospital; d) absconding-from the facility. Serious adverse events comprise e) episode of self-harm and f) death.

To record and report adverse events, we will use the Warwick CTU’s Clinical Trials Standard Operating Procedure 17 part 2 Safety Reporting for Clinical Trials other than those of Investigational Medicinal Products v1.5.

Any adverse event occurring with any participant will be first notified and discussed with the ward in charge. Based on routine hospital care processes, it is the responsibility of the ward in charge to initiate action of either directly providing any care, making a psychiatric referral or making a medical referral. All recorded adverse events will be reported to the core committee and the trial supervisor through monthly reports. These reports will also be submitted to the TMC. Any unexpected adverse event will be reported to Tata Trusts (as the sponsor) along with the India ethics committee, the Central Trial Registry of India as well as the university ethics committee (BSREC) within 15 days of the event.

## Measurements

The study comprises outcome measures and process measures. Other baseline measurements include sociodemographic details, illness history and treatment history.

### *Outcome measures*

Assessment of level of disability will form *the primary outcome for the study*. *WHO Disability Assessment Scale 2.0 (WHODAS 2.0)*, a generic assessment instrument for health and disability that produces standardized disability levels and profiles applicable across cultures and diseases.(29) SITAR will use the simple scoring format sufficient to describe the degree of functional limitation.(29) Three items of WHODAS are not applicable for scoring due to the nature of the setting. These are items 3.4, 4.5 and 6.6. Secondary outcome measures include an assessment of severity of symptoms, assessment of social and occupational functioning and assessment of quality of life. The scales used for these measurements include *The symptom measure- The Clinical Global Improvement Scale (Schizophrenia) (CGI-S)*, a brief, stand-alone assessment of the clinician's view of the patient's global functioning prior to and after initiating a study medication or intervention.(30) The CGI comprises two one-item measures evaluating (a) severity of psychopathology from 1 to 7 and (b) change from the initiation of treatment on a similar seven-point scale.(31) *Social and Occupational Functioning Scale (SOFs)* assesses individual's level of social and occupational functioning and is not directly influenced by the overall severity of the individual's psychological symptoms.(32, 33) *Health related quality of life measure EuroQol-5D (EQ-5D)* is a widely used generic patient reported outcome (PRO) questionnaire designed specifically for cost-utility economic evaluation internationally. The EQ- 5D asks patients to indicate whether they have no, some or extreme problems on each of five dimensions of health: mobility; self-care; usual activities; pain/discomfort, anxiety/depression.(34, 35)

Process (intervention) measurements include the *assessment of need* through a standard form based on Camberwell Assessment of Need (CANSAS).(36) The adaptation draws from prior use of this measure in India through the formative study of needs(37) and need assessment formats used in community setting.(38) This will be carried out by the allocated case managers five times during the study period and will be an indicator of the number of met and unmet needs of the service user at different points during the study. *The Intervention plan*, case managers will draw up a personal care plan collaboratively with the service user and the ward in charge on a monthly basis. Case managers will record the plan on a standard form developed for the intervention and reviewed monthly by the researcher. *The symptoms checklist* has been adapted from ones used in other Indian settings and will record the change in symptoms over the study period and serve as an adjunct to the symptom measure (CGI). The case manager will carry out the measure five times during the study period. *Self-care and other living skills checklist* is adapted to an institutional setting from scales for assessing activities of daily living.(39, 40) Its purpose is to aid the case manager in assessing progress on the intervention plan.

### *Baseline and Follow-up Measurements schedule*

Baseline measurements will be initiated at the start of the study and completed for all in-patients over a three-month period by trained research assistants (RA) who have a Masters' degree in Psychology or Social Work RAs are not involved in the hospital setting, however unmasking is possible and we will record all episodes of unmasking. Inter rater reliability will be established for all the research assistants conducting the measurements.

The intervention will be initiated after completion of the baseline measurements and carried out for a period of six months. At the end of the six-month intervention period, the first outcome measurement will be initiated and completed over a two-month period. The first and second

follow-up outcome measurements will be initiated at three and six months post intervention, respectively, and completed over a two-month period.

The patient sequence will be kept standard for the measurements to ensure uniformity in time between measures. In case of an adverse event where the patient may not be available for measurement as per sequence, accommodation will be made to complete the measure any time during the two-month period of that measurement cycle. In case this is not possible, the patient will be considered as Lost to Follow-up (LFU). Sequence and time frame of measures are summarized in table 1. All patients (except drop-outs as per criteria) will be followed up as per protocol either within the hospital or in the community.

**Table 1 List and time frame for assessments (six months considered from date of first intervention**

			Months												
Assessment	Type	By	0	1	2	3	4	5	6	7	8	9	10	11	12
WHODAS (Disability)	OM	RA	●						●			●			●
SOFS (Social &Occupational functioning)	OM	RA	●						●			●			●
CGI (Symptoms)	OM	RA	●						●			●			●
EQ-5D (Quality of life)	OM	RA	●						●			●			●
Episodes of seclusion & restraint	OM	CM	●	●	●	●	●	●	●	●	●	●	●	●	●
Discharge / adverse events	OM	CM	●	●	●	●	●	●	●	●	●	●	●	●	●
Needs Assessment	PM	CM	●			●			●			●			●
Intervention plan	PM	CM	●	●	●	●	●	●	●						
Symptoms checklist	PM	CM	●			●			●			●			●
Self-care and other living skills checklist	PM	CM	●	●	●	●	●	●	●						
Case management record form	PM	CM	●	●	●	●	●	●	●						
(OM) Outcome Measure (PM) Process Measure (RA) Research Assistant (CM) Case Manager □ intervention time frame															

**Qualitative element of the study**

The qualitative component of the study comprises patient perceptions on the overall reform process and the individual intervention and its felt impact. The SITAR study will use Focus Group Discussions (FGDs) to elicit this. Four FGDs of 8 patients each (16 patients from each study arm) will be conducted in the last quarter of the study period. Since we seek to understand the lived experience of the service user, a phenomenological epistemological perspective is proposed. A basic thematic analysis will be done using NVivo .(41) Verbatim quotes will also be used to highlight findings from quantitative components of the study.

**Data management and analysis**

*Data collection*

Quantitative data will be collected by trained Research Assistants (RAs) using pre-designed; pre-tested tools as included in the protocol. Senior RA will check completeness and accuracy of data gathered on daily basis before electronic data entry.

*Data storage*

The paper data will be stored in secure cabinets, in the PI's cabin at the Tata Trust office in the hospital campus. The office is under CCTV surveillance. The data will be held for ten years post completion of the study.

#### *Data entry and coding*

Data will be coded and entered in an efficient database using MS Excel. Data will be kept confidential and anonymous on password-protected files. The master sheet will be kept separately on MS Excel with password protection. Built-in validity checks will be incorporated in data entry software with flash/warning alerts for incorrect or out of range values.

#### *Data screening, data validation and data editing*

Data will be screened at every stage i.e. pre-randomization, post randomization and closing stage of the trial. This will be done for each and every item of the individual record by student researcher (trial PI). Accuracy of electronic data will be checked through comparison with questionnaire data on a sample basis.

#### *Data analysis*

All results from the trial will be reported according to the Consolidation Standards of Reporting Trials (CONSORT) guideline for randomized controlled trials.<sup>(42)</sup> Descriptive statistics will be presented for participant characteristics and outcomes collected in the trial summarized by treatment arm. Continuous outcomes will be summarized as mean and standard deviation, categorical data will be summarized using frequency and percentage. If data are non-normal, the median and inter-quartile range will be presented.

All of the analyses will be based on the Intention To Treat (ITT) principal where a P value less than 0.05 will be considered as statistically significant. The primary analysis will estimate the treatment effect and 95% confidence interval for the primary outcome (WHODAS) at the 6-month time point using a linear regression model having adjusted for clinically important baseline variables. For all secondary analyses, treatment effects will be estimated using adjusted linear regression models for continuous outcomes and adjusted logistic regression models for binary outcomes. The analyses will be undertaken at each of the follow-up time points (i.e. 6 months, 9 months and 12 months). Where the assumption of normality is not valid, equivalent non-parametric alternatives (e.g. rank-based statistics) will be used.

Every effort will be made to ensure that missing data is kept to a bare minimum in the trial. The level or extent of missingness in data will be assessed at the end of the trial, and if required, additional sensitivity analyses will be undertaken using multiple imputation techniques to impute the missing values.

#### *Data processing*

Data will be processed by the Udaan program at baseline (pre-randomization), during trial (post randomization) and closing stage (outcome assessment). Raw data from the master file will be coded and processed into a data file. The entire data set will be put through an Excel-based double entry process by two independent people. Formula-based comparison of the two sets will be undertaken and discrepancies will be resolved by rechecking with the hard copy of the questionnaire on file. The data file will include both original variables as well as some newly derived variables or transformed variables specific to the study objectives. Statistical Package of Social Sciences (SPSS) will be used for data analysis. The data analyst will be blinded to treatment assignment.

#### *Anonymizing data*

Direct identifiers that allow the identification and communication with an individual participant will be removed. The names of all participants will be replaced with a master list identity (ID) number. The master list containing the ID number will be kept with the PI on a password-protected file, which will be housed in a password, protected firewalled system. The data set for analysis will not include any email address, telephone numbers or home address of patients (where available). Quasi identifiers such as ward numbers will be removed from and variables such as date of admission and date of discharge will be generalized into length of stay.

**PATIENT AND PUBLIC INVOLVEMENT**

Focus Group Discussions (FGDs) are built into the design of the program to incorporate the patient experience of intervention. No patients were involved in the study design.

**COSTING AND POTENTIAL ECONOMIC GAINS OF THE INTERVENTION**

The SITAR study will also include a retrospective bottom-up cost analysis of the individualized intervention in terms of resource or input requirement along with costing of resources for care as usual. Cost elements will include all the resources used in development of the intervention and training material, costs of training, costs of intervention delivery which will include staff time and costs of supervision (people, facilities, equipment and supplies). The costing will be based on actual expenditure incurred through the Udaan program as well as costs components derived through collaboration this will include costs of items received in kind such as clothes, soaps and shampoos and such directly linked to patient care. Actual government spending on patient care will also be done. Costing will be appropriately apportioned to the SITAR study in terms of time allocation of staff based on an analysis of case management records. Given the scope of the study, costs will primarily be presented alongside measures of benefit listed in table one in the form of a cost-consequence analysis. (43) A secondary cost-effectiveness analysis will additionally be performed in which the trial primary outcome will be the measure of effectiveness. (44)

**Ethical Approval and Dissemination**

Ethical approval for SITAR has been obtained from a registered ethics committee in India (Institutional Ethics Committee VikasAnvesh Foundation, VAF/2018-19/012 dated 6/12/2018) and the University of Warwick's Biomedical and Scientific Research Ethics Committee (REGO-2019-2332, dated 21 March 2019), and registered on the Central Trial Registry of India (CTRI/2019/01/017267).

Findings of the study will be presented through scientific publications as well as through a national level dissemination in India along with presentations in different conferences. We also intend to do a policy paper recommending a feasible reform process for psychiatric hospitals in India. Trial results will be published in accordance to CONSORT guidelines.

**CURRENT TRIAL STATUS**

Recruitment of patients was initiated in April 2019. Recruitment was closed in December 2019. The final patient recruited will reach end-point follow-up in December 2020.

**AUTHOR CONTRIBUTIONS**

Tasneem Raja- Principal Investigator, design and implementation of the trial. Wrote first draft of protocol paper.

Helena Tuomainen- Supported the design, protocol development, ethics application and continued supervision, review and editing of manuscript

Jason Madan- Supported the design of economic elements of the protocol.

Dipesh Mistry Supported the development of the data recording and analysis plan

Sanjeev Jain- reviewed and edited the manuscript.

Swaran Singh- primary supervisor on the trial, supported the design, protocol development, ethics application for India and UK, Trial registry, ongoing supervision on the trial.

All Co-authors accepted the final version of the paper.

## **FUNDING STATEMENT**

This work is supported by Tata Education and Development Trust (TEDT) (DI Regional mental hospital Nagpur, circular number 130) and R G Manudhane Foundation for Excellence (MoU with TEDT dated 10<sup>th</sup> Aug 2016).

## **COMPETING INTERESTS STATEMENT**

This trial is part of the PhD program undertaken by the PI Tasneem Raja. She is an employee of the Tata Trusts and the Tata Trusts External Individual educational grants program funds the PhD won on basis of merit.

## **DATA SHARING STATEMENT**

Analyzed data will be shared with the co-authors of the study through a password-protected process. The password for the file will be shared through a phone call made for this purpose. No personal or primary data will be shared. The completely anonymized data set will be made available on request, with due permissions, in keeping with Indian legislation, once primary data analysis is published.

## **Legends**

Figure 1. Graphic representation of Udaan and SITAR

Figure 2. Graphic representation of SITAR

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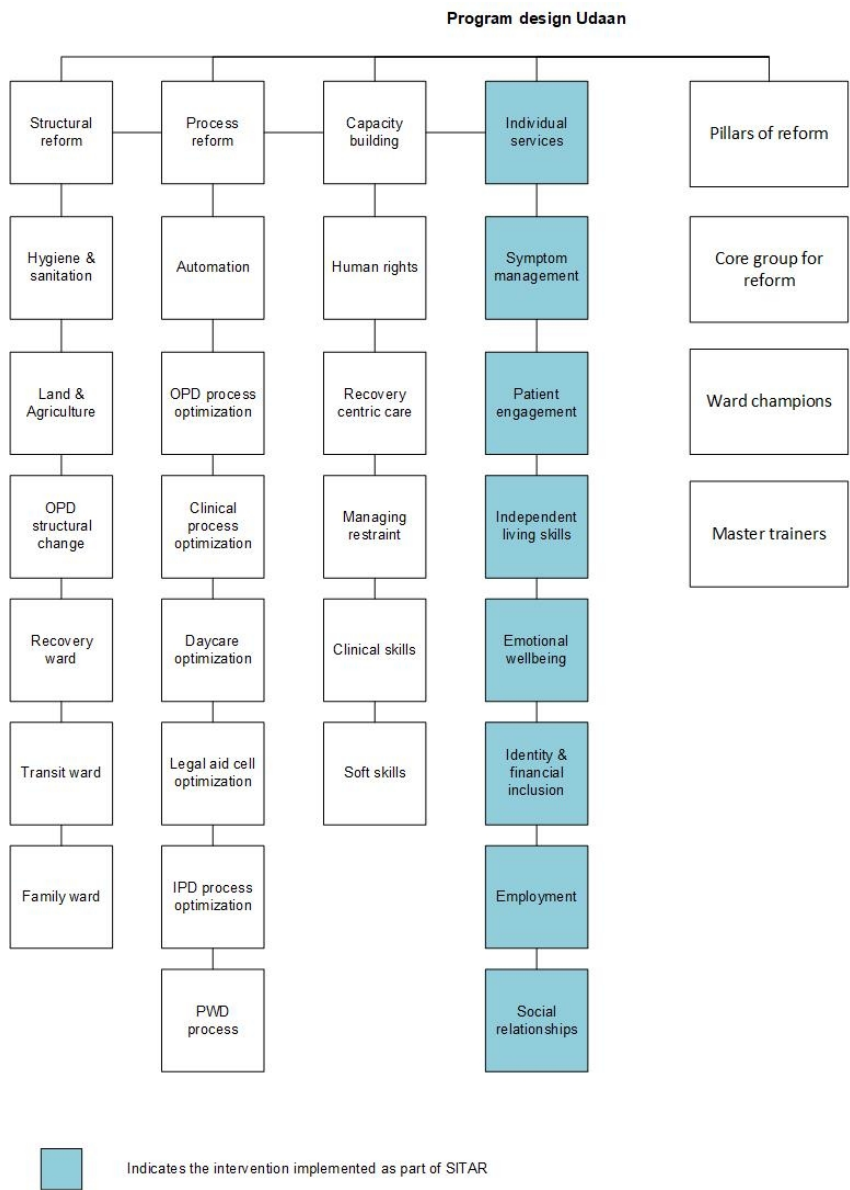


Figure 1 Graphic representation of Udaan and SITAR

72x92mm (300 x 300 DPI)

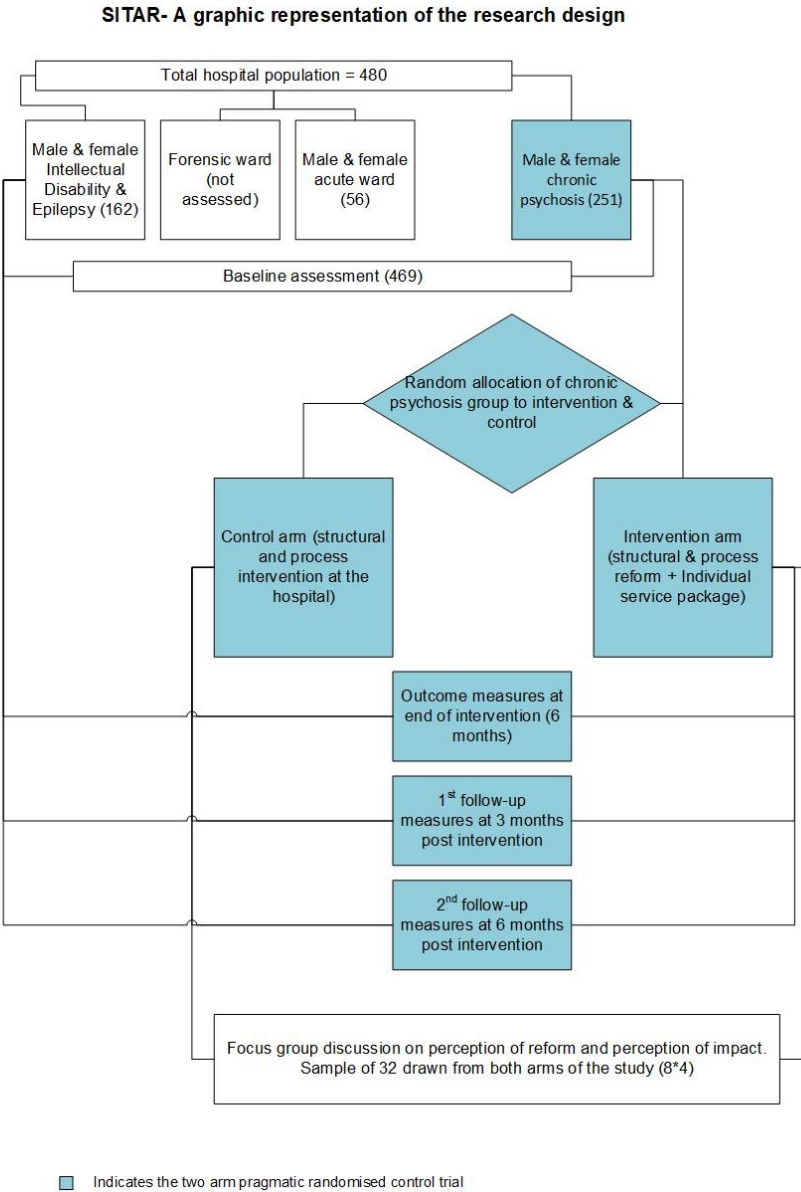


Figure 2 Graphic representation of SITAR  
81x102mm (300 x 300 DPI)

## SPIRIT PROTOCOL FOR SITAR

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

Section/item	Item No	Description
<b>Administrative information</b>		
Title	1	Psychiatric Hospital Reform in Low and Middle-income Countries Structured Individualized Intervention and Recovery – SITAR Trial Acronym – SITAR (Pg 1)
Trial registration	2a	Central Trial Registry (CTR – ICMR) (CTRI/2019/01/017267).
	2b	All items from the World Health Organization Trial Registration Data Set included below the complete SPIRIT protocol
Protocol version	3	Version – 2 <i>31<sup>st</sup> Dec 2018</i>
Funding	4	Tata Trusts
Roles and responsibilities	5a	Tasneem Raja
	5b	Tata Trusts World Trade Centre -1, 26 <sup>th</sup> Floor, Cuffe Parade, Mumbai – 400 005 Tel: +91 - 22 - 6665 8282

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5c *Funder- (pg 15)*

- *MoU with the Government of Maharashtra for the Psychiatric hospital reform (Tata Trusts)*
- *Part funding of the program with other donors (R.G Marudhane Motivation for Excellence Foundation and part funding by the Government of Maharashtra)*
- *The Donors do not have a direct say in the design, data analysis and interpretation / publication of the study findings*

5d *Overall steering committee for Udaan is as per the MoU and is formed by the Government of Maharashtra*

*Coordinating center- Udaan office located on site*

*Data collection- A team of research assistants hired for the purpose and supervised directly by the PI*

*Data management- PI along with M&E manager and senior research assistant to ensure quality check on collection and entry of data.*

*Supervisors- Professor Swaran Preet Singh, Professor Jason Madan and Dr Helena Tuomainen from University of Warwick & Dr Sanjeev Jain from NIMHANS India- will oversee the design and execution of the trial. (Pg12-14)*

Introduction

(pg 3 to 6)

Background and 6a  
rationale

SITAR aims to bridge a critical gap in scientific evidence by studying the impact of reform of psychiatric hospitals on individual patient outcomes. It will offer an evidence based package of reforms for psychiatric hospitals in transition in low and middle-income countries.

The SITAR study is embedded within a larger program called **Udaan**. Udaan is a collaboration of the Tata Trusts (a leading philanthropic foundation in India) with the Government of Maharashtra. The goal of Udaan is to develop the Regional Mental Hospital Nagpur (RMHN) into a center of excellence through a series of structural and process reforms. This is intended as a model that will inform policy change for transition of other psychiatric hospitals in the state of Maharashtra and India.

The key research question is: Do individual recovery plans\* improve patient outcomes, \*\* amongst long stay inpatients\*\*\*, in comparison to care as usual\*\*\*\* in a psychiatric hospital undergoing reform in a low and middle-income country?

\*Individual recovery plan- A structured individual recovery plan based on individual needs assessment

\*\*Patient outcomes refer to change in symptoms of illness, disability levels, social and occupational functioning and quality of life.

\*\*\*Long stay patients- Patients having a continuous period of stay between 12 months and up to 10 years in the Nagpur Regional Mental Hospital in India.

\*\*\*\*Care as usual- For the purpose of this study, care as usual, refers to the structural and process reform in the hospital with a view to modernizing it. This does not include individual recovery plans for patients.

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6b Explanation for choice of comparators

The study compares patient outcomes with care as usual in a psychiatric hospital in India undergoing reform to those with an addition of needs based intensive case management.

The premise of this comparison is that Needs based intensive case management, used in most high resource countries, is a resource intensive intervention. In such a scenario, can individual patient outcomes be modified significantly with larger structural and process reforms in old psychiatric hospitals to meet the needs of current day service users? This comparison has significant value in policy decision making on how meagre resources should be used in low resource settings where mental health care is predominantly provided by psychiatric hospitals set up 100 to 200 years ago.

Objectives  
Hypothesis

& 7

The objectives of SITAR are: (Pg 3-4)  
To determine the effectiveness of structural and process reform of psychiatric institutions on patient level outcomes for in-patients of the hospital.

- a. To compare the effectiveness of structural and process reform with and without an individually tailored recovery plan on patient level outcomes of disability (primary Outcome), symptom severity, social and occupational functioning and quality of life for the long stay patient cohort of the hospital
- b. To determine the costing of implementing an individually tailored recovery plan for long stay individuals in psychiatric hospitals

Primary hypothesis- there is no difference in WHODAS (disability levels) scores between study participants receiving the individual (active) intervention and those receiving usual care (control arm).

Secondary hypothesis- there is no difference in disability outcomes before and after structural and process reform and individual treatment for in-patient service users of the hospital.

Trial design  
(pg 7 & 8)

8 SITAR is a real world implementation study. The trial design is a pragmatic two arm RCT as it is not pragmatically possible to create the ideal study situation of a Randomized Control Trial. The entire in-patient population of the hospital is compiled on a database, for the purpose of this study, mapping socio-demographic variables, history of illness and history of treatment as baseline data (No electronic database of this nature existed prior to this).

The hospital population is divided into four major units, comprising the intellectual disabilities and epilepsy patients' ward forensic ward, acute care ward and the chronic psychosis wards.

Patients fitting the inclusion criteria for the long stay patient cohort (chronic psychosis wards) will be compiled from the larger dataset and randomly assigned to the intervention and control groups.

Intervention – Intensive needs based case management will be carried out for a six-month period. Post measures on all patients who have undergone pre measures will be compiled at completion of intervention (at six months) and at two follow-up intervals post intervention of nine months and 12 months (3 and 6 months after completion of intervention).

The researcher will track fidelity indicators for the intervention as well as process indicators. Loss of sample and the reasons for that will be documented.

The trial also has a qualitative component which brings in the experience of the user and their perception of reform and or intensive case management. This will be done by the researcher through Focused Group Discussions (FGDs) in the last quarter of the one-year study period. People from both arms of the study will be included for this component.

Several steps are proposed to ensure quality control and minimize the risk of bias.

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1. Standardizing the intervention program through an intervention manual comprising of all the intervention protocols. The intervention manual is presented as appendix.
  2. Development of a standard training manual for training of all case managers delivering the individual intervention. The training manual is included in the appendix.
  3. Randomization of the sample to intervention and care as usual arms of the study.
  4. Blinding will be done at two levels. Outcome measurements will be undertaken by researchers independent of the case managers delivering the intervention. Inter-rater reliability for the researchers will be computed. The statistician drawing the randomization tables will be blinded to the allocation of the groups.
- This being a real world setting, it is not possible to mask the case managers to the group allocation. Though the researchers and case managers are independent, masking may not be completely feasible due to the nature of the setting. Episodes of unmasking will be recorded.

Methods: Participants, interventions, and outcomes (Pg 7 to 12)

Study setting	9	Regional Mental Hospital, Nagpur. Country – India. This is a psychiatric hospital set up in 1884 and a major care provider in the central region of India.
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## Eligibility criteria 10

Key Inclusion	Exclusion Criteria
A primary diagnosis of psychosis**	Service users over the age of 60 years*
Continuous length of stay in the hospital $\geq 12$ to 120 months	Service users with neuro-developmental disorders such as epilepsy**
Over the age of 18 years	Service users with Intellectual Disability**
	Service users in Acute Wards***
	Service users in forensic wards****

\*Older people with a longer duration of stay in institutions are not likely to benefit greatly from intensive intervention.

\*\*Based on diagnosis given in case files of the hospital

\*\*\*Service users in acute wards are acutely ill and unable to participate effectively

\*\*\*\*Legal access issues in Forensic ward

The individual needs based intervention will be provided by case managers trained to deliver a standard intervention for the study through the standard training manual of the study.

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- Interventions  
  
(Pg 8-9)
- 11a

This intervention package is based on the premise of contemporary understanding of psychosocial rehabilitation that takes a holistic approach to improving quality of life for a person living with mental illness, reducing disability, improving role function, promoting independence and autonomy based on a hope for the future. Trained case managers will deliver the intervention through a clinical and intensive case management approach that taps in to a functional network of a spectrum of services being created at the hospital level through the reform process. Case managers will draw up a personal care plan collaboratively with the service user and in discussion with the ward in charge, and checked and revised on a monthly basis. Case managers will record the plan on a standard form developed for the intervention and reviewed monthly by the researcher. Each case manager will have a case load of 12-14 service users and will spend at least 8 sessions per case per month of at least 60 minutes each.
- 11b

Intervention will be discontinued under the following circumstances-

  - If the participant wants to discontinue participation
  - An acute illness episode that significantly disrupts time in intervention (beyond four weeks)
  - When the participant is discharged from the hospital and community based intervention is not possible either due to distance beyond Nagpur district, unwillingness of participant or family for home based intervention.
  - In case of death of a participant



11c This is a psycho-social rehabilitation intervention and as such does not involve intervention adherence. One component of the intervention is symptom management. Adherence to medication within this component will be managed in the following manner

- Medication administered under observation while the participant is in hospital
- Psychoeducation on importance of medication to participant and family (where available)
- Addressing side effects in discussion with psychiatrists
- Ensuring medication stock availability when participant is discharged from hospital

11d Relevant concomitant care and interventions that are permitted or prohibited during the trial

All routine interventions available in the hospital (in this case a hospital undergoing structural and process reform) will be available to the participant as concomitant intervention.

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Outcomes  (Pg 11-12)	12	<p>The outcome measures comprise assessment of disability levels, symptom measure, assessment of social and occupation functioning and assessment of quality of life. These four measures are described in detail below-</p> <p>The primary measure is disability levels</p> <p><b>Disability Measure- WHO Disability Assessment Scale 2.0 (WHODAS 2.0)</b> (primary outcome) is a generic assessment instrument for health and disability and produces standardized disability levels and profiles and is applicable across cultures, in all adult populations and is used across all diseases, including mental, neurological and addictive disorders. SITAR will use the simple scoring format, which is the recommended one for a busy clinical setting and constitutes a statistic that is sufficient to describe the degree of functional limitation.</p> <p><b>Symptom measure- The Clinical Global Improvement Scale (CGI)</b> is a brief, stand-alone assessment of the clinician’s view of the patient’s global functioning prior to and after initiating a study medication or intervention (Haro <i>et al.</i>, 2003). The CGI comprises two one-item measures evaluating (a) severity of psychopathology from 1 to 7 and (b) change from the initiation of</p> <p>treatment on a similar seven-point scale.(JOAN BUSNER &amp; and STEVEN D. TARGUM, July 2007)</p> <p><b>Social and Occupational Functioning Scale (SOFS)</b></p> <p>The SOFS focuses exclusively on the individual's level of social and occupational functioning and is not directly influenced by the overall severity of the individual's psychological symptoms (Morosini <i>et al.</i>, 2000). In study it will used to rate functionality over a three month period.</p> <p><b>Health related quality of life measure EuroQol-5D (EQ-5D)</b> is a</p> <p>The EQ-5D is the most widely used generic Patient reported outcome (PRO) questionnaire internationally. The EQ- 5D asks patients to indicate whether they have no, some or extreme problems on each of five dimensions of health: mobility; self-care; usual activities; pain/discomfort, anxiety/depression</p>
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## Episodes of seclusion and restraint

For the purpose of this study, seclusion and restraint are defined as follows:-

Seclusion means the placement and retention of an inpatient service user in a bare room in order to contain a clinical situation that may result in a state of emergency.

Physical restraint refers to the manual holding and restriction of the service user by staff or under their instruction.

Mechanical restraint refers to the use of belts, handcuffs and the like, which restrict the service user's movements or totally prevent the person from moving.

These episodes will be recorded as they occur on the case manager's record form included in (Appendix 5.2.6).

Process/ intervention measures include the following-

- Assessment of need
- The intervention plan
- Symptoms checklist
- Self-care and other living skills checklist

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Participant 13  
timeline (PG 14-15)

*We aim to recruit 100 participants in each arm of the trial. Recruitment will continue up to the point we achieve the number based on inclusion and exclusion criteria of the protocol. Intervention time frame will start as soon as a participant is recruited since this is an individual intervention. We anticipate a two month time frame in completion of recruitment from the time of initiation. This means intervention will run maximum for a period of 8 months to complete the intervention time frame of six month for those recruited last.*

Time line of the trial														
Time (Months)	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Enrolment														
Eligibility screen														
Informed consent														
Baseline assessment														
Allocation														
Intervention														
Outcome measurement														
1st Follow-up measure														
2nd Follow-up measure														
Month 1 starts post ethics approval														

Sample size (pg 8)	14	<p>Study population – 469</p> <p>Sample will be in-patient service user population of the hospital (600 <math>\pm</math> 50 <i>n</i>) excluding the in-patients of the forensic ward and acute ward. This brings the study population to about 515. Service users meeting the inclusion criteria for the study will be randomized on a 1: 1 basis to the two arms of the study post informed consent. For the study to be powered at the 90% level with 5% significance level, the required sample is 170 people, 85 in each arm. Assuming a 15% drop out we aim to recruit 100 people in each arm of the study. For the power calculation, we have assumed a moderate effect size of 0.5. With a minimum clinical difference of a score of 10 points with a <math>\sigma</math> of 20.</p> <p>The effect size and variance was drawn from an Indian study based in the community with non-intensive case management using WHODAS scores as primary outcome measures (Murthy <i>et al.</i>, 2005).</p> <p>People with psychosis in institutional set-ups might have higher disability levels as compared to people living in the community, however most people in LMICs continue to remain in institutions due to the absence of viable pathways of community reintegration. The intervention being offered is intensive with longer case management time than what would be feasible in a dispersed community setting. This forms the basis for assuming a moderate effect size.</p>
Recruitment (Pg 8)	15	<p>The sample will be recruited from the hospital's in-patient service user population based on the inclusion and exclusion criteria. The sample recruitment will be continued until such time the required numbers are fulfilled. Almost 58% of service users are under 1 year of stay at the RMHN with the median length of stay being 15 months. Service users who have crossed the 1-year mark will be put through the recruitment and randomization process as per the study protocol.</p> <p>If a service user is discharged from the hospital during the study period, the case manager will continue to provide intervention as per protocol in the service users' setting to the extent feasible. Dropouts and reasons for lack of end measures will be captured.</p>

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**Methods: Assignment of interventions (for controlled trials) (Pg 8)**

Allocation:

Sequence generation	16a	The study will use a computer generated permuted block randomization schedule
Allocation concealment mechanism	16b	The researcher will create a list of service users meeting the inclusion criteria and consenting to the study and give them a unique ID number. This list will be handed over to the statistician who is independent to the research team
Implementation	16c	. Random allocation of eligible study subjects to two study arms (A and B) will be done by the statistician using ralloc software (version 3.7.6) available in STATA (version 10.1, 2011) module.
Blinding (masking)	17a	Statistician drawing the randomization tables will be blinded to the allocation of the groups and Case Managers delivering the intervention will be blinded to the baseline and outcome measurements.
	17b	Un-blinding post intervention, at the time of the three outcome measures may occur with research assistants conducting measurements. These instances will be recorded and reported.

**Methods: Data collection, management, and analysis (Pg 12-14)**



# Data collection 18a methods

Baseline measurements will be initiated at the start of the study and will be completed for the entire in-patient population over a three-month period. Research assistants trained in using all instruments will carry out assessments.

The intervention will be initiated after completion of the baseline measurements and carried out for a period of six months based on structured protocols. At the end of the six-month intervention period, the first outcome measurement will be initiated and completed over a two-month period. The first and second follow-up outcome measurements will be initiated at three and six months post intervention, respectively, and completed over a two-month period.

All the four outcome measures will be done using standardised instruments as described in the protocol.

Table 4-3 List and time frame for assessments

Assessment	Type	By	0	1	2	3	4	5	6	7	8	9	10	11	12
WHODAS (Disability)	OM	RA	•						•			•			•
SOFs (Social & Occupational functioning)	OM	RA	•						•			•			•
CGI (Symptoms)	OM	RA	•						•			•			•
EQ-5D (Quality of life)	OM	RA	•						•			•			•
Episodes of seclusion & restraint	OM	CM	•	•	•	•	•	•	•	•	•	•	•	•	•
Discharge / adverse events	OM	CM	•	•	•	•	•	•	•	•	•	•	•	•	•
Needs Assessment	PM	CM	•			•			•			•			•
Intervention plan	PM	CM	•	•	•	•	•	•	•						
Symptoms checklist	PM	CM	•			•						•			•
Self-care and other living skills checklist	PM	CM	•	•	•	•	•	•	•						
Case management record form	PM	CM	•	•	•	•	•	•	•						

(OM) Outcome Measure (PM) Process Measure (RA) Research Assistant (CM) Case Manager

*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*

- 18b In the case of an adverse event where the patient may not be available for measurement as per sequence, accommodation will be made to complete the measure any time during the two-month period of that measurement cycle. In case this is not possible, the patient will be considered as Lost to Follow-up (LFU).

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Data  
management

19      Questionnaire data will be collected using paper pencil formats; hand scored, and entered on computer. Quality checks will be done on 20% of the data randomly. Focus group notes and recordings will be transcribed in English as Word files. The Excel Word and SPSS files will be stored on password-protected computers and hosted on secure servers.

Physical data files will be stored in a secure place in locked filing cabinets within the Tata Trusts office. Only the researcher, study statistician and the supervisors will access baseline, outcome measurement and focus group data. Data will be shared with supervisors at the University of Warwick using standard good practice. Password protected data files will be sent over email and the password sent in a separate email. The shared data files will be completely anonymized

review only

## Statistical methods

20a Data analysis will mainly focus on assessing between-the-group differences in effectiveness of interventions, and thereafter finding associations between the outcome and a set of predictors or explanatory variables of the respondents.

The researcher will use descriptive statistics like Mean/Standard Deviation, or Median/Quartile Deviation depending on the distribution of data for describing variables such as scores and other measures while frequency and proportions or percentages will summarize count data.

Inferential statistics: 95% Confidence Intervals will be obtained for all the descriptive measures, especially for efficacy parameters.

Between-the-group differences in means of two groups (Study versus Control) will be tested by independent samples t-test assuming equal variance. Relevant covariates such as gender and age will be adjusted for using linear regression.

Within-the-group differences in means (Baseline to End line) will be tested with Paired t-test for each group separately.

Difference in proportions in two independent groups (Study versus Control) will be tested by Pearson's Chi-square test, while within-the group (before-after) comparisons will be assessed by Mc Nemar's Chi square test.

20b *Additional analysis may be focused on age group based sub grouping and gender based sub grouping of findings.*

20c In a scenario where in the assumption of normality is not valid, equivalent non-parametric alternatives (e.g. Rank-based statistics) shall be used especially for score data. The study will consider a P value less than 0.05 as significant for all variables.

## Methods: Monitoring

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Data monitoring (Pg 10)	21a	<p>Adverse events are defined in the protocol and are not considered an outcome or related to the trial but as events that occur whilst the trial is on. This is specifically so given that this is a psychosocial rehabilitation intervention. Adverse events will be recorded and reported.</p> <p>Harm arising out of the intervention to key stakeholders has been considered along with mitigation strategies and is part of the protocol.</p> <p>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</p>
	21b	<p>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- NA</p>
Harms	22	<p>Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct- included in 21a</p>
Auditing	23	<p>Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor- through the process of supervision</p>
Ethics and dissemination		

Research ethics approval (Pg 14)	24	<p><i>The following has been done</i></p> <ul style="list-style-type: none"> <li>• <i>Memorandum of understanding between Tata Trusts and Government of Maharashtra to undertake a reform program of which the individual intervention (under study) is a part (completed).</i></li> <li>• <i>Permission sought from Hospital administration to initiate the individual intervention package, baseline and outcome measures as defined in the protocol (completed).</i></li> <li>• <i>Ethics clearance sought from a registered ethics committee in India</i></li> <li>• <i>Ethics clearance sought from the University of Warwick ethics committee.</i></li> <li>• <i>Trial registry on the Central Trials Registry of India</i></li> </ul>
Protocol amendments	25	<i>Any modification in protocol will be informed in writing along with reasons to all the parties involved in permission and ethics clearance as stated in section 24 of SPIRIT protocol.</i>
Consent or assent (Pg 8)	26a	<p><i>The PI will obtain all informed consent using the pictorial information sheet and set of cards attached with the protocol.</i></p> <p><i>Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)</i></p>
	26b	<i>Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable</i>
Confidentiality (Pg 12- 14)	27	<p><i>Data will be collected in hard copies which will be stored in locked cabinets in the Tata Trusts office. The data will be entered into excel sheets which will be password protected on password protected computes. All data will be anonymised before sharing with the supervisor at University of Warwick. The file sent over email will be password protected and password will be shared in a separate email. A similar process will be used with the statistician analysing the data. These are the only two entities with whom data will be shared.</i></p>

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Declaration of interests	28	<i>The PI is an employee of the Tata Trusts. Tata Trusts is a non-sectarian philanthropic organization based in India. It is also one of the funders of the Udaan program within which this PhD study is nested.</i>
(Pg 15)		
Access to data	29	<i>The PI, statistician and university supervisor will have access to the data</i>
(Pg 14)		
Ancillary and post-trial care	30	<i>This being a psychosocial intervention study, continuing services is an important consideration. Tata Trusts will train the Government hospital staff in case management based psychosocial intervention with the training material developed for this study.</i>
Dissemination policy	31a	<i>The following modalities will be used for dissemination of results-</i>
(Pg 14)		<ul style="list-style-type: none"><li><i>• Part of the yearly process dissemination of the larger Udaan program</i></li><li><i>• Scientific publications as part of the PhD</i></li><li><i>• PhD thesis made available in the public domain</i></li><li><i>• Policy brief for the Government based on the findings of the study</i></li><li><i>• Tool kit of the final tools and manuals used for the study made available in the public domain</i></li></ul>
	31b	<i>Primary authorship will be with the PI. Supervisors will be invited to be co-authors on all publications. No professional writers will be used.</i>
	31c	<i>NA</i>
Appendices		
Informed consent materials	32	<i>Informed Consent and Participant Information Sheet in pictorial format enclosed with the protocol.</i>
		<i>Model consent form and other related documentation given to participants and authorised surrogates</i>

Biological  
specimens

33 NA

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