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PSYCHIATRIC HOSPITAL REFORM IN LOW-INCOME AND
MIDDLE-INCOME COUNTRIES; STRUCTURED
INDIVIDUALISED INTERVENTION AND RECOVERY
(SITAR)

By

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A thesis submitted in fulfilment of the requirements for the
degree of Doctor of Philosophy in Health Sciences

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Abbreviations

CGI	Clinical Global Improvement Scale
CEA	Cost Effectiveness Analysis
CM	Case Manager
CUA	Cost Utility Analysis
DMHP	District Mental Health Programme
EEG	Electro Encephalography
EIC	East India Company
EPHPP	The Effective Public Health Practice Project
EQ-5D	EuroQol-5Dimensions
GDP	Gross Domestic Product
HRQoL	Health Related Quality of Life
ICER	Incremental Cost Effectiveness Ratio
ICUR	Incremental Cost Utility Ratio
ID	Intellectual Disability
IDN	Identity Number
INR	Indian Rupee
IP	In-Patient
LMIC	Low- and Middle-Income Country
LoA	Leave of Absence
MHCA	Mental Health Care Act (2018)
MoU	Memorandum of Understanding
NHRC	National Human Rights Commission
OP	Out-Patient
PI	Principal Investigator
PIL	Public Interest Litigation
PSW	Psychiatric Social Worker
RA	Research Assistant
RATS	<i>Relevance, Appropriateness, Transparency and Soundness</i>
RGMFE	R G Marudhane Motivation For Excellence
RMHN	Regional Mental Hospital Nagpur
SCARF	Schizophrenia Research Foundation
SD	Standard Deviation
SITAR	Structured Individual inTervention And Recovery
SMD	Severe Mental Disorders
SOFAS	Social and Occupational Functional Assessment Scale (SOFAS)
SOP	Standard Operating Procedure
SPSS	Statistical Package of Social Sciences
TT	Tata Trusts
UNCRPD	United Nations Convention on Rights of Persons with Disabilities
USD	United States Dollar
WHO	World Health Organization
WHODAS	World Health Organization Disability Assessment Schedule
WTP	Willingness To Pay
WWI	World War I

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“Optimism is the faith that leads to achievement. Nothing can be done without hope and confidence.”

Helen Keller

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Declaration

This thesis is submitted to the University of Warwick in support of my application for the degree of Doctor of Philosophy. It has been composed by myself and has not been submitted in any previous application for any degree.

Parts of this thesis have been published/presented at international conferences by the author:

Publications

- Raja, T., Tuomainen, H., Madan, J., Mistry, D., Jain, S. & Singh, S. (2020b) Psychiatric hospital reform in low-income and middle-income countries Structured Individualised Intervention and Recovery (SITAR): A two-arm pragmatic randomised controlled trial study protocol. *BMJ Open*, 10 (5)
- Raja, T., Tuomainen, H., Madan, J., Mistry, D., Jain, S., Easwaran, K. & Singh, S. P. (2021) Psychiatric hospital reform in low-and middle-income countries: a systematic review of literature. *Social Psychiatry and Psychiatric Epidemiology*, 1-17.
- Raja, T., Bang, A. & Sethi, A. (2021) *Finding Abdul*. [online] Available from: <https://www.foundingfuel.com/article/finding-abdul/> (Accessed May 21st).

Associated publications

- Huddar, A., Raja, T., Jain, S. & Singh, S. P. (2020) From schizophrenia to sainthood–Tajuddin Fakir. *Asian Journal of Psychiatry*, 102465.

Conferences

- Plenary session on Psychiatric hospital reform, Aug 2018. International conference on Schizophrenia ICONS, Chennai, India, 2018.
- Psychiatric hospital reform- changing the global health narrative, Healthier Longer Lives, Fountain House, in partnership with World Health Organization (WHO) Collaborating Centre for Global Mental Health at Columbia University Medical Center, Grand Challenges Canada and citiesRISE, New York, November 2018.

Abstract

Background: Low- and Middle-Income countries (LMICs) like India have large treatment gaps in mental health care. People with Severe Mental Disorders (SMD) face impediments to their clinical and functional recovery and have many unmet needs. The infrastructure and standards of care are poor in colonial-period mental hospitals, with no clear pathways to discharge and reintegration into the community. Despite concerns over quality of care and human rights violations these hospitals continue to provide the majority of mental health care for SMD in most LMICs. LMICs need a pragmatic approach to implementing mental health, with evidence-based reforms of psychiatric institutions to meet the needs of service users today.

Objective: The aim of the research was to examine the impact of hospital reform on outcomes for long-stay patients. We compared whether *larger structural and process reform of a mental hospital brings about change in patient outcomes or a case management based individual service package is needed to effectively translate larger hospital reform into discernible difference in outcomes for long-stay patients often living in closed hospital wards.*

Methods: This research study comprised three interlinked phases in a mixed methods design. In phase one, a systematic literature review was undertaken to examine evidence on psychiatric hospital reform in LMICs. Phase two comprised a pragmatic randomised clinical trial, called Structured Individualised inTervention And Recovery (SITAR), to study the impact of psychiatric hospital reform. The trial also aimed to study the modality in which reform would reach the service user. SITAR used Need-Based Intensive Case Management (NB-ICM) within the context of the hospital. 'Patients' experiences of reform were also studied using qualitative methodology. In the third phase, an economic evaluation was undertaken to study the affordability of psychiatric hospital reform as a viable care pathway for very vulnerable people who are long-stay in psychiatric hospitals.

Results: Systematic psychiatric hospital reform has a positive impact on outcomes of disability, symptom, social and occupational functioning, and quality of life. NB-ICM has an important role to play in terms of patient's lived experience of reformed care, it however, did not show a significant impact on measured outcomes in the time period of the study.

Conclusion: Systematic reform of psychiatric hospitals appears feasible and affordable and might be an important alternative to the limited care pathways for people with Severe Mental Disorders who have high care needs in LMICs.

Introduction

The SITAR trial was an embedded evaluation of a larger program of reform, called Udaan, of one psychiatric hospital in India. This clinical trial aimed to bridge a critical gap in scientific evidence by studying the impact of reform on individual patient outcomes of reducing disability, improving symptoms, improved social and occupational functioning and a better quality of life. The trial also aimed to study the impact of individual case management offered through Need Based Intensive Case Management (NB-ICM) and its impact on patient outcomes in the context of larger hospital reform.

SITAR used Need-Based Intensive Case Management (NB-ICM) within the context of the hospital seeking to answer the research question- *‘whether larger structural and process reform of a mental hospital brings about change in patient outcomes or a case management based individual service package is needed to effectively translate larger hospital reform into discernible difference in patient outcomes especially for those who are long-stay often living in closed hospital wards.’*

The research undertaken for this thesis includes the following-

- A systematic review of literature on psychiatric hospital reform in LMICs.
- Development of the evaluation of (Udaan) in the form of SITAR trial.
 - Documentation of systematic reform of the Regional Mental Hospital Nagpur (Udaan) as a case study.
 - Development of the methodology and methods for SITAR trial and its execution
 - Development of the Needs Based-Intensive Case Management (NB-ICM). This formed the intervention component of the SITAR trial.
 - Development of NB-ICM training manual for case managers
- Economic evaluation of Udaan and SITAR.

Overview of the thesis structure

The thesis is laid out in 10 chapters. **Chapter One** sets the scene and is a review of literature on psychiatric hospitals, their evolution and the process

of deinstitutionalisation. The chapter also discusses the role that psychiatric hospitals play in contemporary mental health care in the larger context of LMICs and specifically in India.

Chapter Two presents findings of a systematic literature review on psychiatric hospital reform, for the last four decades in the context of LMICs.

Chapter Three presents the case study of the Udaan program- the reform of the Regional Mental Hospital of Nagpur (RMHN). This chapter provides the details of the programme that was evaluated through the SITAR trial.

Chapter Four describes the methodology and protocol of the SITAR Trial.

Chapter Five describes the Needs Based-Intensive Case Management (NB-ICM) which comprises the 'intervention' in the SITAR trial.

Chapter Six discusses the unprecedented pandemic situation and its impact on my PhD.

In **Chapter Seven**, the quantitative results of the SITAR trial have been presented.

Chapter Eight covers the qualitative research findings of the SITAR trial where I have explored the lived experience of hospital reform and the impact this reform has had on the lives of long-stay patients of the hospital.

The embedded economic evaluation of Udaan and SITAR is presented in **Chapter Nine** and discusses the costs of reform in comparison to costs of care as usual.

Chapter Ten presents the discussion and reflection on the quantitative, qualitative and economic evaluation findings. I have closed chapter ten with a personal reflection of my journey as a PhD student and the skills I have gained on this journey.

1 Psychiatric hospitals and their role in contemporary mental health care

1.1 Introduction

Severe Mental Disorders (SMDs) contribute significantly to the global burden of disease, disability and mortality (Charlson *et al.*, 2016; Gabbard & Crisp-Han; Vigo *et al.*, 2016). People living with SMD, especially in Low- and Middle-Income Countries (LMICs), often endure appalling conditions. The individual with SMD is frequently cut-off from participation in any of the usual experiences that are routinely associated with living (Chatterjee *et al.*, 2003; Kleinman, 2009; Patel *et al.*, 2018).

There are major barriers to accessing appropriate care, with limited resources leading to large treatment gaps. In the absence of effective care pathways, individuals and families often turn to folk healers for help. As they run out of resources – physical, emotional and financial – to care for the mentally ill family member, protection turns into rejection. Many people with SMD languish in large hospitals, abandoned by family and forgotten by policy makers (Chadda *et al.*, 2001; Chatterjee *et al.*, 2003; Kleinman, 2009; Kohn R, 2004; Lilford *et al.*, 2020; Patel, 2007; Saxena *et al.*, 2007; Vos *et al.*, 2015).

The stigma accompanying severe mental illness encompasses families, spans across generations and is experienced around the world. No country or anti-stigma campaign has made a serious dent in the cycle of misery experienced by the individual and their families. (Chatterjee *et al.*, 2003; Kleinman, 2009; Morgan *et al.*, 2018; Whitley & Campbell, 2014).

This stigma governing millions of lives affected by severe mental illness across the globe truly constitutes “Ground Zero” of global mental health (Kleinman, 2009). While conceptually mental health as a human right lies at the centre of sustainable development and the goals thereof, evidence indicates that people living with SMD experience increasing levels of violence and abuse followed by compulsory detention and treatment (Carr, 2018; Lancet., 2015).

1.2 “Lunatic asylums” as Care providers for severe mental illness

Mental health has remained an area of concern to humankind over thousands of years. Scholars of ancient Greece, India and China had explanatory models of the causes of diseases rooted in the imbalance of life forces or humors, and consequently, their cure was based on redressing imbalances ranging from herbal potions to yoga and massages (Cohen *et al.*, 2014).

Since the beginning of the recorded history of mental health, care of the mentally ill has remained the responsibility of their families. Institutional care was largely provided by temples, churches and other such places of religious or spiritual importance, when families could not take care of them. Confinement of the mentally ill can be traced back to the Syrian Catholic churches as early as the third century AD. Institutional care in the medieval Islamic world was very different to the exorcism provided in the churches. Though shackling was common, the atmosphere was relaxing, combined with various treatments ranging from diets and bloodletting leeches, to dance, music and theatre. By the 13th century, institutional care for the mentally ill could be found in most parts of the world (Cohen *et al.*, 2014; Tuke, 1813).

The first mental asylums in North America appeared around 1773 in the colony of Virginia and by the first half of the 19th century, state run mental asylums sprouted all over the United States. While institutional care in England can be traced back to the 15th century, the great expansion of public asylums began in 1808 (Cohen *et al.*, 2014; Farreras, 2019).

The establishment of asylums in Britain was a reflection of the ideological changes of the Victorian era and the growing secularism of eighteenth-century England in which madness was considered treatable. “Institutional care” was thus considered a humane approach to dealing with insanity in the absence of viable medications (Payne, 2009; Porter, 1987). Asylum growth was further driven by demands of families going through an industrialized 20th century and the stresses it placed on the resources of the family (Andrews, 2003; Pinto, 2018).

As European powers colonised much of Africa and Asia, Western psychiatry and mental asylums spread through the world (Cohen *et al.*, 2014; Keller, 2005). “Lunatic asylums” also reflected a complex interaction between mental illness, race, gender and imperial ideology, and served as yet another form of social control in the colonies (Buxton, 2018; Leckie, 2004; Vaughan, 1991).

As the dominant form of care, “lunatic asylums” were an important focus of discussion in the precursors of the five leading English language medical and psychiatric journals (Cohen & Minas, 2017). The centrality of asylums to care for the mentally ill, especially in England, is also reflected in the Lancet Commission on Lunatic Asylums which sought to determine the general character of asylums and their systems of treatment (Shaw & Middleton, 2016; The Lancet Commission, 1876).

Nomenclature around care for the severely mentally ill gradually underwent a change and the word ‘asylum’ slowly lost its association with the care of mentally ill people in institutional settings. “Lunatic asylums” began being called mental hospitals (Pasmore, 1923).

1.3 Asylums as places of human rights violations and the emergence of deinstitutionalisation

The dichotomous analysis of asylums being curative and coercive spaces has remained an overarching theme in the historiography of asylums (Murthy *et al.*, 2016; Pinto, 2018; Sisti *et al.*, 2015; Tullidge, 1835). Asylums have been described as “total institutions” sharing characteristics with establishments like prisons, military and monasteries. Asylums have a debilitating effect on people living in them, fostering institutional dependency and leading to a loss in social and vocational competencies over a period of time, leaving them less capable of managing their own lives in the wider world beyond the institution (Goffman, 1961; Goldstein, 1979; McEwen, 1980; Penney, 2010). Researchers have also pointed out the important role mental hospitals continue to play in the care of very vulnerable people (Jones & Sidebotham, 2013; Mondal, 2009; Murthy *et al.*, 2017).

Concerns over living conditions and treatment of patients grew alongside the spread of institutions. Several inquiries into the conditions of asylums were conducted throughout the 19th and 20th centuries. (Hawkes, 1857; Mills &

Jain, 2009; Rajpal, 2015; Swartz, 2010; The Lancet Commission, 1876). Commentaries on the criticism of institutional care were also published by the Lancet Commission on Lunatic Asylums in the 19th century (The Lancet Commission, 1876).

The mid-20th century witnessed a social and cultural transformation as mental health care moved away from mental hospitals to community-based settings in many parts of the world. Construed as an administrative apparatus, deinstitutionalisation (closure of hospitals and asylums, and cuts in the number of in-patient beds) was driven by a combination of factors including, growing awareness of poor living conditions in these hospitals; human rights violations patients experienced while living in them; rising costs of mental hospitals, and advances in psychotropic medication (Novella, 2008; Shen & Snowden, 2014; Thornicroft & Bebbington, 1989; Whitaker, 2001).

Beginning as a trickle in the 1960s, deinstitutionalisation had turned into a deluge by the 1980s despite evidence of the problems it caused, largely due to the absence of alternate care pathways and infrastructure (Payne, 2009).

Deinstitutionalisation remains the dominant discourse in mental health, emphasised by the World Health Organization (WHO) as a central strategy to mental health care. The lack of clarity on clinical processes and outcomes of deinstitutionalisation, along with a lack of commensurate development of community-based mental health care services, has led to criticism of its effectiveness, and consequent increase in homelessness and imprisonment of people living with severe mental illness (Lamb & Weinberger, 2001; Pycha *et al.*, 2011; Sayers, 2001; Sisti *et al.*, 2015; Thornicroft & Tansella, 2006). National governments reflect and propagate deinstitutionalisation in varying degrees in policy statements, which is often done to meet international standards or declarations through some level of implementation (Shen & Snowden, 2014).

1.3.1.1 Deinstitutionalization in the colonised world

Closure of hospitals and development of community care approaches in Western Europe and North America coincided with the end of colonial rule in most parts of the colonised world. This power shift left little opportunity for

the development of alternate care systems in the newly decolonised world, where psychiatric hospitals continue to dominate what exists of mental health systems. (Cohen *et al.*, 2014; Shen *et al.*, 2017).

1.4 Mental hospitals: current trends

Mental hospitals continue to remain the crux around which care for the severely mentally ill revolves (Chatterjee, 2017). Most countries have mental hospitals, except a few small island nations in the Americas and Western Pacific, where their small populations make such facilities unviable. European countries such as Iceland, Italy and Sweden started deinstitutionalising mental hospitals in the second half of the 20th century. (Morris *et al.*, 2012).

Despite a shift from institutions to general hospital psychiatric wards and community-based residential facilities, mental hospitals continue to contribute about 80% of beds in mental health care globally, with higher income countries having a far higher share of hospital beds than lower income countries. Between 2011 and 2014, higher income countries saw a 5% drop in mental hospitals and a 30% decrease of mental health care beds (Morris *et al.*, 2012). Currently, mental hospitals account for 11.3 beds per 100,000 people globally, with low income countries at 1.6, lower-middle income countries at 5.1, and upper-middle income countries at 16.7 median beds per 100,000 people (WHO, 2018). Data on mental hospital beds between 2005 and 2011 point to a continued, albeit slow, process of deinstitutionalisation with a reduction of about 11 beds per 10 million people (Morris *et al.*, 2012). In comparison to 11.3 beds per 100,000 in mental hospitals there are only 1.4 beds per 100,000 in general hospital psychiatric wards globally (Morris *et al.*, 2012; WHO, 2018). Thus, globally, 62% of beds for mentally ill patients are in mental hospitals, 21% in general hospital units and 16% in community-based residential facilities (WHO, 2018).

Despite the reduction in mental hospital beds, there has been a 20% increase in the global median admission rate. People with non-affective psychosis comprise one-quarter to one-third of mental hospital admissions; those with bipolar disorders and major depression constitute one-tenth of the admissions. More than half of the overall admissions are diagnosed with other mental disorders. In LMICs, mental hospitals serve the dual function of

an acute care service along with a high percentage of people who stay longer than a year, indicating a more institutionalised function of mental hospitals (WHO, 2018).

Continuity of care remains an issue post discharge, especially in lower income settings (Lora *et al.*, 2017). The median admission rate per 100,000 people is 8.6 in low-income countries, 32.2 in lower-middle income countries and 56.3 in upper-middle income countries (WHO, 2018). Nine percent of people in mental hospitals stay more than a year in low- and middle-income countries. This number is at 11% in lower-middle income countries and at 29% for upper-middle income countries (WHO, 2018). Globally seven out of 10 mental health care professionals work in mental hospitals (Morris *et al.*, 2012).

Services for psychosocial interventions focused on rehabilitation, especially for those with severe mental illness, are scant. Less than 50% of all developed countries have reported having such services at a majority of their treatment points. Only 25% countries in the WHO South-East Asia Region reported having psychosocial interventions at a majority of their services (Morris *et al.*, 2012). Outpatient services, non-hospital-based community residential facilities, follow-up care and psychosocial interventions mark the critical elements of community-based care. With a vast majority of developed countries not providing these services and a dearth of such services in the low- and middle-income world, mental hospital-based services remain the only viable form of care globally (WHO, 2018).

The proportion of mental health resources allocated to mental hospitals is an important proxy measure of the centralisation of mental health care systems. Globally 67% of mental health resources were allocated to mental hospitals, with LMICs at 73% and high-income countries at 54% (Morris *et al.*, 2012). In 2017, lower-middle income countries show reducing expenditure (50.47%) of allocated resources on mental hospitals, however resource allocation to mental hospitals continues to remain high in low income and upper middle income countries (WHO, 2018)

Median government expenditure per capita on mental health across LMICs is relatively small – US\$0.02 in low-income countries, US\$1.05 in lower-middle and US\$2.62 in upper-middle income countries. For low-income

countries 100% of their total spend is on mental hospitals, for lower-middle income countries it is 50.48% and for upper-middle income countries, 85.88% (WHO, 2018).

It is also important to note that overall, financial resources allocated for mental health by governments and from development assistance remains alarmingly low for many of the poorest countries of the world. Despite an absolute increase in funding since 2007, development assistance for mental health has never exceeded 1% of the global development assistance for health and was just US\$0.85 per DALY, compared with \$144 for HIV/AIDS and \$48 for tuberculosis and malaria in 2013 (Patel *et al.*, 2018).

1.5 Evolution of psychiatry in India

1.5.1 Precolonial times

The Ayurveda and Unani systems of medicine practised in India during the pre-colonial era have references to understanding personality and temperament, and recognition and treatment of mental ailments. A combination of herbal medicines, rituals and faith healing, along with practices like yoga and meditation formed the predominant modes of treatment (Sharma, 2006; Somasundaram *et al.*, 1986; Wig, 2015). There are some accounts of a collection of “curious humans” in India before the arrival of the East India Company in 1608 such as Shah Daula’s shrine in Gujarat and Punjab (Shaw, 1932) and the presence of some sort of an asylum for the mentally ill at Dhar in Mandu, Madhya Pradesh, in the 15th century during the Khilji reign (Sharma & Varma, 1984). The Portuguese brought with them modern medicine and hospitals in the 17th century to Goa, however, mental asylums and the segregation of “lunatics” was a British concept (Sharma, 1946; Sharma & Chadda, 1996; Somasundaram, 1987).

Modern psychiatry was ushered into colonial India by the British with the establishment of the first asylum in Calcutta (Kolkata) in 1787, possibly to cater to the needs of European soldiers and Indian sepoys employed by the East India Company (EIC). The focus was custodial rather than curative (Ernst, 2011; Nizamie & Goyal, 2010).

An overview of Asylums- their growth and current status in India			
First phase of asylums in colonial India	1858-1914	1914-1947	Post Independence
1787-First asylum, Calcutta 1794- Kilpauk, Madras (Chennai) 1795- First asylum for native Indian soldiers Monghyr, Bihar 1806-asylum at Colaba, Bombay 1818- Bengal inquiry into conditions of asylums 1821-asylum at Patna, Bihar 1840-asylum at Lahore, Punjab (Pakistan) 1840-Investigation of the state of native lunatics 1854- asylum at Banaras 1855-asylum at Dacca (Bangladesh)	1858- Lunacy Act 1858-asylum at Agra 1862-asylum at Bareilly 1864-asylum at Nagpur 1865-asylums at Poona, Dharwad, Ahmedabad, Ratnagiri & Hyderabad 1866- asylums at Jabalpur, Madhya Pradesh & Elichpur Bihar 1871-asylums at Waltair and Trichinappally in Southern India 1874-asylums Bhowanipore (Calcutta), Patna, Dacca, Behampur & Dulanda (Calcutta) and Cuttack 1876-asylum at Tezpur, Assam 1905- Central supervision of asylums 1912-Indian Lunacy Act	1914-World War I 1918- Central European Institute of Psychiatry- Ranchi (currently CIP-Ranchi) 1923- Lunatic asylums renamed as mental hospitals Charge shifts from inspector general prisons to civil surgeons Psychiatrists to be appointed as full time officer Introduction of rehabilitation services 1930-Introduction of family units 1933- First OP service at RG Kar MC, Calcutta -Edwin Mapother's visit to India Formation of the association of medical superintendents 1946- Taylor's report of mental hospitals in India and Cylone Bhole committee report-1946 First policy recommendation	7 new MHs in Gujarat, J&K, Punjab, West Bengal and Delhi- post independence 1955-AIIMH (NIMHANS) starts training of mental health professionals 1960s- Out patients clinics started by mental hospitals Expansion of GHPUs in the 1960s Landmark PIL-1981-Upendra Baxi vs UP led to NHRC appointed as monitoring body for mental hospitals 1990s NMHP-1982 Mental Health Act- 1987 DMHP-1996 2003- NMHP re-strategized, Mental hospitals to be developed as teaching institutes 2016- DMHP in 1/3 rd of India's districts 2018 Mental Health Care Act

Figure 1-1: An overview of asylums-their growth and current status in India

1.5.2 First phase of asylums in colonial India

The development of asylums in India can be distinguished into different phases (Figure1-1). The earliest phase began in the late 18th century under the EIC with the establishment of the first asylums in Calcutta, Bombay and Madras. It is noteworthy that the establishments of these early asylums coincided with one of the most politically and socially unstable phases in Indian history, with Mughals losing power, the rise of Marathas in most of central India and the Sikhs in the north. This phase lasted up to 1857 (Menon, 1946; Pinto, 2018; Sharma & Chadda, 1996; Wig, 2015).

In the consequent decades, asylum gates were opened for the native poor. Asylums held a precarious position between the judicial and medical branches of the colonial government, and clinical practices were 'permeable' to indigenous ideas and local practices. Although the responsibility for governance was increasingly given to doctors, psychiatric practice held competing and complementary ideas about the definition of "insanity" and its treatment (Bhattacharyya, 2013; Ernst, 2011). European and Indian natives were both housed in Indian asylums, though segregated until 1821. After

1821, government officials sent mentally ill Europeans to any of the three asylums of Bombay, Madras or Calcutta for brief periods until they could be sent back to Europe. Indian asylums were a visible feature of the social and political distance between the ruler and the ruled, a hallmark of colonial power in India (Jain, 2003). Even in the early stages of their establishment, the asylums housed Indian natives who were largely homeless wanderers picked up by the police on the streets. The government believed that families and communities should provide for those who were not a threat to self or others. The confinement of the mentally ill in British India echoed the administrative, institutional, and therapeutic patterns and preconceptions prevalent in Britain during the early 19th and 20th century (Ernst, 2007).

Conditions in mental hospitals came under scrutiny early on in India, particularly with respect to their custodial and restrictive nature and common occurrence of human rights violations. The Bengal Enquiry of 1818 and investigation of the state of native lunatics in 1840 were first of several such enquiries (Jain, 2003; Murthy *et al.*, 2016).

1.5.3 1858 to 1914

The period from 1858 to 1914 consisted of laying an institutional network and the development of a legal framework for the care of the mentally ill. This development was marked by two major events – the shifting of power from the East India Company to the Crown and the Lunacy Act of 1858. The act provided guidelines on the establishment of asylums and procedures for admitting patients. This act was further modified in 1888 to include guidelines to the admission of the criminal mentally ill and remained the backbone of the legal apparatus for dealing with the insane. Psychiatric care in modern India continues to echo the framework laid out during this period (Mills, 2006; Pinto, 2018; Somasundaram, 1987). At least 16 new asylums were built between 1860 and 1870, and many asylums built earlier were expanded (Mills, 2006). The period between 1858 and 1880 saw an exponential increase in the number of mentally ill housed in asylums. While largely admitted by state officials, mentally ill patients in many instances were enrolled into asylums by the community as well, as they realised there was an opportunity to shift the cost of care to the administration. The treatment regimen during this time was a combination of moral management and drug

treatments aimed at subduing the patient and then engaging them in work. This largely remained the norm in most asylums until 1914. Non-medical European officers ran these asylums with equally untrained staff. Concerns over the living conditions in asylums resulted in the transfer of their control from the inspector general of prisons to the directorate of health services, and at the local level, to the civil surgeons in 1905. The intent to have central supervision by legislation led to the Indian Lunacy Act of 1912 (Mills, 2006; Sharma, 1946).

1.5.4 1914 to 1947

The beginning of World War I (WWI) ushered in a new and distinct phase of psychiatry in India. Two important trends dominate the period from 1914 to 1947. The first was increased demand for institutions and their consequent expansion and the second was the increased use of asylums by the community. Indian soldiers returning with shell shock needed to be accommodated and this put pressure on the asylums, especially the ones in the Bombay Presidency. The years after 1914 were characterised by gradual expansion of existing asylums, in contrast to the grand building of new ones in the earlier phase. The increasing use of the asylum by the community is reflected in an especially dedicated ward at the Yerwada mental asylum in Pune for women from the Parsee community – a commercial and elitist community of Bombay – with a fund to appoint a culturally similar nurse paid for by the Parsees. The pressures of WWI and the deployment of European officers overseas resulted in the ‘Indianisation’ of most of the senior posts of the asylums. It was also during this time that psychiatry entered general medical training and the Grant Medical College of Bombay appointed a professor of psychiatry. Indian doctors were increasingly at work in mental hospitals and were now trained in psychiatry (Mills, 2006).

The evolution from asylums to more humanistic mental health institutions in India began in the 1920s marked by significant developments – internationally, by the development of psychotropic medicines, and in India, by the development of general psychiatric units. The first psychiatric outpatient clinics were set up in 1933 in Calcutta and 1938 in Bombay. Independent India saw a surge in primary care and community worker services; however, non-mental health specialists were used only by a handful

of psychiatric hospital settings such as those in Amritsar, Madras and Calcutta (Chadda & Sood, 2018; Menon, 1946; Van Ginneken *et al.*, 2014).

1.5.5 Psychiatry in a newly independent India

Vestiges of colonial psychiatry continued to dominate the provision of mental health care in India. Probably the best accounts of institutional care in India are found in the reviews conducted by Edwin Mapother in 1938 and Moore Taylor's report tabled in the Bhole Committee Report of 1946 (Bhole, 1946; Jain, 2003).

Mapother was invited to Ceylon by Dr S.T. Gunasekara, who was the first Ceylonese Medical Director of the island. Dr Gunasekara and Mapother drew their connection from being associated with the Rockefeller Foundation which likely put the Maudsley psychiatrist uppermost in the mind of the new Medical Director of Ceylon when he turned his attention to the mental health of the island. The result of this trip was to be a series of documents that provide a snapshot of psychiatry in South Asia in the years before the Second World War and the subsequent end of the British Empire (Mills & Jain, 2007).

The Government of India set up the 'Health Survey and Development Committee', popularly known as the 'Bhole Committee' in 1943 to draw up the scheme of health services for the newly emerging independent India. The recommendations made by the committee remain a landmark in the development of health services in the country (Bajpai & Saraya, 2011). Lt. Col Moore Taylor was the superintendent of European Hospital in Ranchi (today the Central Institute of Psychiatry-Ranchi) till 1946. He was asked to review the mental health situation in India and make recommendations as part of the Bhole committee. The European hospital of Ranchi was one of the two hospitals of India which had some positive reviews in Mapother's reports. Taylor had several meetings with Mapother in London and used these discussions to outline proposed reform of psychiatric services in Independent India (Aich *et al.*, 2018; Jain *et al.*, 2018).

These reports discussed the poor condition of asylums and made several recommendations for independent India to take forward (Bhole, 1946; Jain, 2003; Murthy *et al.*, 2016; Nagaraja & Murthy, 2008).

Colonel Taylor's key observations were -

- “The majority of the mental hospitals in India were outdated and were designed for detention and safe custody without regard to curative treatment.
- “The worst of them were Punjab Mental Hospital, Thane Mental Hospital and Nagpur Mental Hospital. These hospitals had the savour of the workhouse and the prison and should be rebuilt.
- “Seven of the largest mental hospitals in India had men appointed as superintendents at salaries that a first-class mechanic in Tata Works would get.
- “The subordinate medical staff are also untrained in psychiatry with one medical officer for 200 patients.
- “The position regarding ward attendants and nursing staff is especially unsatisfactory in terms of inadequacy of numbers and insufficiency of training” (Bhore, 1946).

Most of Colonel Taylor's observations resonate with the situation of mental hospitals in India today (Murthy *et al.*, 2016).

Since India's independence, superintendents of mental hospitals met periodically to discuss improvements in living conditions and facilities in the hospitals and the need for comprehensive care and training. Change, however, has been slow and less significant. The first report of the Human Rights Commission of 1999 found the situations observed by Colonel Taylor remained unchanged. (Channabasavanna & Murthy, 2004). A few reasons for the lack of fast and visible change are: 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 of superintendents (Murthy *et al.*, 2016).

In 1975, the World Health Organization published the papers presented at the seminar on “Organization of Mental Health Services in Developing Countries,” which was yet another milestone and saw a series of developments (World Health Organization, 1975). The National Institute of Mental Health and Neuro Sciences (NIMHANS) started its Community Psychiatry Unit in 1974 (National Institute of Mental Health and

Neurosciences, 2018) which, in years to come, would lay the foundation of community based mental health care in the country. WHO launched a multi-country study to develop and examine a model to provide basic mental health services through the existing health system (World Health Organization, 1975). The study that became famous as the Raipur Rani experiment brought to light the kind of mental health problems prevalent in a rural community for the first time (Murthy *et al.*, 1978; Wig *et al.*, 1981). At about the same time, the country was trying out other community-based programs. NIMHANS's Sakalwara programme, was one such pilot, which coincided with the declaration of Alma Ata (Van Ginneken *et al.*, 2014).

Independent India struggled to evolve community-based services for mental health care and announced a National Mental Health Program in 1982, becoming one of the first LMICs to develop such a programme. NIMHANS launched the Bellary community mental health programme in 1985 for a period of five years. (Van Ginneken *et al.*, 2014). This programme formed the basis for the District Mental Health Program launched in 1996 (Gururaj *et al.*, 2016). The DMHP was launched in one district each of the four states of Andhra Pradesh, Assam, Rajasthan and Tamil Nadu and gradually spread to 27 districts by 2002, 100 districts in 2007 and 123 districts in 2012, with the current coverage being less than one-third of the districts in the country (Murthy *et al.*, 2016). The story of community-based mental health through the DMHP is diverse, with varied accounts of it being a highly medicalised form of service that has not panned out into reality on the ground (Jacob, 2011; Jain & Jadhav, 2009; Sarin & Jain, 2013).

1.5.6 Mental health care legislation in India

Legislation played a critical role in the spread of asylums in Britain in the 19th century, with acts such as the Asylums Act of 1808 and 1845 allowing counties to build asylums and the Poor Law Act of 1834 that included “idiots” as “lunatics” and allowed them to be admitted to asylums. These laws had a bearing on the evolution of mental health care legislation in India (Pinto, 2018).

India got its first mental health legislation under British rule in 1858. These guidelines were further modified in 1888 by a specially appointed committee in Bengal with a focus on the admission and treatment of criminal lunatics

(Sharma & Chadda, 1996). The 1912 Lunacy Act saw the first winds of change where it moved mental asylums from inspector generals of prisons to civil surgeons. The legislation also mandated appointment of specialists in psychiatry as full-time officers and all asylums were brought under central government rule. This act continued into Independent India until it was replaced by the Mental Health Act of 1987. The 1987 Act continued in its emphasis of psychiatric institutions reforming many provisions of the 1912 Act and bringing vigilance over the conditions in psychiatric hospitals (Ganju, 2000; Kala & Kala, 2007; Van Ginneken *et al.*, 2014). The 1987 Mental Health Act has only recently been replaced by the Mental Health Care Act (MHCA) of 2018 which is aligned to the principles of United Nations Convention on Rights of Persons with Disabilities (UNCRPD) (The Gazette of India, 2017). The MHCA, passed at length after discussions, emphasises community-based care. Though it has attracted praise for its focus on human rights, there are serious concerns on the disparities between what the law proposes and the costs of its implementation, especially in a country like India which spends less than one percent of its health budget on mental health care (Duffy & Kelly, 2019; Patel V, May 18 2016; Rao *et al.*, 2016; Sachan, 2013).

1.5.7 Psychiatric hospitals in current day India

Judicial intervention has been a principal driver of change in the condition of mental hospitals in India. One of the first Public Interest Litigations (PILs) on the state of mental health care was filed by Dr Upendra Baxi in 1981 regarding the inhuman condition of a home for the mentally ill in Agra. This PIL was the basis on which the Supreme Court of India handed over monitoring of mental hospitals to the National Human Rights Commission (NHRC) in the 1990s. Other PILs such as BR Kapoor vs Union of India, which led to the transformation of the Shahdara mental hospital to the Institute of Human Behaviour and Allied Sciences (IHBAS) (Murthy *et al.*, 2016), have been instrumental in the reformation of mental hospitals.

Another key incident that brought attention to the plight of people with severe mental illness was the 2002 Erwadi temple fire, which killed 26 people. The tragedy also led to calls for the reform of mental hospitals in India. Figure 1-

2 discusses the Erwadi incidence in further detail (Antony, 2002; Huddar *et al.*, 2020; Murthy *et al.*, 2015; Murthy, 2001; Trivedi, 2001).

The National Mental Health Program (NMHP) launched in 1982 was re-strategized in 2003. Modernising state mental hospitals became the cynosure of the reformation effort, and 11 such hospitals were designated as centres of excellence. Some state hospitals, such as the Regional Mental Hospital Nagpur (RMHN), received funding for development as teaching institutes (Ministry of Health & Family Welfare, 2016). However, not all of this translated into reality – the RMHN does not yet have a Psychiatric Social Work teaching course in place.

Erwadi- A turning point in India's mental health care

Around predawn on 6th of August 2001, the little town of Erwadi, 350 kilometers south of Chennai in Tamil Nadu woke up to shrieks and wails. A freak fire had broken out on the precincts of the town shrine. The fire trapped 43 people with severe mental illness who were chained in a little shanty made of coconut palms. The towners initially thought these were the usual rantings emanating from the privately owned shanty, but they soon saw a blaze erupting from the shanty. The fire claimed 26 lives, 11 of whom were women. The country erupted in an outrage over the plight of people living with a severe mental illness not just at this shrine but many such across the country. The Government ran an investigation into all such shrines across Tamil Nadu. Families whose loved ones were kept at such shrines were offered a place in mental hospitals. However, most families refused this offer choosing instead to keep their family member in a shanty with chains. Shortage of mental health professionals, a largely bio-medical approach to psychiatry and people's own cultural beliefs and tradition place faith healers and healing shrines as a key provider of mental health care services in contemporary India. There have been diverse approaches to deal with their presence from countering them to working alongside them as an important stakeholder and the first point of access for mental health services.

Even today the shrine at Erwadi continues to house people with a mental illness. Since 2015, the shrine is visited by a government appointed psychiatrist on a regular basis.

The Regional mental hospital of Nagpur shares space with the famous shrine dedicated to Tajuddin. Tajuddin regarded as a saint, was a soldier of the Indian army under the British and was admitted to the mental hospital in 1892. People with severe mental illness, discharged from the hospital and not taken in by their families are often seen at this shrine.

Figure 1-2: Erwadi - A turning point in India's mental health care

India currently has 47 mental hospitals with 18,307 beds spread inequitably across different states. A varying degree of annual occupancy is reported by hospitals, with some being as low as 17% and some at 100%. At least nine hospitals report having closed wards while information for the same is

missing for most hospitals. In general, living conditions have improved since the last decadal report by the NHRC. However, overcrowding, especially in the older and larger hospitals of Maharashtra, Kerala and West Bengal continue to remain a serious issue. Other issues include involuntary admission and violation of women’s rights, compulsory head shaving and inadequate sanitation. Durations of in-patient hospital stay have reduced considerably. 65% patients have a hospital stay of less than three months. These findings have been drawn from the last decadal report of the NHRC (Murthy *et al.*, 2016). A nationwide survey of mental hospitals published in 2019 additional indicated that at least 36.25% people living in mental hospitals have been there for more than a year. The average age of patients in Indian mental hospitals is at 45 years. Women constitute a larger proportion of the long-stay patients. About 33% of those who end up in long term institutional care are brought by their families. The median duration of institutional stay is six years, with 11.4% having lived in institutional care for over 25 years. Most long-stay patients live in closed wards (77%) with 1% in solitary confinement. While most long-stay people express a desire to return to their families, this is often not possible, due to a resistance on the part of families in accepting them back (Narasimhan *et al.*, 2019). Most hospitals have at least 50% staff vacancies. This affects the staff patient ratio and has an impact on the range of services offered (Murthy *et al.*, 2016; Nagaraja & Murthy, 2008). Table 1-1 describes the state wise distribution of mental hospitals in India. This information was drawn from the state wise reporting covered in the decadal report of NHRC (Murthy *et al.*, 2016).

Table 1-1: State-wide distribution of mental hospitals in India

States and Union Territories?	No. of Govt- MHs	Occupancy	No. of closed wards	State mental health plan	State mental health rules
Andaman & Nicobar	0	NA	NA	No	NI
Andhra Pradesh	1	63%	6	No	NI
Arunachal Pradesh	1	NI	NI	NI	NI
Assam	1	100%	0	NI	NI
Bihar	1	17%	NI	NI	NI
Chandigarh	1	NA	NA	No	NI
Chhattisgarh	1	60%	2	NI	NI
Dadra & Nagar Haveli	0	NA	NA	No	NI
Daman & Diu	0	NA	NA	NI	NI
New? Delhi	1	87.70%	11	Yes	Yes

States and Union Territories?	No. of Govt- MHs	Occupancy	No. of closed wards	State mental health plan	State mental health rules
Goa	1	NI	NI	No	NI
Gujarat	4	NI	NI	No	Yes
Haryana	1	2.50%	2	No	No
Himachal Pradesh	1	62.90%	NI	No	No
Jammu & Kashmir	2	NI	NI	NI	NI
Jharkhand	2	96%	0	NI	NI
Karnataka	2	57% *	7	Yes	Yes
Kerala	3	NI	NI	Yes	Yes
Lakshadweep	0	NA	NA	NI	NI
Madhya Pradesh	2	NI	NI	No	No
Maharashtra	4	Ni	Ni	No	No
Manipur	1	NA	NA	No	No
Meghalaya	1	49%	7	NI	NI
Mizoram	0	NA	NA	NI	NI
Nagaland	1	56%	Nil	NI	NI
Odisha	1	NI	NI	No	No
Puducherry	0	NA	NA	NI	NI
Punjab	1	NI	NI	No	No
Rajasthan	2	NI	NI	No	NI
Sikkim	0	NA	NA	No	NI
Tamil Nadu	1	NI	NI	No	NI
Telangana	1	NI	NI	No	No
Tripura	1			No	No
Uttarakhand	1	80%	NI	NI	NI
Uttar Pradesh	3	76.13%	8	NI	NI
West Bengal	4	NI	NI	No	NI
	47		43		
* information only for DIMHANS. NA-Not applicable. NI -No information or not reported					

India's mental health care needs are very high with almost 200 million people currently living with a diagnosable mental illness and very little availability of care (Sagar *et al.*, 2020). The pressure to deinstitutionalise patients from mental hospitals following western mental health care models is evident in the low utilisation of beds in newer hospitals, and increasing trends of systematic trans-institutionalisation of long-stay people with severe mental illness from hospitals into places like old age homes and beggars' homes that are not equipped to deal with the needs of people with SMD (Barnagarwala, 2020). This clearly calls for much needed reform of mental hospitals and their role in fulfilling service user needs in contemporary India.

1.6 Conclusion

“Lunatic asylums,” “mental hospitals” or “psychiatric hospitals;” all names for institutions for the care of mentally ill, remained an area of interest in the scientific community for a large part of the 20th century. However, this interest has sharply declined in the last three decades (Cohen & Minas, 2017) . Additionally, the emerging field of global mental health has prioritised research into community mental health (Frankish *et al.*, 2018) with a focus on common mental disorders and depression, while neglecting mental hospitals. Hospitals and long-stay institutions are not mentioned in any of the top 25 Grand Challenges in Global Mental Health (Collins *et al.*, 2011; Patel V, May 18 2016). The appalling conditions and abuse in these hospitals and their exposure has been left to media, non-governmental organisations and human rights commissions. There is a disconnect in the community-based focus of global mental health and what is happening to the seriously mentally ill, often behind the closed walls of institutions. The shift in the global mental health narrative to community-based care has left these hospitals in a time warp. LMICs need a pragmatic approach to implementing mental health, with evidence-based reforms of psychiatric institutions to meet the needs of service users today. There is an urgent need for robust research to point the way forward in reinventing the role of psychiatric hospitals – in humane and evidence-based care – for people with severe mental illness.

2 Systematic review of literature for SITAR

2.1 Chapter overview

Psychiatric hospitals or mental asylums grew around the world in the colonial era. Despite concerns over quality of care and human rights violations, these institutions continue to provide the majority of mental health care in most low- and middle-income countries (LMICs). We sought to review the evidence of mental hospital reform and associated patient outcomes using an integrative review methodology. This chapter presents the systematic literature review methodology and our findings thereof. This literature review has been brought out as a publication 'Psychiatric hospital reform in low- and middle-income countries: a systematic review of literature (Raja *et al.*, 2021). The paper is presented in Appendix 12.1.

2.2 Introduction

Mental asylums are a hallmark of the globalisation of psychiatry. Established globally by European colonisers, they continue to provide care for the severely mentally ill. They account for the majority of mental health care available in LMICs, and continue to consume a bulk of the financial resources allocated for it. Care provided in mental hospitals is shaped by a range of factors including legal reforms passed in the late 20th and early 21st century (Chatterjee, 2017; Fisher *et al.*, 2009; WHO, 2018). Table 2-1 provides a snapshot of mental health services and resource allocations in LMICs.

Table 2-1: Mental Health Service Availability and Resource Allocation In LMICs

Variables	Upper-Middle Income Countries	Lower-Middle Income Countries	Low-Income Countries	Total
Median rate of mental health care facilities per 100,000	0.5	0.1	0.1	0.22
Median rate of mental hospital facilities per 100,000	0.07	0.03	0.01	0.06
Median rate of mental health care beds per 100,000	24.3	6.3	1.9	16.4
Mental hospital beds per 100,000	16.7	5.1	1.6	11.3
Median mental health admission rate per 100,000	117.2	43.8	17.0	99.1
Median mental hospital admission rate per 100,000	56.3	32.2	8.6	56.3
Population of mental hospitals with stay > 5 years	12%	5%	1%	8%

Variables	Upper-Middle Income Countries	Lower-Middle Income Countries	Low-Income Countries	Total
Population of mental hospitals with stay for 1-5 years	17%	6%	8%	10%
Population of mental hospitals with stay < 1 year	70%	89%	91%	82%
Median per capita government expenditure on mental health	2.62 US\$	1.05 US\$	0.02 US\$	2.5 US\$
Median per capita government expenditure on mental hospitals	2.25 US\$	0.53 US\$	0.02US\$	
Mental health workforce per 100,000	20.6	6.2	1.6	9
(WHO, 2018)				

2.3 Objectives of the systematic literature review

Given this backdrop, a systematic review of literature synthesizing research on psychiatric hospital reform, particularly in LMICs, was essential to frame stronger, more appropriate reform programmes. The review aimed to understand the process and outcome of psychiatric hospital reform in LMICs by:

- Distilling evidence and scientific literature around mental hospital reform in LMICs and documenting the process and outcome of reform.
- Understanding the impact of structural and process reform of psychiatric hospitals on patient outcomes in LMICs.
- Identifying gaps in current evidence and research with regard to the reform of psychiatric institutions in LMIC country settings.

2.4 Methods

We adopted an integrative review methodology for this study. It includes the four steps of a systematic process, i.e. search, appraisal, synthesis and analysis. This allows for inclusion of both experimental and non-experimental research (Booth *et al.*, 2012). The review protocol was registered on PROSPERO CRD42019130399. We followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Statement and Consolidated Standards of Reporting Trials (CONSORT) Statement (Moher *et al.*, 2011).

2.4.1 Eligibility criteria

The review sought to identify papers that studied mental hospitals or similar long-term care facilities in 137 LMICs. Studies conducted between 1980 and May 2019, that focused on any aspect of reform for adults (*age 18 and upwards*) with severe mental illness and published in English were considered. In addition, we did a citation search of all included publications. Studies excluded were: non-English publications, studies from high-income countries, interventions in general hospital and community settings for adolescents / children (*below age 18*), and those that studied non-Severe Mental Disorders (SMDs). Studies published before 1980 were also excluded. The detailed PICOs for the review is shown in Table 2-2.

Table 2-2: PICOS for the systematic literature review

Population	People living in an institute Mental hospitals / Psychiatric hospitals / Asylums / Psychiatric institutions in Low- and Middle-Income Country (LMICs) as defined by the World Bank
Intervention	Intervention in the institutional setting Transition / Reform / Change / Modernisation / Improvement / de-institutionalisation
Comparator	People who have not received the intervention or to the setting prior to the intervention A comparator is not necessary
Outcomes	Change in patient level indicators – symptoms, functionality. Process indicators such as length of stay, number of admission episodes, etc.
Study Design	Randomised and non-randomised study designs (All publications) From 1980 till date

2.4.2 Search strategy and data sources

A two-pronged search strategy was used a) database search and b) hand searching to identify relevant studies.

We searched five databases: Medline, PsycINFO, Web of Science, Scopus and Cochrane using the key words and combinations reflected in Table 2-3 below. We used a country specific search since the combination of key words for LMICs does not appear readily on databases. We conducted this search between Nov 2019 and February 2020. For the hand search, we examined the reference lists of all identified studies. The search strategy and syntax are given in Table 2-3.

Table 2-3: Search strategy and syntax

Search Terms	
Population	
Adults	
Setting	
Mental hospital	
Psychiatric hospital	Resources
Mental asylums	Bibliographic & Journal Databases
Psychiatric institutions	APA PsycINFO
	PubMed/Medline
Intervention	Cochrane Reviews
Reform	Web of Science
Change	Scopus
Modernisation	
Improvement	
Deinstitutionalisation	
Location	
Low- and middle-income countries (lower, mid, and upper mid income) as defined by the World Bank – 137 countries	

2.4.3 Data extraction and quality assessment

The first author (*T.R.*) ran the primary search, assessed eligibility criteria for all retrieved papers and assessed the quality of all included studies. The first author also extracted data for all included studies with 100% of the samples being extracted independently by another author (*K.E.*). RATS (*Relevance, Appropriateness, Transparency and Soundness*) qualitative research review guidelines were used for the quality assessment of the seven qualitative studies. The RATS scale comprises 25 questions that assess the relevance of the research question, appropriateness of the methods used, transparency of the study and methods, and soundness of the approach used for interpretation of findings. For the purpose of this review, each question on the RATS scale was assigned a binary value (*yes - 1 point and no - 0 points*) to effectively make a judgement on the quality of the included qualitative research papers. This approach was drawn from a previous systematic review using multiple types of studies (Godlee *et al.*, 2003; Leamy *et al.*, 2011). The Effective Public Health Practice Project (EPHPP) (Evans

et al., 2015) was used to assess the quality of the five quantitative studies included in the review. The four reports included from the citation search of included studies were not assessed for quality since they are reports, three of them are country reports and one is a programme report.

Data was extracted and tabulated independently by two authors (*T.R. and K.E.*) for all papers meeting the eligibility criteria. The data extraction tool was developed by the first author (*T.R.*) and was modelled on the data extraction templates for RCTs and non RCTs (Cochrane., 2014). The tool comprised the following categories: general information (*title of the study, study authors, type of study, journal of publication, year of publication, country of study*), intervention setting (*type of facility, study period, number of patients in the study, length of stay, admission and discharge process*), costing details (*annual budget of the institution*), reform components (*triggers, elements and cost of reform*), and outcomes (*patient data on clinical, social and functional outcomes*).

2.5 Results

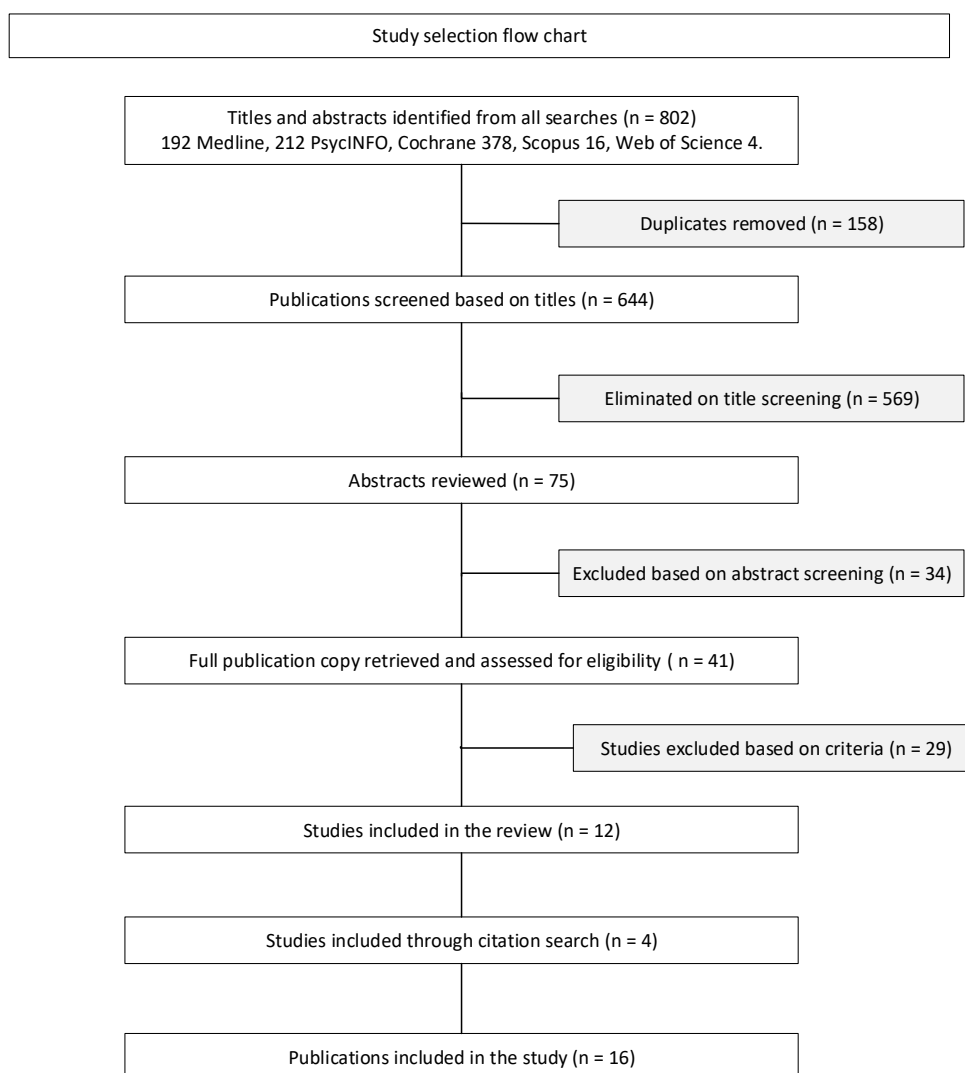


Figure 2-1: Study selection flow chart

802 studies were identified through the database search of which, following exclusion of duplicates, abstract reviews, and full text reviews 12 studies met the inclusion criteria. The hand search yielded four additional reports. Of the 16 studies included in this review, seven were varied qualitative studies including, two case studies, one personal reflection, one ethnographic study, one observational study and one historical study. Five of the 16 included articles and reports were quantitative studies. Of these, two were randomised controlled trials, one was a non-randomised control trial, one case control study and one quasi-experimental study. The four publications found through citation search included three country level reports and one programme

report. Quality assessment indicated high variability with nine of the 12 assessed studies as weak, two as moderate and one as high quality. The study selection flow chart is included as Figure 2-1.

2.6 Data synthesis

A preliminary synthesis was developed using tabulation. Data was directly reported and cumulated where possible for quantitative variables. For qualitative data, emergent themes were drawn out and a vote count was undertaken to identify the frequency with which themes appeared. The studies covered a publishing period from 1994 to 2017 and represented eight countries: India (Murthy *et al.*, 2017; Murthy *et al.*, 2016; Nagaraja & Murthy, 2008; Parivartan, 2015; Varma, 2016), China (Fan *et al.*, 1994; Jin & Li, 1994; Xiang *et al.*, 2007), South Africa (Kruger & Lewis, 2011; Uys *et al.*, 1996), Brazil (Bandeira *et al.*, 2015; Huf *et al.*, 2012), Argentina (Hillman, 2007), Grenada (Fisher *et al.*, 1988), Georgia (Makhashvili & van Voren, 2013) and Sri Lanka (Ganesan, 2017). All the studies were based in state run psychiatric hospitals. A total of 112 hospitals were covered through these studies, out of which, there were 60 unique hospital settings (studies in India were done in the same hospital). The number of hospitals covered per country ranged from 47 in India to one each in Grenada and Sri Lanka (Bandeira *et al.*, 2015; Fan *et al.*, 1994; Fisher *et al.*, 1988; Ganesan, 2017; Hillman, 2007; Huf *et al.*, 2012; Huf *et al.*, 2011; Jin & Li, 1994; Kruger & Lewis, 2011; Makhashvili & van Voren, 2013; Murthy *et al.*, 2017; Murthy *et al.*, 2016; Nagaraja & Murthy, 2008; Parivartan, 2015; Uys *et al.*, 1996; Varma, 2016; Xiang *et al.*, 2007). A high variability was found in the number of patients/number of beds with some studies covering as low as 10 patients (Uys *et al.*, 1996), with the highest being 237 from India (Parivartan, 2015). The three qualitative studies do not mention any numbers (Makhashvili & van Voren, 2013; Murthy *et al.*, 2017; Varma, 2016). Since there is high variability in the numbers reported, no further analysis was undertaken. Characteristics of all included studies are reported in Table 2-4 below.

Table 2-4: Characteristics of studies included in the systematic literature review

No	Quality Rating	Full citation	Country	Method	Number of hospitals	Study participants	Number of patients / beds in hospital or unit	Duration of stay
1	EPHPP (score 3/ on?) Weak	Uys, L., Mhlaluka, N. & Piper, S. (1996) An evaluation of the effect of programme changes in an acute psychiatric unit. <i>Curationis</i> , 19 (3): 21-27.	South Africa	Quantitative Study- Quasi-experimental study	1	34	520 female admissions unit	-
2	RATS (score 5/25) Weak	Varma, S. (2016) Disappearing the asylum: Modernizing psychiatry and generating manpower in India. <i>Transcultural Psychiatry</i> , 53 (6): 783-803.	India (<i>Institute for Mental Health & Neurosciences - Kashmir</i>)	Qualitative study- Ethnographic study	1	-	-	-
3	RATS (score 3/25) Weak	Murthy, P., Isaac, M. & Dabholkar, H. (2017) Mental Hospitals in India in the 21st century: Transformation and relevance. <i>Epidemiology and psychiatric sciences</i> , 26 (1): 10-15.	India (<i>RMH Pune, LGBRIMH-Assam, Hospital for mental health - Gujarat</i>)	Qualitative Study-Report	3	-	-	-
4	EPHPP (score 3) Weak	Krüger, C. & Lewis, C. (2011) Patient and social work factors related to successful placement of long-term psychiatric in-patients from a specialist psychiatric hospital in South Africa. <i>African Journal of Psychiatry</i> , 14 (2):	South Africa (<i>Weskoppies Hospital - 10 wards accommodating long-stay patients</i>)	Quantitative cross-sectional descriptive study	1	271	1067	12.78 years

No	Quality Rating	Full citation	Country	Method	Number of hospitals	Study participants	Number of patients / beds in hospital or unit	Duration of stay
5	RATS (score 17/25) Moderate	Bandeira, P. M., Haddad P. Souza, C., da Silva Guimarães, J. C., de Almeida Filho, A. J. & de Almeida Peres, M. A. (2015) Psychiatric nursing in integrated wards accommodating both female and male patients: a historic pioneering reform initiative implemented by the Institute of Psychiatry, a Unit of the Federal University of Rio De Janeiro, Brazil. <i>Issues in mental health nursing</i> , 36 (10): 791-798.	Brazil (<i>Institute of psychiatry-Federal University- Rio de Janeiro</i>)	Qualitative study- Historical social study (thematic oral history technique)	1	4 nurses & 3 nursing technicians	2 wards of 50 beds each	
6	RATS (score 3/25) Weak	Makhashvili, N. & van Voren, R. (2013) Balancing community and hospital care: a case study of reforming mental health services in Georgia. <i>PLoS Med</i> , 10 (1): e1001366.	Georgia	Qualitative- Case study	6		Average of 1000 beds each	-
7	RATS (score 13/25) Weak	Jin, D. & Li, G. (1994) The role of human rights and personal dignity in the rehabilitation of chronic psychiatric patients: a rural therapeutic community in Yanbian, Jilin. <i>The British journal of psychiatry</i> , 165 (S24): 121-127.	China (<i>Yanbian community psychiatric hospital-branch</i>)	Observational study, no comparator, / control group	1	81 patients with schizophrenia	120 total patients	14.2 years
8	EPHPP (score 3) Weak	Fan, Z., Huang, J., Wu, Q. & Jiang, S. (1994) Comparison of standard locked-ward treatment versus open-ward rehabilitation treatment for chronic schizophrenic patients:	China (<i>Guangzhou-Canton</i>)	Non-randomised control trial	1	90 (final measures on 86)	700	4.9 to 7.9 years

No	Quality Rating	Full citation	Country	Method	Number of hospitals	Study participants	Number of patients / beds in hospital or unit	Duration of stay
		a one-year controlled trial in Canton. <i>The British Journal of Psychiatry</i> , 165 (S24): 45-51.						
9	RATS (score 7/25) Weak	Fisher, F. D., Griffith, E. E. & Mahy, G. E. (1988) Recent developments in the Grenada mental health program. <i>Psychiatric Services</i> , 39 (9): 980-985.	Grenada	Case study	1	-	150	-
10	RATS (score 5/25) Weak	Ganesan, M. (2017) Transforming an out-of-dated psychiatric hospital into a patient friendly space: a matter of taking risks. <i>Intervention</i> , 15 (1): 76-81.	Sri Lanka (Colombo)	Personal reflection	1	-	900	-
11	EPHPP (score 2) Moderate	Xiang, Y.-T., Weng, Y.-Z., Li, W.-Y., Gao, L., Chen, G.-L., Xie, L., Chang, Y.-L., Tang, W.-K. & Ungvari, G. S. (2007) Efficacy of the community re-entry module for patients with schizophrenia in Beijing, China: outcome at 2-year follow-up. <i>The British journal of psychiatry</i> , 190 (1): 49-56.	China (<i>Chaoyang Mental Health Care Institute</i>)	Randomised control trial	1	103	4500 patients with schizophrenia receive OPD & IPD services	-

No	Quality Rating	Full citation	Country	Method	Number of hospitals	Study participants	Number of patients / beds in hospital or unit	Duration of stay
12	EPHPP (score 1) Strong	Huf, G., Coutinho, E. & Adams, C. (2012) Physical restraints versus seclusion room for management of people with acute aggression or agitation due to psychotic illness (TREC-SAVE): a randomized trial. <i>Psychological medicine</i> , 42 (11): 2265-2273.	Brazil (<i>Instituto Philippe Pinel, Rio de Janeiro</i>)	Randomised control trial	1	105	70 in patients & 30 emergencies per day	-
13	Not rated	Hillman, A. (2007) Ruined lives: segregation from society in Argentina's psychiatric asylums. <i>Washington DC: Mental Disability Rights International and Center for Legal and Social Studies</i> ,	Argentina (<i>Hospital Escuela de salud mental- San Luis, Cabred Hospital- San Luis, Borda Hospital- San Luis</i>)	Report	8 psychiatric hospitals across the country 3 (reporting reform)	-	Average of 1000 beds each	Four to seven days Not mentioned for the other two hospitals
14	Not rated	Murthy, P., Kumar, S., Desai, N. & Teja, B. (2015) Mental Health Care in India—old aspirations, renewed hope. <i>Report of the Technical Committee on Mental Health. New Delhi: National Human Rights Commission</i> ,	India	Report	47 hospitals in total. Each hospital reported reform		79,947 in-patient admissions annually	less than 1 month = 37% 1 to 3 months is 30% 3- 6 months is 8% 6 months or more is 25%

No	Quality Rating	Full citation	Country	Method	Number of hospitals	Study participants	Number of patients / beds in hospital or unit	Duration of stay
15	Not rated	<i>Parivartan INCENSE; completion Available</i> (2015) <i>Grant report.</i> Available from: https://parivartantrust.in/wp-content/uploads/2020/04/INCENSE-Phase-1-2.pdf (Accessed May 6th 2021). India:	India (RMH Pune, LGBRIMH-Assam),	Report	2	237 (200 in Pune and 37 in Tezpur)	-	median duration of 12 years in Pune and 18 years in Tezpur
16	Not rated	Nagaraja, D. & Murthy, P. (2008) Mental health care and human rights. <i>New Delhi: National Human Rights Commission,</i>	India	Report	36		3,62,793 new registrations	-

12 studies described a trigger for reform in mental hospital settings (Bandeira *et al.*, 2015; Fan *et al.*, 1994; Fisher *et al.*, 1988; Ganesan, 2017; Hillman, 2007; Huf *et al.*, 2012; Jin & Li, 1994; Kruger & Lewis, 2011; Murthy *et al.*, 2016; Nagaraja & Murthy, 2008; Uys *et al.*, 1996; Varma, 2016). The reasons that triggered reform are listed in Table 2-5 and include poor quality of care particularly for long-stay patients in mental hospitals. India and Argentina report judicial intervention as a key trigger for reform in colonial era mental hospitals.

Table 2-5: Triggers for reform

Triggers of reform	No. and % of studies	Country	Studies
Country level transformation of mental health care	2 (12.5%)	Brazil, Grenada	(Bandeira <i>et al.</i> , 2015; Fisher <i>et al.</i> , 1988)
Judicial intervention	4 (25%)	India, Argentina	(Hillman, 2007; Murthy <i>et al.</i> , 2016; Nagaraja & Murthy, 2008; Varma, 2016)
Patients with long duration of hospital stay	2 (12.5%)	South Africa	(Kruger & Lewis, 2011; Uys <i>et al.</i> , 1996)
Suicide	1 (6.25%)	China	(Jin & Li, 1994)
Poor quality of life for patients	3 (18.75%)	China, Sri Lanka	(Fan <i>et al.</i> , 1994; Ganesan, 2017; Jin & Li, 1994)
Need for evidence-based use of restraint or seclusion	1 (6.25%)	Brazil	(Huf <i>et al.</i> , 2012)

The process of admission and discharge in mental hospitals was also a variable for data extraction. Only two Indian studies reported admission details. Mental hospital admissions in India are largely through judicial intervention and court orders (Murthy *et al.*, 2016; Nagaraja & Murthy, 2008). Only one study from South Africa described the discharge process, which included transfer to another institution, a short-term leave of absence, or discharge.

Elements of reform described in the studies were categorised into structural reform (refurbishment of hospital infrastructure), process reform (reform of clinical and non-clinical hospital processes) and capacity building / training of hospital staff. This framework to categorise reform processes was adapted from the Udaan reform framework (Raja *et al.*, 2020).

Seven (43.75%) of the 16 studies included in the review reported structural elements of reform, captured in Table 2-6. In India, hospital infrastructure

was improved (Murthy *et al.*, 2016; Nagaraja & Murthy, 2008; Varma, 2016), and community housing services established (Murthy *et al.*, 2017; Parivartan, 2015). In Georgia, a large 250 bedded hospital was closed and, in its place, multiple, smaller 40 bedded units were established for long-stay patients (Makhashvili & van Voren, 2013). In Argentina, hospital infrastructure was used to initiate half way homes (Hillman, 2007).

Table 2-6: Elements of structural reform

Elements of structural reform	No. and % of studies	Country	Studies
Closure of a large hospital and opening of smaller facilities	1 (6.25%)	Georgia	(Makhashvili & van Voren, 2013)
Infrastructural improvement	3 (18.75%)	India	(Murthy <i>et al.</i> , 2016; Nagaraja & Murthy, 2008; Varma, 2016)
Halfway home within the hospital	1 (6.25%)	Argentina	(Hillman, 2007)
Community living services	2 (12.5%)	India	(Murthy <i>et al.</i> , 2017; Parivartan, 2015)

Process reform was reported in 14 (87.5 %) studies. This has been categorised and reported in Table 2-7.

There were several process reforms initiated in Indian mental hospitals, including reforms in medical management (Murthy *et al.*, 2016). There was a shift in the process of admissions with hospitals moving away from admissions through legal intervention to voluntary admissions (Murthy *et al.*, 2016; Nagaraja & Murthy, 2008). There was an initiation of more open wards as evidenced in two country level reports, shift in restraint and seclusion processes, and a reduction in the use of custodial cells for isolation (Murthy *et al.*, 2016; Nagaraja & Murthy, 2008). Simultaneously, community-based services linked to mental hospitals were also initiated (Nagaraja & Murthy, 2008). An introduction of psychosocial interventions with a focus on Activities of Daily Living (ADL) and rehabilitation services including employment were reported. (Murthy *et al.*, 2017; Parivartan, 2015) Greater inclusion and involvement of family members in the treatment and care process was noted as well. (Murthy *et al.*, 2016).

In China, process reforms in mental hospitals saw a move from closed to open wards (Fan *et al.*, 1994), and initiation of community-based services in

tandem with mental hospitals (Xiang *et al.*, 2007). Further, patient involvement in hospital management and promotion of non-hierarchical relationships between staff and patients through a structured engagement process was reported (Jin & Li, 1994). Psychosocial interventions were introduced (Fan *et al.*, 1994; Jin & Li, 1994; Xiang *et al.*, 2007) along with discharge planning, structured community re-entry and the involvement of family (Xiang *et al.*, 2007). Other reforms included introduction of personal / coloured clothes instead of uniforms for patients living in mental hospitals (Jin & Li, 1994).

Argentina shifted towards open wards and reform in medical management of patients in hospitals (Hillman, 2007).

Brazil had reforms in restraint and seclusion practices (Huf *et al.*, 2012) and introduced mixed-gender wards to promote social interaction among patients (Bandeira *et al.*, 2015).

In South Africa, the process of medical management and clinical services (Kruger & Lewis, 2011) along with structured discharge planning was initiated (Uys *et al.*, 1996).

Reform in medical management and structured discharge planning were reported in the mental hospital in Grenada (Fisher *et al.*, 1988).

Sri Lanka saw a change in restraint and seclusion practices, change in nursing practices (involvement of nursing staff in intake assessment and treatment planning) and changes in the way meals were distributed to patients with the introduction of a buffet style self-service system (Ganesan, 2017).

Table 2-7: Elements of process reform

Elements of process reform	No. and % of studies	Country	Studies
Reform in the process of medical management	4 (25%)	India, South Africa, Grenada and Argentina	(Fisher <i>et al.</i> , 1988; Hillman, 2007; Kruger & Lewis, 2011; Murthy <i>et al.</i> , 2016)
Reform in admission process from custodial to voluntary	2 (12.5%)	India	(Murthy <i>et al.</i> , 2016; Nagaraja & Murthy, 2008)

Elements of process reform	No. and % of studies	Country	Studies
Introduction of open wards	6 (37.5%)	India, China and Argentina	(Fan <i>et al.</i> , 1994; Hillman, 2007; Jin & Li, 1994; Murthy <i>et al.</i> , 2016; Nagaraja & Murthy, 2008; Parivartan, 2015)
Introduction of community-based services linked to the hospital	3 (18.75%)	India, China	(Nagaraja & Murthy, 2008; Parivartan, 2015; Xiang <i>et al.</i> , 2007)
Reform of restraint and seclusion procedures	4 (25%)	India, Brazil, Grenada and Sri Lanka	(Fisher <i>et al.</i> , 1988; Ganesan, 2017; Huf <i>et al.</i> , 2012; Nagaraja & Murthy, 2008)
Introduction of mixed-gender wards to promote social interaction	1 (6.25%)	Brazil	(Bandeira <i>et al.</i> , 2015)
Patient involvement in hospital management	1 (6.25%)	China	(Jin & Li, 1994)
Promotion of an equal relationship between staff and patients	1 (6.25%)	China	(Jin & Li, 1994)
Structured discharge planning	3 (18.75%)	China, Grenada and South Africa	(Fisher <i>et al.</i> , 1988; Uys <i>et al.</i> , 1996; Xiang <i>et al.</i> , 2007)
Change in nursing practices to increase patient interaction	1 (6.25%)	Sri Lanka	(Ganesan, 2017)
Introduction of psychosocial interventions including ADL, employment and other rehabilitation activities	5 (31.25%)	India, China	(Fan <i>et al.</i> , 1994; Jin & Li, 1994; Murthy <i>et al.</i> , 2017; Parivartan, 2015; Xiang <i>et al.</i> , 2007)
Engagement with family	2 (12.5%)	India, China	(Murthy <i>et al.</i> , 2016; Xiang <i>et al.</i> , 2007)
Introduction of coloured clothes instead of uniforms for patients	1 (6.25%)	China	(Jin & Li, 1994)
Introduction of a meal management system (buffet)	1 (6.25%)	Sri Lanka	(Ganesan, 2017)

Six (37.5%) of 16 studies reported capacity building of staff and covered four countries (Table 2-8).

Three studies from India reported the development of mental hospitals as teaching and research institutions (Murthy *et al.*, 2016; Nagaraja & Murthy, 2008; Varma, 2016).

The study from Grenada reported a formal training programme for staff along with recreational activities such as a multi-disciplinary journal club to augment staff capabilities (Fisher *et al.*, 1988).

In Sri Lanka, staff engagement was used as a means to shift practices and enhance capabilities (Ganesan, 2017).

A study from South Africa reported a trained team dedicated to the care of long-stay patients (Kruger & Lewis, 2011).

Table 2-8: Hospital staff training and capacity building

Elements of staff training and capacity building	No and % of studies	Country	Studies
Development of mental hospitals as teaching and research institutes	3 (18.75%)	India	(Murthy <i>et al.</i> , 2016; Nagaraja & Murthy, 2008; Varma, 2016).
Formal training programme for hospital staff	1 (6.25%)	Grenada	(Fisher <i>et al.</i> , 1988)
Staff engagement in changing of practice	1 (6.25%)	Sri Lanka	(Ganesan, 2017)
Trained & dedicated team for management of long-stay patients	1 (6.25%)	South Africa	(Kruger & Lewis, 2011)

It was particularly interesting to note that none of the studies report data on costs incurred for reform.

Outcome measures were reported by seven (43.75%) of 16 studies from South Africa, India, China, Brazil and Grenada (Fan *et al.*, 1994; Fisher *et al.*, 1988; Huf *et al.*, 2012; Jin & Li, 1994; Parivartan, 2015; Uys *et al.*, 1996; Xiang *et al.*, 2007) (Table 2-9).

In China, clinical outcomes reported improvement in psychiatric symptoms (Fan *et al.*, 1994; Xiang *et al.*, 2007), reduction in episodes of relapse (Jin & Li, 1994; Xiang *et al.*, 2007) along with a reduction in suicides (Jin & Li, 1994). Functional outcomes reported were an improvement in personal appearance (Fan *et al.*, 1994) and improvement in engagement with employment (Jin & Li, 1994; Xiang *et al.*, 2007). Social outcomes of reform reported from China were improvement in staff and patient interactions (Jin & Li, 1994), improvement in interaction with family (Jin & Li, 1994) and improvement in overall social functioning (Fan *et al.*, 1994; Xiang *et al.*, 2007).

Clinical outcomes reported from Brazil were reduction of time in restraints through the use of seclusion as a technique instead of mechanical restraints (Huf *et al.*, 2012) and discharge of patients from the hospital (Huf *et al.*, 2012).

Grenada saw the discharge of patients from hospitals as a clinical outcome of reform, emphasising short term care and rapid return of patients to the community. (Fisher *et al.*, 1988).

Social outcome reported from South Africa was improvement in staff and patient interaction (Uys *et al.*, 1996).

India reported integration with family as a social outcome of reform (Parivartan, 2015).

Table 2-9: Outcomes of reform

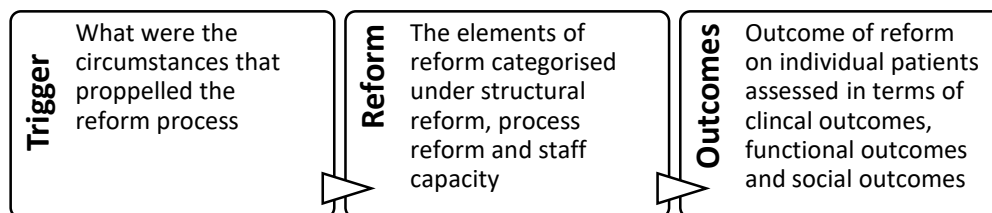
Type of outcome	Outcomes	No and % of studies	Country	Studies
Clinical	Improvement in psychiatric symptoms	2 (12.5%)	China	(Fan <i>et al.</i> , 1994; Xiang <i>et al.</i> , 2007)
	Reduction in relapse of illness	2 (12.5%)	China	(Jin & Li, 1994; Xiang <i>et al.</i> , 2007)
	Reduction in time in restraint / isolation	1 (6.25%)	Brazil	(Huf <i>et al.</i> , 2012)
	Reduction in suicide	1 (6.25%)	China	(Jin & Li, 1994)
	Discharge of patients from hospital	2 (12.5%)	Grenada, Brazil	(Fisher <i>et al.</i> , 1988; Huf <i>et al.</i> , 2012)
Functional	Improvement in personal appearance	1 (6.25%)	China	(Fan <i>et al.</i> , 1994)
	Improvement in engagement with employment	2 (12.5%)	China	(Jin & Li, 1994; Xiang <i>et al.</i> , 2007)
Social	Improvement in staff and patient interaction	2 (12.5%)	South Africa, China	(Jin & Li, 1994; Uys <i>et al.</i> , 1996)
	Improvement in interactions with family/ integration with family	2 (12.5%)	China, India	(Jin & Li, 1994; Parivartan, 2015)
	Improvement in overall social functioning	2 (12.5%)	China	(Fan <i>et al.</i> , 1994; Xiang <i>et al.</i> , 2007)

2.7 Discussion

This review was undertaken with an objective to bring together research on psychiatric hospital reform in LMICs to understand the process of reform and the resulting patient related outcomes. The review aimed to identify gaps in current evidence and research with regard to the reform of psychiatric institutions in LMICs.

The conceptual framework used for this narrative review was based on the review question and explored the relationship between the circumstances

that propelled change or reform in mental hospitals and the elements of reform and the associated patient outcomes.



2.7.1 Dearth of research

There is clearly a dearth of research on mental hospital reform processes. We found only 16 studies from 137 countries across a period of four decades. State run mental hospitals continue to play a key role in providing services in most parts of the world. They deal with an increasingly challenging population with a large number of people having extended periods of hospital stay (Fisher *et al.*, 2009; WHO, 2018). Downsizing of mental hospitals and deinstitutionalisation comes ridden with its own problems of trans-institutionalisation, homelessness and imprisonment of people living with severe mental illness (Carr, 2018; Lamb & Weinberger, 2001; Lancet., 2015; Thornicroft & Bebbington, 1989). In such a scenario, mental hospitals need to reinvent themselves to meet the needs of the very vulnerable population they serve. This reform needs to be backed by robust evidence on reform and its clinical, social and functional outcomes, and the costs thereof. This is a key requirement for governments and policy makers to make informed decisions and improve the landscape of mental health service delivery.

2.7.2 Drivers of reform

Change or reform appears to be driven by the need to make a difference in the quality of life of long-stay patients (Fan *et al.*, 1994; Ganesan, 2017; Jin & Li, 1994; Kruger & Lewis, 2011; Uys *et al.*, 1996). Often such reform is catalysed by judicial action or higher level reform of the country's mental health system as seen in India, Argentina and Brazil (Bandeira *et al.*, 2015; Fisher *et al.*, 1988; Hillman, 2007; Murthy *et al.*, 2016; Nagaraja & Murthy, 2008; Varma, 2016) The need for improved clinical practice and reduction in violation of basic human rights also triggered reform as evidenced by the

modified use of restraints or seclusion as in the case of Brazil (Huf *et al.*, 2012; Huf *et al.*, 2011).

2.7.3 Optimisation of resources

Mental hospitals in most parts of the world have been established during the colonial era and urgently require refurbishment or renovation of old infrastructure. As hospitals are downsized, their infrastructure has been modified to create facilities that more appropriately serve patient needs. For instance, using old hospital wards as a half-way home as seen in Argentina (Hillman, 2007) and the creation of open wards as in China and Brazil (Bandeira *et al.*, 2015; Fan *et al.*, 1994). In India, several infrastructural changes have been carried out across hospitals to improve living conditions for patients (Murthy *et al.*, 2016; Nagaraja & Murthy, 2008; Varma, 2016). Infrastructural changes have also been associated with the simultaneous development of community living services (Murthy *et al.*, 2017; Parivartan, 2015) while downsizing hospitals into more compact, acute care units (Makhashvili & van Voren, 2013).

2.7.4 Process reform as a catalyst to improve quality of life

Although often unplanned, most reform seems to be centred around a change in processes. Reform of processes – largely comprising shifts in clinical and medical management protocols is directly linked to improving the quality of life for patients in mental hospitals (Fisher *et al.*, 1988; Ganesan, 2017; Hillman, 2007; Huf *et al.*, 2012; Huf *et al.*, 2011; Kruger & Lewis, 2011; Murthy *et al.*, 2016; Nagaraja & Murthy, 2008; Uys *et al.*, 1996; Xiang *et al.*, 2007). Large scale shifts such as changes in admission processes and moving from custodial to voluntary admissions (Murthy *et al.*, 2016; Nagaraja & Murthy, 2008), the introduction of open wards (Fan *et al.*, 1994; Hillman, 2007; Jin & Li, 1994; Murthy *et al.*, 2016; Nagaraja & Murthy, 2008; Parivartan, 2015), greater integration of psychosocial services and an incremental push towards improving autonomy and dignity of long-stay patients have been seen globally (Bandeira *et al.*, 2015; Fan *et al.*, 1994; Ganesan, 2017; Jin & Li, 1994; Murthy *et al.*, 2017; Parivartan, 2015; Xiang *et al.*, 2007). Further, greater attention is paid towards more intangible and experiential elements of care. Shifts in clothing policies, food service timings

and processes and access to leisure and recreation have all contributed significantly to an improvement in functioning and overall quality of life for patients.

2.7.5 Mental health professionals as key drivers of recovery-oriented practice

Capacity building of staff was seen as an associated and significant piece of the reform process where countries like India (Murthy et al., 2016; Nagaraja & Murthy, 2008; Varma, 2016) have made a central push for all mental hospitals to transform into centres of excellence that are front runners of training, research and knowledge creation. Training of staff has been, in varying degrees, an important conduit of reform in psychiatric hospital settings (Fisher et al., 1988; Ganesan, 2017; Kruger & Lewis, 2011).

2.8 Study limitations

A major limitation of this review is the variable quality of the studies included, with most studies being of poor quality. Published literature from countries that have experienced massive mental health reform such as that of Brazil (Candiago *et al.*, 2011) are available in languages other than English. Their inclusion was beyond the scope of this review. Detailed quantitative analysis is limited by the quality of included studies as well as the variability in measures. This has implications on the extent of evidence and its ability to answer the question this review focused on – the extent of scientific evidence around psychiatric hospital reform and its associated patient related outcomes in the context of low- and middle-income countries.

2.9 Conclusion

Mental hospitals remain an integral part of psychiatric services globally. In some parts of the world, these hospitals form a majority of, and in some cases, the entire service continuum of mental health care (WHO, 2018). Mental hospitals however, are not static entities, but are evolving and finding renewed relevance in the global landscape of de-institutionalisation and community-based services (Chatterjee, 2017). Most of this evolution and reform of hospitals appears unplanned and de-linked to evidence. There is a large gap in scientific evidence that needs to be bridged urgently such that

future reform processes may be more informed and planned as specific interventions, with the potential of generating evidence on the effectiveness of reform.

In the next chapter, we present a case study of systematic hospital reform of a mental hospital in India through the Udaan program.

3 Psychiatric hospital reform at the regional mental hospital of Nagpur - Udaan, a case study

3.1 Chapter introduction

This chapter covers the structural and process reforms undertaken at the Regional Mental Hospital-Nagpur (RMHN) called Udaan, an initiative of Tata Trusts, in collaboration with the Government of Maharashtra. As the Principal Investigator (PI) of Udaan, I developed its design and led the execution of the programme along with the management of all partner collaborations. This chapter presents the design of Udaan and positions its evaluation in the form of the SITAR trial.

3.2 Udaan – a background

In India, mental hospitals play a crucial role in the care of vulnerable people and continue to remain a legitimate locus of care for people in need of its services (Murthy *et al.*, 2017). Given that shutting down psychiatric institutions is not feasible in most LMICs, there is an urgent need for evidence-based reform of these hospitals. The Udaan programme was designed to address this need.

Udaan is a partnership between Tata Trusts and the Government of Maharashtra. It was formalised through a Memorandum of Understanding (MoU), to develop the RMHN as a centre of excellence through systematic hospital reform. This MoU draws on the Tata Trusts' experience of over 25 years in mental health care in India.

Udaan (which in Hindi means 'to soar') comprises four key reform elements:

- a. Structural: Refurbishment of colonial infrastructure to meet current service user needs.
- b. Process: Standardisation of clinical and non-clinical processes at the hospital.
- c. Capacity Building: Standardisation of training for hospital staff across cadres.
- d. Individualised Care Services: Introducing the Needs Based Intensive Case Management (NB-ICM) – an individual need based, recovery oriented, service package for patients delivered through intensive case management.

Udaan's programme elements are detailed in Figure 3-1 (Raja *et al.*, 2020).

3.3 Regional Mental Hospital - Nagpur (RMHN) – setting the context

Maharashtra is a state in the western peninsular region of India. Nagpur, one of the largest cities in the state, is in the centre of the country (Figure 3-2).

The Nagpur Lunatic Asylum, as RMHN was originally called, was one of two such institutions within the Central Provinces of India –today it comprises the states of Maharashtra, Madhya Pradesh and Chhattisgarh. Documentary evidence dates the establishment of this asylum to July 4, 1864 (Survey of Institutional Facilities for care of mental defectives in mental hospital, 1948). The asylum, in line with the practices of the time in the UK and other parts of India, diagnosed “inmates” with mental illnesses or insanity, with diagnoses ranging from mania and melancholia to dementia, idiocy and epileptic and toxic insanity (Annual Report on the Lunatic Asylums in the Central Provinces, 1895).

In 1875, the asylum added a fence to separate the women from the men in the institute. This marked an important indicator of gender segregation in the asylum. As one of the two asylums in the Central Provinces, it was compared and scrutinised with Jubbulpore Asylum, which housed similar types of service users. In 1907, a decision was taken to bring the women from Jubbulpore to the Nagpur asylum, increasing its female population (Annual Report, 1907). By 1910, the Jubbulpore asylum was shut down and the male population was also transported to Nagpur (Annual Report, 1910).

After this point, the hospital developed slowly throughout the early 1900s, as new buildings were added, and others were removed from active use. Though the hospital was first granted over 200 acres of land, only 100 acres were used. Several attempts were made during this time to sell the unused land piecemeal; some were successful, others were not. In the 1930s in particular, 12.5 acres of land were put up for auction, but getting buyers proved to be a difficult task (Vidharba Archives, 1935).

The service users at RMHN worked in agriculture, weaving, spinning, cooking, construction, repairs, and other small tasks. Occasionally, there were smaller entertainment programmes like magic shows and excursions.

In 1926, gramophones and sweets were distributed at festivals (Annual Report, 1907; Srivastava, 2014).

During the partition of India, some Muslim service users were transferred to Punjab Asylum, to what would become the current mental hospital in Lahore (Jain, 2018). Following India's independence, Nagpur Lunatic asylum was renamed Regional Mental Hospital – Nagpur (Nagpur District Gazetteer). It is currently one of 47 government psychiatric hospitals in the country (Murthy *et al.*, 2016).

Based on hospital records, today, RMHN stands on 52 acres of land. It has 940 in-patient beds with an average in-patient occupancy of 600 and an annual out-patient foot fall of 50,000 individuals. The hospital continues to provide service to approximately 5,000 new patients every year with about 800 annual in-patient admissions.

Programme Design Udaan

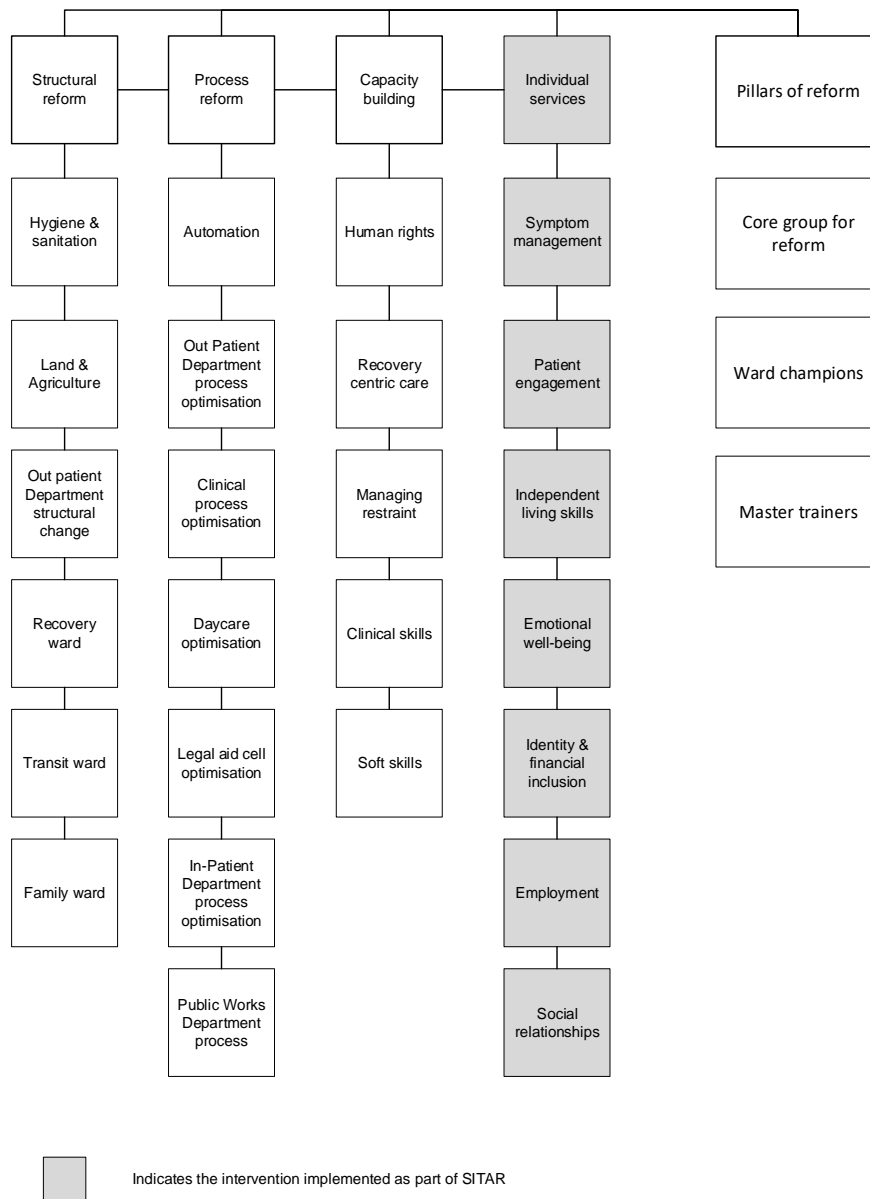


Figure 3-1: A graphic representation of the Udaan programme

For the purpose of this assessment, the Regional Mental Hospital – Nagpur (referred to as facility) was broadly divided into out-patient and in-patient units, explained in Figure 3-3. The out-patient department consisted of consultation rooms, registration counter, the pharmacy, social workers' room, occupational therapist's room, Electro Encephalography (EEG) lab, record room, medical officer's room, nursing station, legal aid room, and the day care centre.

The in-patient facility was divided into three separate categories to provide an in-depth understanding of the functioning of the facility. The three categories were: Intellectual Disability (ID) and epilepsy wards, the Admission/Emergency/Medical wards, and Chronic wards. ID and epilepsy wards included the following male and female wards respectively - ward numbers 4 and 5; and 17, 18, 19. Admission wards included the following male and female wards respectively - ward numbers – 8 and 20; chronic wards included the following male and female wards respectively – ward numbers - 11, 13, 14, 15, 16, 21, 23. In context to RMHN, acute wards are those that house patients on admission or patients from other wards of the hospital who need constant medical or psychiatric attention. Chronic wards are those that house severely mentally ill patients who are medically and psychiatrically stable.

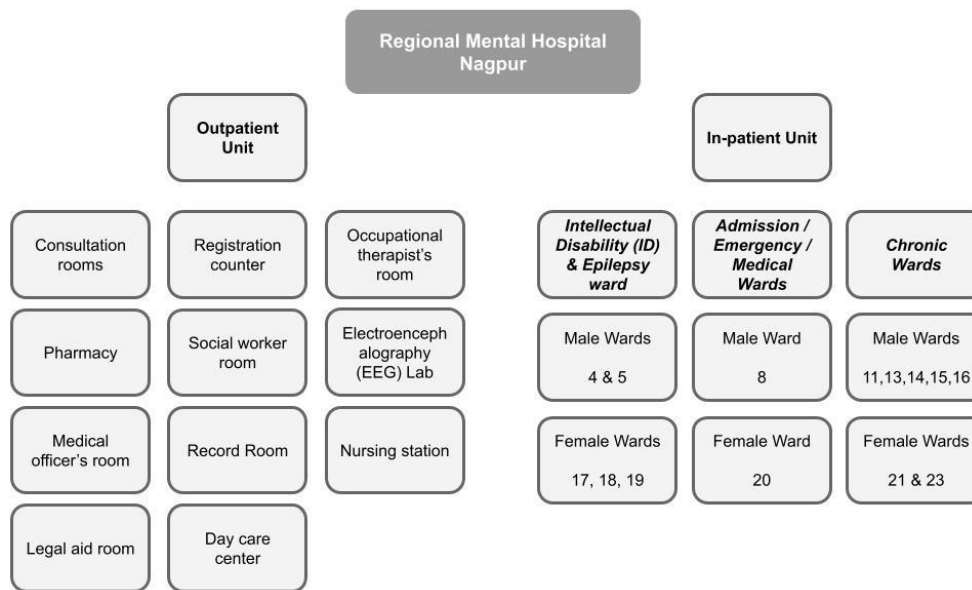


Figure 3-3: A diagrammatic representation of RMHN's care system

All necessary permissions and approvals from the government were obtained before the team visited the facility. Consent forms were made in the local language and informed consent was obtained before each interview. These have all been stored in a safe space at the facility.



Figure 3-4: Regional Mental Hospital Nagpur

3.5 Key findings of the baseline facility assessment

The baseline facility assessment aimed to gain an in-depth snapshot of the state of hospital functioning across all four reform domains – structure, process, capacity building and patient care services. The sections below outline critical findings. Figure 3.4 is a picture of the view of RMHN as one enters the hospital.

3.5.1 Hygiene and sanitation

The hygiene and sanitary conditions of the facility needed significant improving. Few facilities were available to the staff and service users, with the majority of the bathrooms being dirty or non-functional. The kitchen and food quality needed better management, while water coolers and purifiers were required to improve the quality of drinking water.

The lack of clean linens and clothing for service users affected their personal hygiene, while their health and safety was further compromised by mosquitoes and snakes. Another area of concern was the “dirty habits ward” (a term used by the hospital attendants to refer to the ID & Epilepsy wards), in which the sanitary conditions needed significant attention.

3.5.2 Training of professionals

The assessment indicated a large unmet need for training on routine issues such as fire safety and standard operating procedures within the facility. Additionally, training on rights of persons with mental illness, recovery-oriented care and alternatives to seclusion and restraints was also required.

3.5.3 Documentation and policies

The facility lacked standard operating procedures and documented policies for carrying out different activities. This included care processes, permissions and administrative processes.

3.5.4 Quality of health services

The treatment offered appeared largely medical with little or no psychosocial intervention. Even though the facility had an occupational therapy department and a day care centre, it appeared that these centres were not utilised at optimum levels.

3.5.5 Provision of basic necessities

Team members conducting the facility assessment felt that some basic necessities should be made available to service users. These included toothbrushes, toothpaste, towels, combs, undergarments, sanitary pads, etc.

3.5.6 Structure and facilities

The facility needed renovation and painting as it lacked proper maintenance and quality furnishings. It also needed to be more friendly for persons with disabilities.

3.5.7 Communication

The facility assessment team found the institution did not allow any contact with the external world, with no mechanism for service users to make phone calls to relatives. Communication within the facility was hampered by the general layout and placement of wards and dormitories. Within the wards, the nursing station was not centrally located. There was a great distance between the wards, which made them difficult to manage, particularly during emergencies. There was no system of communication between the wards.

These findings also echoed the findings of the National Human Rights Commission and reflect the conditions of most mental hospitals across India (Murthy *et al.*, 2016; Nagaraja & Murthy, 2008).

Table 3-1: Facility assessment scorecard

Theme	Out-patient	In-Patient-MR & Epilepsy	In-patient-Admissions	In-patient-Chronic
Theme 1: The right to an adequate standard of living and social protection	AI	NI	NI	NI
Theme 2: The right to enjoyment of the highest attainable standard of physical and mental health	AI	AI	AI	AI
Theme 3: The right to exercise legal capacity and the right to personal liberty and the security of person	NI	NI	NI	NI
Theme 4: Freedom from torture or cruel, inhuman or degrading treatment or punishment and from exploitation, violence and abuse	NI	NI	NI	NI
Theme 5: The right to live independently and be included in the community	NI	NI	NI	NI
<p>Achieved in full (A/F) - There is evidence that the criterion, standard or theme has been fully realised.</p> <p>Achieved Partially (A/P) - There is evidence that the criterion, standard or theme has been realized, but some improvement is necessary.</p> <p>Achievement Initiated (A/I) - There is evidence that steps have been taken to fulfil the criterion, standard or theme, but significant improvement is necessary.</p> <p>Not Initiated (N/I) - There is no evidence of attempts or steps towards fulfilling the criterion, standard or theme.</p> <p>Not Applicable (N/A) - The criterion, standard or theme does not apply to the facility in question (e.g., rating sleeping quarters for outpatient or day treatment facilities)</p>				

3.6 Initiating the process of reform

Udaan was initiated with a vision to enhance the quality of care for people with SMDs at the psychiatric hospital. It was aimed at safeguarding their dignity, promoting autonomy and facilitating their return to recovery and full participation in society. A participatory ethnographic observation of all the processes of the hospital was planned as an entry level strategy to familiarise the Udaan team and embed them within the microcosm of the hospital. The idea, from the point of conception of the program, was to work alongside and within the system as a collective.

For the 12 out-patient (OP) care processes, 15 hours of participatory observation per observer (five observers) was undertaken. For the 26 in-

patient (IP) processes, 40 hours of participatory observation per observer (five observers) was undertaken.

The observers documented their observations in accordance with a pre-developed template. A consensus meeting was held with all observers to document the final compilation of all observations for each process using the same template.

3.6.1 A participatory reform framework

Udaan envisaged reform as a sustained participatory and collaborative process with the hospital staff and service users.

Sharing of observations through structured forums was vital. The preliminary observations were shared in three workshops to which staff were formally invited (the external baseline through QualityRights, the OP and IP observation reports). Space for participation was created through three forums, each with a different function and staff were asked to volunteer their participation.

The core reform group comprised 14 staff members including social workers, nursing staff, ward attendants and a dietician constituted by a hospital order. The group was presided over by the Medical Superintendent. The core reform group played a multi-faceted role in advocating for change with the hospital administration. It acted as an execution extension of the administration and served as a link between staff and administration. Its function was to design and implement macro reform processes such as Standard Operating Procedures (SOPs) and monitor their implementation on ground.

The core group decided the first ten areas of reform. This decision was made through a workshop wherein findings of all the baseline reports were examined and a consensus based decision was made.

The ward champions group was envisaged as a last mile representation of staff who worked in the wards. It comprised 36 people, predominantly ward attendants and junior nursing staff. This group was responsible for identifying challenges and barriers as well as opportunities for reform.

The third forum for staff participation was through the master trainers' group which comprised 17 members of the hospital staff. Udaan used a cascade model of training where-in these 17 master trainers were first trained in each module and were then supported in further training the other hospital staff.

All participatory groups were initiated with staff participation and service users were gradually added on. The core reform group now has three service users as its members (Udaan, 2017 18). Figure 3.5 shows a core committee meeting in progress.



Figure 3-5: A core committee meeting in progress

3.7 Structural reform

Structural reforms comprised refurbishment, re-design and re-use of old, colonial infrastructure to meet current service user needs. These reforms encompassed a wide range including reclaiming land for agriculture and reuse of dilapidated custodial cells to house several new services such as a men's salon, women's beauty parlour, a library and a meditation room.

Old, dilapidated cottages were refurbished as family wards, old ward complexes were turned into three halfway homes -- one for women and two for men -- with interiors redone to allow for private cabins for service users.

Toilets and showers were either refurbished or built from scratch and open stone benches were built outside the wards to facilitate social interaction.

A ward complex facing the main highway was renovated as a day care complex which can be used by the hospital's service users as well as by people from the surrounding community through the District Mental Health

Programme serving as an interface between hospital based and community-based services.

These were accompanied by refurbishments and structural changes in the Out-Patient Department (OPD), allowing ease of interaction and service.

A total of 259 structures were redeveloped or built anew as part of hospital reform. The number and type of structures developed are listed in Table 3-2 below (Udaan, 2018; Udaan, 2019).

Table 3-2: Structures reformed in collaboration with the Government

Structure	Units	Structure	Units
Acute ward refurbishment	1	Dish washing sinks	10
Washroom refurbishment	28 (old)	Halfway home units	3
	28 (new)	Family wards	6
Toilet refurbishment	75 (old)	Green compost unit	3
	3 (new)	Open shower bath facility	1
Handwashing platforms	6	Open shower bath facility	1
Dining sheds	4	Amphitheatre	1
Men's salon	1	Stone benches	50
Beauty parlour	1	Meditation hall	2
Library	2	OPD pharmacy extension	1
OPD refurbishment	1	VC hall refurbishment	1
OPD exterior facelift	1	Day care	1
Water storage tank	1	Refurbishing space for setting up a bakery	1
Recreation hall refurbishment	1	Mosquito net installation	15
Flooring outside wards	9	Sewage treatment plant	1
Medical record room	1	Total structures	259

Reclaiming overgrown land for agriculture as an employment pathway for long-stay patients.



Personal hygiene and maintenance for in-patients through a men's salon and women's beauty parlour.



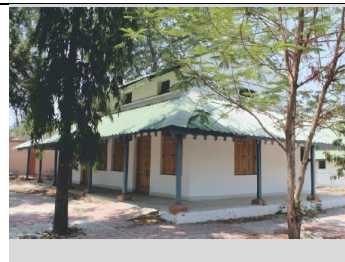
Setting up of handwashing platforms to facilitate the simple behavioural change of regular handwashing.



Construction of stone benches in the open spaces around wards to facilitate social activity and interaction amongst patients.



The refurbishment of old structures as cottages to serve as open family wards.



Photographs taken from Udaan reports (Udaan, 2018; Udaan, 2019)

Figure 3-6: Examples of reform under Udaan

3.8 Process reforms

In accordance with the baseline facility assessment, all the hospital processes and their existing workflows were charted out. Processes were divided into clinical, non-clinical and departmental workflows. Nine clinical processes were modified based on current guidelines in clinical psychiatry with expert organisations such as the Schizophrenia Research Foundation (SCARF). This included a first ever training module for ward attendants. Eleven non-clinical processes and 14 departmental workflows have been modified.

Udaan followed a systematic and staged method of process reform involving ten steps. The initial steps followed include: (i) a preliminary documentation of processes as they existed (ii) evidence-based modification (iii) training of staff (iv) compiling the final process / SOP (v) ratification of the SOP by the hospital administration. These steps are described in the figure below (Udaan, 2018; Udaan, 2019). Processes reformed under Udaan are presented in Table 3-4. The approach to process reform is presented as Figure 3-7.

Table 3-3: Processes reformed under Udaan

Clinical	Non-clinical	Departmental workflows/alternative therapies
ECT administration	Sanitation	Psychiatry department
Managing crisis/restraint	PWD procedures	PSW OPD
Sentinel events policy and procedures	Salon and beauty parlour	PSW IPD
Clinical prescription	Buffet meal system	Pharmacy (OPD and IPD)
Acute ward	Safe drinking water	Lab (OPD and IPD)
Family ward	Movie club	ID and Epilepsy wards
Recovery ward	Library and meditation room	Geriatric wards
Transit ward	Registration	Stable SMD wards
Suicide risk assessment and management	Patient branch and leave of absence	Dance and movement therapy
	Core committee	Vocational rehabilitation
	Donations	OT Department
		Kitchen
		Guard room
		Nursing personnel management

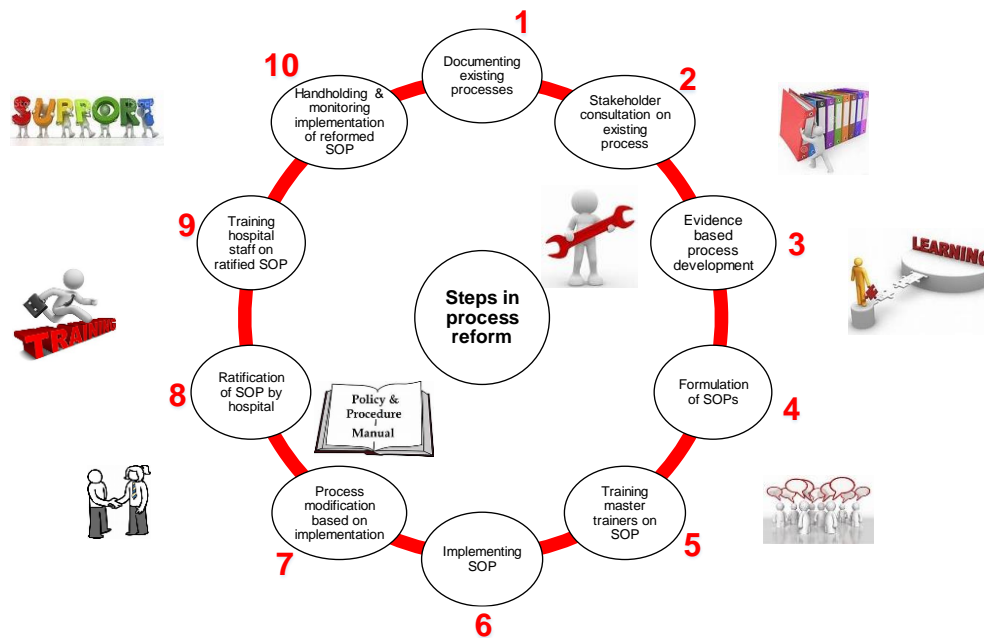


Figure 3-7: Steps of reforming a process at RMHN

3.9 Capacity building

Building hospital staff capacity through a structured and ongoing training program was the third segment of Udaan’s hospital reform programme. A cascade model of training was used to transfer capabilities to ensure sustainability. Master trainers serve as the central group of hospital staff members trained on all the SOPs, department workflows and structured training modules. 17 master trainers, taught by a panel of experts, focused on training their peers in batches of 20. Udaan supervised and provided logistical support for the sessions conducted by the master trainers. Available standard manuals were adapted to suit the needs of the setting. Training topics included but were not limited to: Mental Health Act (2017), human rights and mental health and suicide risk assessment and management. Examples of protocol based trainings included the sentinel events protocol, clinical prescription guidelines and management of seclusion and restraint (Udaan, 2018; Udaan, 2019).

3.10 Individual patient services

This fourth service segment of the Udaan programme was designed to address the unmet needs of service users with SMDs who reside in institutions for extended periods of time, or “long-stay patients”. In the context of Udaan, we defined long-stay patients as those that had a continued stay in hospital between one and ten years. Need-Based Intensive Case Management (NB-ICM) was used as the intervention and comprises the ‘intervention’ component of the SITAR trial. NB-ICM is described in detail in Chapter 5: Needs Based Intensive Case Management.

The overall theory of change for Udaan and SITAR is presented as Appendix 12.3.

3.11 Conclusion

The reforms undertaken through the Udaan programme are in no way unique by themselves. These reforms have been documented in several other state-run psychiatric hospitals throughout the Low- and Middle-income world. However, the combination of these reform elements in a single programme in a systematic manner, aimed at generating practise-based evidence through outcome evaluation, is what makes Udaan unique. This chapter was included in the thesis to provide an understanding of the range of reforms that the hospital has undergone and to bring out the context of the SITAR trial. Most of the reform elements planned under Udaan have been completed.

4 Methodology and protocol of the SITAR trial

4.1 Rationale and background of the structured individualised intervention and recovery (sitar) trial

This trial sought to answer important questions around the nature and process of reforms that promote human rights, dignity and recovery in institutional care in Low- and Middle-Income Countries (LMICs). What should care within institutions look like for those who need to use them long term? This study sought evidence-based answers to this question. This chapter presents the protocol of the SITAR trial. This protocol was published in 2020 'Psychiatric hospital reform in low-income and middle-income countries Structured Individualised inTervention and Recovery (SITAR): a two-arm pragmatic randomised controlled trial-study protocol' and is included here as Appendix 12.2.

SITAR aimed to bridge a critical gap in scientific evidence by studying the impact of reform of psychiatric hospitals on individual patient outcomes.

4.2 Structured Individualised Intervention and Recovery (SITAR)

The Structured Individualised Intervention and Recovery (SITAR) study was embedded within the Udaan program described in detail in chapter 3. In a clinical trial we tested whether Need Based Intensive Case Management (NB-ICM) improves patient outcomes in long-stay in-patients, in comparison to care as usual in a psychiatric hospital undergoing reform in an LMIC. The objectives of the SITAR trial were:

1. 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:

- To determine the effectiveness¹ of structural and process reform of psychiatric institutions on patient-level outcomes for in-patients of the hospital.
 - To develop a standard individual recovery plan intervention in the form of NB-ICM.
 - To develop a standard training package for case managers carrying out the individual recovery plan intervention.
2. To determine the costing of reform and the additional costs of implementing an individually tailored recovery plan for long stay individuals in psychiatric hospitals.

Intensive case management calls for high resources and may not be feasible in low-income settings. We sought to compare patient outcomes emerging from larger structural and process reform in old psychiatric hospitals with patient outcomes when intensive case management was included with the reforms. This comparison has significant value in policy decisions 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. Table 4-1 defines the Population, Intervention, Comparison and Outcome (PICO) for SITAR. NB-ICM is discussed in detail in chapter 5. This chapter presents the methodology of the SITAR trial.

Table 4-1: PICO for the SITAR Trial

Population	Intervention	Comparison	Outcome
Long-stay patients with a primary diagnosis of psychosis in mental hospitals	Need Based-Intensive Case Management (NB-ICM)	Care as usual Psychiatric hospital reform	Disability Symptoms Social and Occupational functioning Quality of life

4.3 Methods

4.3.1 Study design and management

The SITAR trial was a pragmatic, parallel arm, single blind randomised control trial at a single site, the Regional Mental Hospital Nagpur (RMHN, the

¹ Efficacy trials (explanatory trials) determine whether an intervention produces the expected result under ideal circumstances. Effectiveness trials (pragmatic trials) measure the degree of beneficial effect under “real world” clinical settings (Gartlehner G, 2006.).

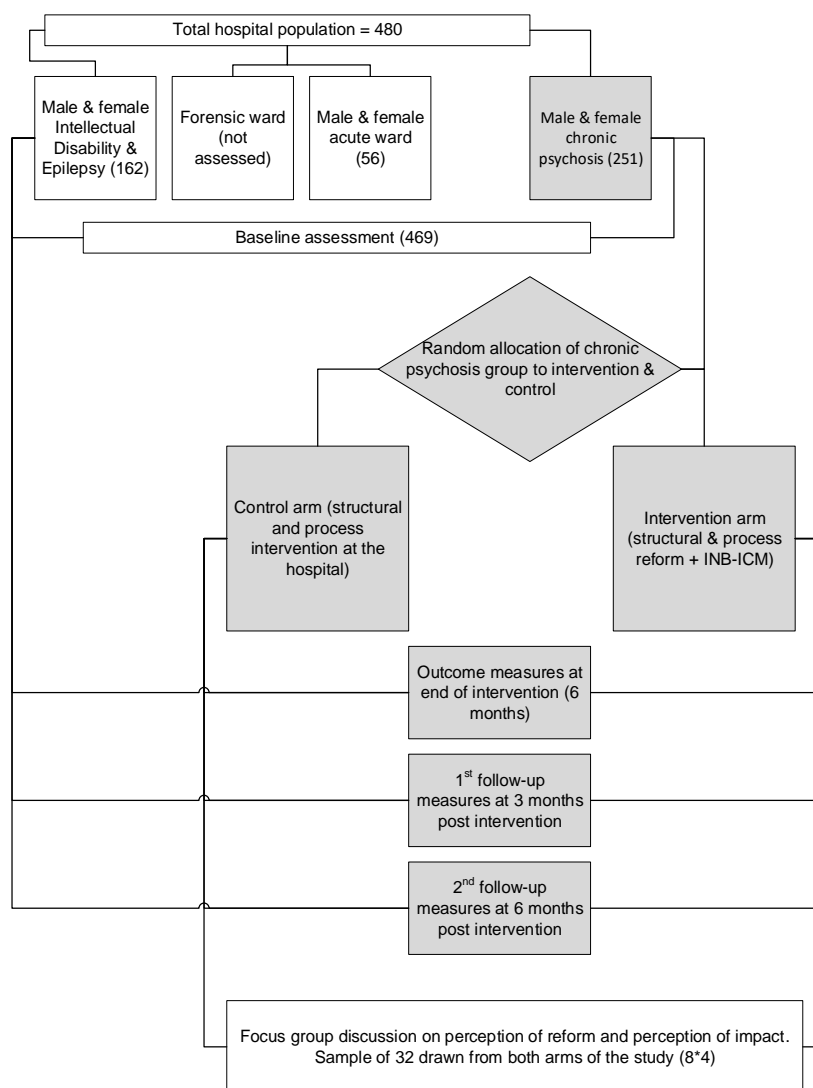
site is described in detail in chapter 3: psychiatric hospital reform at the regional mental hospital of Nagpur (RMHN) - Udaan, A Case Study

Recruitment of patients for the study was initiated after completion of permissions, ethics approval and trial registry.

The in-patient population of the hospital was compiled in a database, mapping socio-demographic variables, history of illness and history of treatment as baseline data. Patients fitting the inclusion criteria were identified and randomly assigned to the intervention and control arms of the study.

The intervention (NB-ICM), for patients allocated to the intervention arm, was carried out for a six-month period. Post-measures on all patients who had undergone pre-measures were undertaken at completion of intervention (six months) and at two follow-up intervals post-intervention of nine months and 12 months (three and six months after completion of intervention). For the control arm, post-measures were at six, nine and 12 months to baseline. The SITAR study design is presented graphically in Figure 4-1.

SITAR- A graphic representation of the research design



□ Indicates the two arm pragmatic randomised control trial

Figure 4-1: Graphic representation of the SITAR Trial design

Several steps were undertaken to ensure quality control and minimise the risk of bias.

1. Use of a standard case management intervention (intervention manual developed for the trial).
2. Randomisation of the sample to intervention and care as usual arms of the trial.

3. Outcome measurements were undertaken by researchers independent of the case managers delivering the intervention. Interrater reliability for the researchers was computed. The statistician supervisor supporting the data analysis was blinded to the allocation of the groups.
4. Each case manager was supervised at least once every month on at least 20% of the cases undertaken by them. Joint monthly meetings of all case managers were held for case reviews and sharing of experiences and discussion on overcoming barriers.
5. The primary supervisor conducted a site visit and met the case managers to assess fidelity of intervention.

We used the SPIRIT protocol to guide the development of the trial protocol. It is included as appendix 12.5

Given the nature of the setting, there was a risk of contamination across arms especially since the hospital staff providing care as usual in both arms were the same. We believe this has had a minimal bearing given the meagreness of engagement of hospital staff with the patients. No specific element was added to address the minimal risk of this contamination.

The trial was coordinated by the UDAAN office located at RMHN and was managed by the student PI with supervision from the supervisors and oversight by the Trial Management Committee (TMC). The TMC comprised of members from the University of Warwick and mental health experts from India.

4.3.2 Participant Eligibility and Recruitment

In-patients at baseline comprised all service users admitted to RMHN. Patients meeting the inclusion criteria for the study were randomised to the two arms of the study. Service users were eligible if they had 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 were over 18 years of age. Service users were excluded from the study if they were over the age of 60 years, had a neuro-developmental disorder such as epilepsy, an intellectual disability or were in acute and forensic wards.

4.3.3 Sample Size

For the study to be powered at the 90% level with 5% significance level, the required sample was 170 people, 85 in each arm. Assuming a 15% drop out we had aimed to recruit 100 people in each arm of the study. We closed recruitment in October 2019 (intervention arm n = 90 and Control n = 92, CONSORT flow chart for SITAR Figure 7.1).

We aimed to achieve 90% power with a sample size that allowed us to detect a minimum clinical difference of 10 points in the primary outcome (WHODAS) at six months with a standard deviation of 20. This equates to a moderate effect size of 0.5 (Cohen, 1988). 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 (Murthy *et al.*, 2005). We anticipated people with psychosis in institutional set-ups to 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 rather than functionality. The intervention being offered through the SITAR trial was also more intensive with longer case management time than what would be feasible in a dispersed community setting.

4.3.4 Ethical Approval

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). The hospital permission letter and the ethics approval letters are presented in Appendix 12.6.

4.3.5 Informed Consent

The treating psychiatrist assessed the service users' ability to participate in the study as well as ability to consent. The psychiatrist provided consent for those patients unable to give consent but deemed appropriate for the intervention. This was especially important in this intervention since it was a 'need-based' psychosocial intervention. Based on inability to consent, patients who may need the intervention most might be left out of the study.

The consent by the treating psychiatrist was to ensure equitable inclusion. Additionally, the ward in-charge signed off on the consent. The study was explained pictorially to the service user with the aid of a specially designed flip chart. Signatures and or thumb impressions were taken on simple consent forms drawn up in Hindi and Marathi. Service users were assured that their refusal to participate / consent to the study would have no impact on the care they receive. The informed consent forms used for SITAR as well as the pictorial card set are included in Appendix 12.7

4.3.6 Randomisation

We used a computer-generated permuted block randomisation schedule for the allocation of recruited subjects to the two trial arms. The researcher created a list of service users meeting the inclusion criteria and consenting to the study and gave them a unique ID number. This list was then handed over to a statistician, independent to the research team. Random allocation of eligible study subjects to two trial arms (A and B) was done by the statistician using Ralloc software (version 3.7.6) available in STATA (version 10.1, 2011) module.

Patients in the control arm went through the same baseline and follow up measurements as the intervention arm. The control arm, however, did not receive the intervention of Needs Based Intensive Case Management (NB-ICM) during the trial period, the control arm continued 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 (Murthy *et al.*, 2016; Varma, 2016).

4.3.7 Discontinuation of Intervention

The intervention was discontinued in the following conditions: 1) If the participant wanted to discontinue participation 2) An acute illness episode that would significantly disrupt time in intervention (beyond four weeks) 3) When the participant was discharged from the hospital and community-based intervention was 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.

4.3.8 Adverse events - recording and reporting

Given the nature of the study population and the chronicity of their illness, certain events were expected. The study protocol classified these events under 'adverse events' and 'serious adverse events'. Adverse events comprised 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 comprised e) episode of self-harm and f) death.

To record and report adverse events, we used the Warwick CTU's Clinical Trials Standard Operating Procedure 17-part 2 Safety Reporting for Clinical Trials.

Any adverse event occurring with any participant was first notified and discussed with the ward in-charge based on routine hospital care processes. All recorded adverse events were reported to the core committee and the trial supervisor through monthly reports. Any unexpected adverse events were to 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. We did not encounter any unexpected adverse events. The adverse events reporting process for the SITAR trial is presented as Figure 4-2. The adverse events record form is included in Appendix 12.8

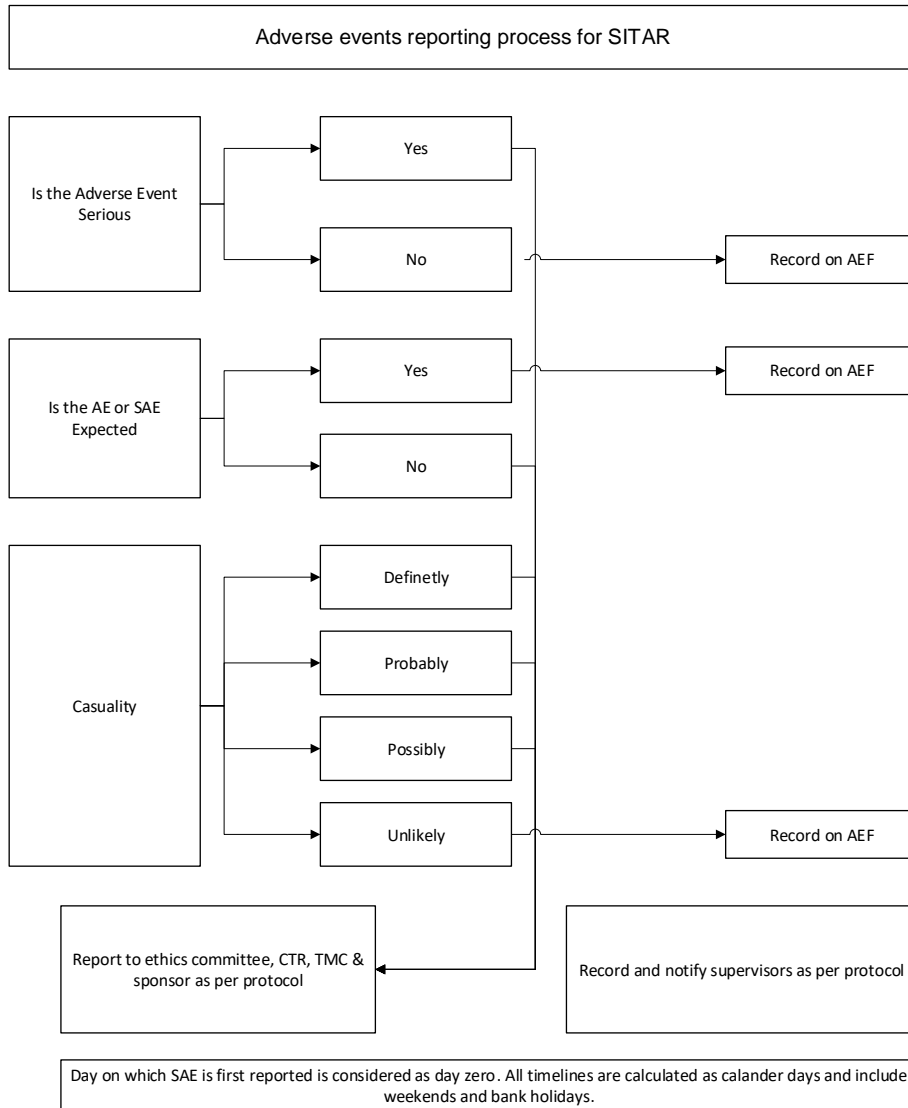


Figure 4-2: Adverse events reporting process for the SITAR Trial

4.3.9 Measurements

The study comprised outcome measures and process measures. Other baseline measurements include sociodemographic details, illness history and treatment history. The list of included variables is given in Appendix 12.9.

4.3.9.1 Outcome measures

Assessment of level of disability at six months was the primary outcome for the trial. We used the WHO Disability Assessment Scale 2.0 (WHODAS 2.0 proxy version), a generic assessment instrument for health and disability that produces standardised disability levels and profiles applicable across cultures and diseases (Üstün, 2010). We used the complex scoring method where summary scores were converted into a metric from 0 to 100 where 0 indicates no disability and 100 indicates full disability. Three items of WHODAS 2.0 were not applicable for scoring due to the nature of the setting. These are items 3.4 (staying by himself or herself for a few days), 4.5 (sexual activities) and 6.6 (how much has his or her health been a drain on his or her financial resources or that of the family). These items were replaced with the average score for that particular domain as suggested by the WHODAS manual and other validation studies of WHODAS (Lokkerbol *et al.*, 2021; Üstün, 2010).

Secondary outcome measures included an assessment of severity of symptoms, assessment of social and occupational functioning and assessment of quality of life. The scales used for these measurements were 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 (Haro *et al.*, 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 & and STEVEN D. TARGUM, July 2007) .

Social and Occupational Functioning Assessment Scale (SOFAS) was used to assess the individual's level of social and occupational functioning. SOFAS is not directly influenced by the overall severity of the individual's psychological symptoms (Morosini *et al.*, 2000; Saraswat *et al.*, 2006).

Health related quality of life was measured using EuroQol-5D (EQ-5D). This 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 (Devlin *et al.*, 2016; Janssen *et al.*, 2013). The outcome measures tools used for the trial are included as Appendix 12.10

4.3.9.2 Process (intervention) measurements

These included the assessment of need, intervention plan, symptoms assessment and assessment of self-care and other living skills carried out by case managers to guide the development of the monthly individualised intensive case management plan.

4.3.10 Baseline and follow-up measurements schedule

Baseline measurements were initiated after ethics clearance and were completed for all the in-patients of RMHN (n= 469) between April 1, 2019 and May 31, 2019. These were conducted by trained research assistants (RAs) who had a Master's in Psychology or Social Work. RAs were not involved in the hospital setting; however, unmasking was possible and we have recorded all episodes of unmasking. Interrater reliability was established for all the research assistants conducting the measurements and is presented in appendix 12.11.

RAs completed the measurement based on discussion with the patient, discussions with the ward nurse and attendants and their own observation of the patient. Proxy measures have been used in prior studies for people with severe mental illness (Kim *et al.*, 2010; Koopmans *et al.*, 2020).

The intervention was initiated after completion of the baseline measurements on June 1, 2019 and carried out for six months. We recruited patients meeting the inclusion criteria up to October 2019. The last follow-up measures were completed in November 2020 as per the protocol of measurements at baseline, six months, nine months and 12 months. The assessment schedule is presented in Table 4- 2.

The patient sequence and RAs conducting the measures was kept standard for the measurements to ensure uniformity in time between measures. In case of an adverse event where the patient was not available for measurement as per sequence, accommodation was made to complete the measure any time during the two-month period of that measurement cycle. In cases where this was not possible, the patient was considered as a dropout. All patients (except dropouts as per criteria) were followed up on as per protocol, either within the hospital or in the community.

Table 4-2: List and time frame of measurements for the SITAR trial

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 □ intervention time frame

Process measures of needs assessment, Intervention plan, symptoms checklist, self-care and other living skills checklist and the case management form were completed only for the intervention patients

4.3.11 Data management

4.3.11.1 Data collection

Quantitative data were collected by trained Research Assistants (RAs) using pre-designed, pre-tested tools as included in the protocol. Senior RAs checked completeness and accuracy of data, which was counterchecked by the PI, daily, before electronic data entry.

4.3.11.2 Data storage

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

4.3.11.3 Data entry and coding

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

4.3.11.4 Data screening, data validation and data editing

Data were screened at every stage i.e., pre-randomisation, post-randomisation and closing stage of the trial. This was done for each item of the individual record by the student researcher (trial PI).

4.3.12 Data analysis

All results from the trial were reported according to the Consolidation Standards of Reporting Trials (CONSORT) guideline for randomised controlled trials and is reported in detail in chapter 7: Quantitative Results of the SITAR Trial (CONSORT., 2010).

Every effort was made to ensure that missing data were kept to a bare minimum in the trial. The level or extent of missing data was assessed at the end of the trial. We did not require additional sensitivity analyses to impute the missing values.

4.3.12.1 Data processing

Data were processed by the PI who maintained a weekly follow-up of patients recruited on the trial. Raw data from the master file was coded and processed into a data file. The entire data set was put through an MS Excel-based double entry process by two independent people. Formula-based comparison of the two sets was undertaken and discrepancies were resolved by re-checking the hard copy of the questionnaire on file. The data file includes both original variables as well as some newly derived variables or

transformed variables specific to the study objectives. Statistical Package of Social Sciences (SPSS) was used for data analysis.

4.3.12.2 Anonymizing data

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

4.3.13 Qualitative element of the study

The qualitative component of the study comprised patient perceptions on the overall reform process, the individual intervention and its felt impact. The SITAR trial used Focus Group Discussions (FGDs) to elicit this. The methodology for the qualitative component is discussed in detail in chapter 8 Qualitative Analysis - Focus Group Discussions (FGDs); SITAR Trial.

4.3.14 Costing and potential economic gains of the intervention

The SITAR trial also included a retrospective bottom-up cost analysis of the individualised intervention in terms of resource or input requirement, along with costing of resources for care as usual. The detailed methodology is reported in the chapter 9: Health economic analysis of Udaan and SITAR.

4.3.15 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. Trial results will be published in accordance with CONSORT guidelines.

4.4 Conclusion

Udaan was a complex intervention. We chose a mixed methods design for its evaluation through the SITAR trial. A pragmatic randomised controlled trial was used given the messy real world setting of a psychiatric hospital. The qualitative aspects of the study allowed for the inclusion of patients'

experiences of reform and the impact these reforms have had on their lives. The economic evaluation was included to shed light on the real costs of reform of a colonial-era hospital and the benefits thereof.

5 Needs Based Intensive Case Management (NB-ICM)

5.1 Introduction

This chapter describes the NB-ICM intervention used for the SITAR trial and process indicators used as part of the trial. The intervention is described in line with the 'Better reporting of interventions: Template for Intervention Description and Replication' (TIDieR) checklist and guide (Hoffmann et al., 2014).

5.2 Rationale and objectives of the intervention

The individual intervention package for the SITAR trial was developed as a component of overall reform under the Udaan programme. This intervention package was based on a contemporary understanding of psychosocial rehabilitation which takes a holistic approach of improving quality of life for a person living with mental illness – reducing disability, improving role function, promoting independence and autonomy – based on the hope for a better 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 (Anthony *et al.*, 1990; Burns, 2010; Holloway & Carson, 1996; Patterson & Leeuwenkamp, 2008; Wolfson *et al.*, 2009; World Health Organization, 1997). ICM evolved from two original models of care, Assertive Community Treatment (ACT) and Case Management (CM) (Dieterich *et al.*, 2010). It is a highly valuable intervention for those with severe mental illness and prolonged hospitalisation (Dieterich *et al.*, 2010).

Persistent disability is experienced by a majority of people living with a severe mental health condition, despite the best evidence-based treatment (Marshall *et al.*, 2005). Stigma, inaccessible or inappropriate treatment services, unemployment, poor quality housing and lack of social and leisure opportunities complicate the social disablement arising out of severe mental disorders (Kopelowicz *et al.*, 2007). Living in an institutional setup further exacerbates disability and loss in functionality (Goffman, 1961; Goldstein, 1979).

The unmet needs of people with severe mental illness have paved the way towards development of comprehensive service approaches integrating pharmacological and psychosocial treatments flexibly adapted to patients' changing needs and interests (Balaji *et al.*, 2012; Kopelowicz *et al.*, 2007; Kulhara *et al.*, 2010; Lockwood & Marshall, 1999; Maden *et al.*, 1993; Sayal & Maden, 2002). Coordinated case management-based approaches are being used in many parts of the world as standard treatment options for people with severe disability arising out of mental illness (Lieberman & Kopelowicz, 2002; Marshall & Lockwood, 1998; National Collaborating Centre for Mental Health, 2014; Solomon, 1992).

The NB-ICM service package for this study was designed on the basis of functional equivalence, cultural relevance and practical trade-offs; the three elements that must be considered in service design (Anthony *et al.*, 1990; Bachrach, 1984). Case managers were trained to deliver the intervention through a clinical and intensive case management approach which included the functional network of a spectrum of services created at the hospital level through the reform process. Its premise and principals, rather than a set of interventions, has defined the use of case management as an approach to intervention.

5.2.1 Principles of intervention

- The intervention was based on an objective assessment of current needs of the service user and provided a comprehensive package of services to meet the range of individual needs.
- The case manager worked collaboratively with the person in developing a personalised care plan drawing from the larger context of available opportunities within the hospital, created through the ongoing reform process.
- The intervention was provided in a continuous and accessible manner. In the context of SITAR, two components of accessibility were considered. The case manager had to be familiar with the language used by the service user and the service user had a way of reaching the case manager if he / she needed to do so.
- The care plan was individualised and designed to meet the unique needs relevant to the service user's cultural context. It drew on the

strengths and potential of the individual and an assessment of unmet needs and focused on the reduction of personal distress and disability.

- The care plan was a combination of environmental adaptation and personal empowerment, strengths, resources and context of each person. It allowed the individual service user to set their pace of recovery.
- Care provided through this approach was continuous and consistent – first provided by the Udaan team and then transferred to the hospital staff.
- The team of case managers and reform staff provided the intervention. The allotted case manager had the primary responsibility for planning, coordinating and delivering care, drawing on the resources available in the intervention setting.

The case management approach to intervention was based on the broad premises of heterogeneity of the individual with a severe mental illness and a broad conceptualisation of what constitutes therapeutic interventions. The intervention was provided through and dependent on the relationship between the case manager and the service user (Surber, 1994).

5.2.2 Objectives of the intervention package

In the context of SITAR, the objectives of NB-ICM were to address the following unmet needs of service users:

- Persisting symptoms through appropriate pharmacological management and appropriate psychosocial support. It also included diminishing and eliminating, wherever possible, the adverse physical and behavioural consequence of symptom management as well as those arising out of prolonged institutionalisation.
- Basic needs of adequate accommodation and food in the context of living in a large psychiatric hospital.
- Personal functioning and improving activities of daily living in terms of skills and access to opportunities.
- 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.
- Occupational functioning, employment, identity and citizenship and financial inclusion.
- Connecting to family and community where feasible.

5.3 The intervention components

The intervention (NB-ICM) comprised of eleven components – accommodation, safety and food, psychoeducation, symptom management, physical health, emotional wellbeing, self-care and other living skills, social relationships, connecting with family, leisure activities, occupational and financial inclusion, and spiritual needs. Intervention elements were broadly divided into individual and systemic level interventions. The interventions for each of the components are described in the Table 5-1 below.

Table 5-1: NB-ICM – Individual and systemic intervention by component

Components	Individual interventions	Systemic interventions
Accommodation safety and food	<p>Psychoeducation on clean surroundings and the individual's role in keeping cleanliness.</p> <p>Behavioural goals on maintaining one's bedding, sunning it adequately and using clean linen.</p> <p>Ensuring personal needs for adequate food are met.</p> <p>Identifying and working on anger and resentment issues.</p> <p>Identifying and working on conflicts with other service users or ward staff.</p> <p>Identifying the cause of restraint episodes and developing a plan to address them.</p>	<p>Cleanliness of the ward.</p> <p>Ensuring that the person has access to clean bedding and linen.</p> <p>Helping maintain supply / stock of clean linen at the ward level.</p> <p>Coolers in summer and protection in winter.</p> <p>A buffet style food distribution process.</p> <p>Systemic intervention to ensure reduction in long hours between meals.</p> <p>Training of ward staff on de-escalation of crisis to bring down restraint and isolation.</p>
Psychoeducation	<p>Information about the illness and the symptoms associated with it.</p> <p>Information on where the individual was and the kind of treatment, they were undergoing.</p> <p>Side effects of medication and how these could be managed.</p>	<p>Group sessions on information about symptom and treatment options.</p> <p>Development and display of standard material giving information on illness and treatment used in one-to-one sessions and also displayed through movie clubs as intermission breaks.</p>
Symptoms	<p>Assessment of current symptoms through the symptoms checklist.</p> <p>Adherence management.</p>	<p>Ensuring a regular consult with the psychiatrist.</p> <p>Addressing medication-stockout issues.</p>

Components	Individual interventions	Systemic interventions
	<p>Psychoeducation on illness and its management including adherence.</p> <p>Development of a plan to reduce negative and cognitive symptoms using engagement techniques.</p> <p>Set of yoga asana developed by experts, encouraging the person to do them every day.</p> <p>Training on relaxation techniques.</p> <p>Stimulation and thinking games such as Tangram, which involves putting together shapes to form objects, frequency tally and memory game with cards (Case managers will be taught these games and materials will be provided in the form of a kit).</p> <p>If literate – encouraging borrowing of books from the library based on interest.</p> <p>If not literate – doing reading sessions together.</p> <p>(Some of the activities in this section may overlap with other sections such as leisure & physical health).</p> <p>Training in problem solving skills (CBT).</p> <p>Encouraging participation in dance and movement sessions.</p>	<p>Follow-up on administration of long-acting injectable.</p>
Physical health	<p>Psychoeducation on physical health and wellness.</p> <p>Plan on reducing tobacco use, if present.</p> <p>Plan on access to dental and ophthalmic treatment.</p> <p>Menstrual hygiene – assessing need for and creating access to sanitation products.</p>	<p>Setting up a process of specialist physical health and wellness camps such as ophthalmic, dental, etc.</p> <p>Doing group education sessions on physical health and wellness and on menstrual hygiene for women.</p> <p>Facilitating a gynaecological consult.</p>
Self-care	<p>Assess skill deficit in self-care and collaboratively develop a task-based plan using the self-care checklist.</p>	<p>Ensure the individual has access to hygiene products and / or a personal kit.</p> <p>Make systemic provision for things like a mirror which aid in personal grooming.</p> <p>Make systemic provision for the individual to be able to handle personal utilities.</p>

Components	Individual interventions	Systemic interventions
Social relationships	<p>Focus on building a rapport with the individual based on acceptance and trust.</p> <p>Identify who the person bonds with amongst the ward staff and service providers, with other service users in the ward and / or other people who frequent the ward.</p> <p>Build a plan to enhance this social network that the individual has using opportunities created by the reform process.</p> <p>Help the individual become part of a peer support group.</p> <p>In case the individual is being discharged, assess the availability of social networks and help the individual make social connections.</p>	<p>Create opportunities for individuals to build a social network.</p> <p>Develop a volunteer base for non-clinical engagement with service users.</p> <p>In cases where families are known, help with regular contact with the individual's local environment.</p>
Family relationships	<p>Draw and document information regarding the service user's family of origin.</p> <p>Understand the individual's experience with the family and make note of concerns he / she may have at reconnecting with the family.</p> <p>Initiate a dialogue.</p> <p>In case of possibility of the service user returning to the family, make connection with the reintegration team and work on preparing the family to receive the service user back home.</p>	<p>Work with the hospital social worker in tracing the family.</p> <p>Initiate communication with the family, promote family visits to the hospital.</p> <p>Pre-discharge preparation and discharge of the service user through the process of the system</p> <p>Explore opportunities for the individual to go back to the family environment in small trial slots through the Leave of Absence (LoA) process.</p>
Leisure activities	<p>Encouraging the individual to take up at least two hobbies that are of interest to her/him.</p> <p>Encouraging the individual to participate in games such as carrom, snakes-and-ladders, and puzzles like the tangram.</p> <p>Encouraging the individual to participate in sports at ward level as well as in larger groups at hospital level.</p> <p>Ensuring access to the movie club and library.</p> <p>Encouraging volunteers to conduct group reading sessions.</p> <p>Ensuring outing opportunities for the individual; the outings could be only for the individual, or s/he could be a part of group outings</p>	<p>Identifying barriers faced by the individual in accessing the available leisure activities.</p> <p>Working with the system to overcome these barriers.</p> <p>Working with the system to develop opportunities for group outings.</p>

Components	Individual interventions	Systemic interventions
Occupational & Financial Inclusion	<p>Explore employment history and work-related skills.</p> <p>Identify training needs.</p> <p>Plan to address skill deficit and or training needs.</p> <p>Explore the presence of identification documents.</p> <p>Promote at least two hours of employment time per day through any of the modalities available.</p> <p>Ensure identification documents are in place and accessible.</p> <p>Link for bank accounts.</p> <p>Support the use of wages and promote personal choice.</p>	<p>Work with the system to access employment opportunities within and outside the system.</p> <p>Create a systemic mechanism of access to identification documents.</p> <p>Work on a systemic pathway for financial inclusion.</p>
Spirituality	<p>Promote individual choice.</p>	<p>Work with the system in creating access to pursuing religious beliefs.</p> <p>Creating access to pursuits like yoga and meditation.</p>

Psychoeducation was used as an approach in various components of the intervention, both for engaging with service users as well as a tool for psychosocial rehabilitation (Baruah *et al.*, 2012; Betancourt *et al.*, 2002; Macpherson *et al.*, 1996). The overall goal of psychoeducation was to help the service user formulate a functional concept of the illness, provide comprehensive information about the illness and the treatment, enhance self-efficacy and empowerment, improve adherence, support emotional relief and instil hope (Kissing & Pitschel-Walz, 2011).

A sample of the pictorial psychoeducation aid developed for the intervention is presented in Figure 5-1.

Sample cards from the pictorial aid developed for NB-ICM as part of SITAR

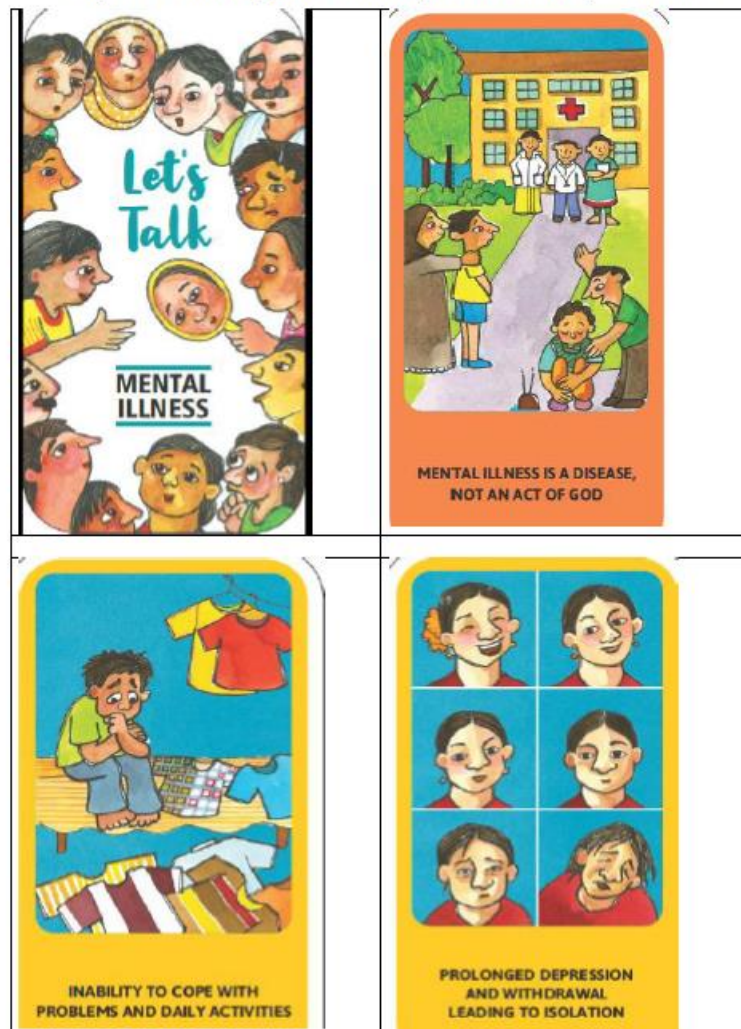


Figure 5-1: Sample cards from the pictorial tool for NB-ICM

Functional outcomes in schizophrenia (which forms a bulk of the study population) is moderated by a range of factors including cognitive function, motivation, insight and extent of untreated illness amongst others (Bowie *et al.*, 2018; Rajji *et al.*, 2014). Along with ensuring pharmacotherapy, special attention was given to addressing negative and cognitive symptoms through a recovery-oriented care plan (Klingberg *et al.*, 2011; Rector & Beck, 2012; Reddy & Mythri, 2016).

While cognitive impairment may be consistent in schizophrenia, everyday functional skills in the domains of self-care and social skills vary by the

environmental setup and may be influenced by the kind of social support an individual receives (Harvey et al., 2009; Velligan et al., 2008). In the context of this intervention, the psychiatric hospital was considered as a large community comprising thousand people at any given point. This includes service users and service providers. This community was used as the reference point in advancing the development of social skills for the individual service user based on an assessment of need.

Most admissions to psychiatric hospitals in India are through law enforcement (issue of a court order initiated by city police for the wandering mentally ill) (Murthy *et al.*, 2016; Narasimhan *et al.*, 2019). Given this, the intervention was designed to piece together information from the service user and locate family wherever feasible.

The psychiatric hospital environment in India has little to offer service users in terms of leisure activity. Once admitted, life continues in an institutionalised manner often moving from one meal to the next. (Murthy *et al.*, 2016; Nagaraja & Murthy, 2008; Narasimhan *et al.*, 2019). Structural and process reform was focused on widening the basket of opportunities; however, access to these opportunities was inequitable. NB-ICM sought to use opportunities in the system to maximise leisure time for the patients based on their choice.

Preparing service users for employment was envisaged through four different stages – from highly supervised sheltered workshop conditions to independent employment in formal workspaces akin to community settings. Formal employment spaces included the Tata Trusts Udaan office which is in a separate part (to the in-patient wards) of the 52-acre hospital and the cafeteria started for staff and OPD visitors under the broader hospital reform.

5.4 Role of the case manager providing the intervention

The role of the case manager included providing and brokering direct services for to the service user, and advocating for a feasible environmental adaptation to meet their unmet needs. (Kanter, 1989; Thornicroft, 1991). Following were the tasks of a case manager:

- Engaging and building a relationship with the service user.

- Assessment of the person's need for care as per a pre-defined time schedule.
- Development of a monthly care plan based on the assessment.
- Provision of care through psychoeducation, counselling and training.
- Linking up of relevant services to meet unmet needs of the services user.
- Intervening for feasible environmental change as an advocate for the service user.
- Maintaining records of case management as per protocol.

5.5 Training of case managers

The student researcher trained the case managers using a training package especially designed for the trial. The training addressed a basic understanding of severe mental disorders and the disability associated with it. Training focused on developing an understanding of recovery and associated interventions, geared toward building case management skills, specifically addressing the three common problems of need-based case management approaches. These three common problems are: A) case managers have not noticed a problem or have not adequately assessed need B) they have not been able to obtain interventions that were needed or C) case managers have been unaware of interventions that could have addressed a particular need (Marshall *et al.*, 1995).

The training approach was multi-layered using adult principles of learning, focusing on building content and skills, including counselling and problem-solving. The training, comprising four modules totalling 48 hours and 30 minutes, was conducted as an off-site residential training. It was completed in seven days. The training layout and curriculum is presented as Appendix 12.14. The detailed training manual developed for this study is available on request.

In total, 24 people from the Udaan team were trained through the programme. Two types of assessments were carried out to measure the programme's efficacy. The first was a 100-item questionnaire that was scored one point for every correct response, completed pre- and post-training. As can be seen in Table 5-2, the case managers' scores increased

after training (mean 40.5 increasing to 52.4, $p < 0.01$) illustrating the effectiveness of the training package.

Table 5-2: Summary scores from questionnaire at pre- and post-training

	Pre test scores (n=24)	Post-test score (n=24)
Mean	40.54	52.43
SD	9.61	7.82
Range	24-59	40-69
Mean of difference	-11.89	
SD of difference	7.48	
95% CI of difference	-15.05 -8.73	
p value	P < 0.000	

The second assessment was a skills assessment done by the panel of trainers for each participant using simulation on real case histories.

Of the 24 people trained, 10 case managers were chosen for this study. All the case managers had a master's degree in humanities or psychiatric social work with at least two years of experience working with people with severe mental disorders. There was one attrition during the study and cases were reallocated to the remaining nine case managers.

5.6 Allocation of case managers

Case managers had an average case load of ten at a given point in the study. They were allocated keeping in mind language familiarity and gender of the participant. The mean number of case management sessions held was 59.6 with a SD of 16 for each service user over a six-month period. The average number of sessions was higher than the anticipated 48 sessions per patient (eight sessions per month for six months) as described in the protocol (Raja *et al.*, 2020).

5.7 Intervention provision

The relationship between the case manager and the service user formed the fundamental premise of the intervention. Thus, engaging and building a relationship with the service user was a necessary first step as well as a continuous process throughout the intervention (Harris & Bergman, 1988). The importance of having a positive connection has been well emphasised in literature and a positive connection is considered therapeutic in itself. (Balancio, 1994). Case managers held several individual and group

activities such as playing games and group discussion sessions. Art and theatre-based engagement sessions received the most participation from service users.

5.8 Intervention plan

Based on the mapping of unmet needs, the case manager drew up a monthly personal care plan on a standard bespoke form adapted from the formats used in community settings in India (Chatterjee *et al.*, 2014), included as Appendix 12.13.4. The care plan was developed collaboratively with the service user, in discussion with the ward in-charge and social worker for the ward. The plan comprised goals agreed upon for the month for each domain of unmet need. These set of tasks, aimed to cover as many unmet needs as possible, captured the detailed description of interventions at the individual level as well as those that may be needed at a systemic level.

For each month, the reported inclusion of each need domain within each patient's intervention is presented graphically in Figures 5-2 to 5-7. Most commonly, the intervention plan comprised individual and systemic interventions. For need domains such as information, emotional well-being, social relationships, engaging with family and participating in leisure activities; more work was done at the individual level. The reported inclusion of each need domain in the intervention package across, individual and systemic, over time are presented graphically in Figures 5-8, 5-9 and 5-10. For most domains, interventions intensified over the first three months and was tapered toward the end of the intervention period. For domains such as occupational engagement, interventions at all three levels continued till the end. Systemic intervention was also phasic and occurred only in certain months as opposed to individual and, individual and systemic intervention, which was continuous. The detailed table for each component of intervention by need domain over time is presented in Appendix 12.15.

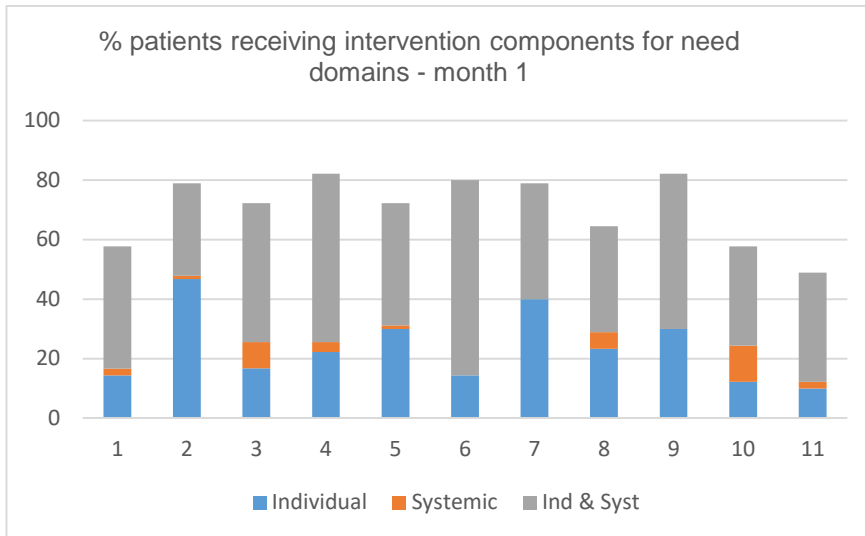


Figure 5-2: Type of intervention by need domain at month 1 of intervention

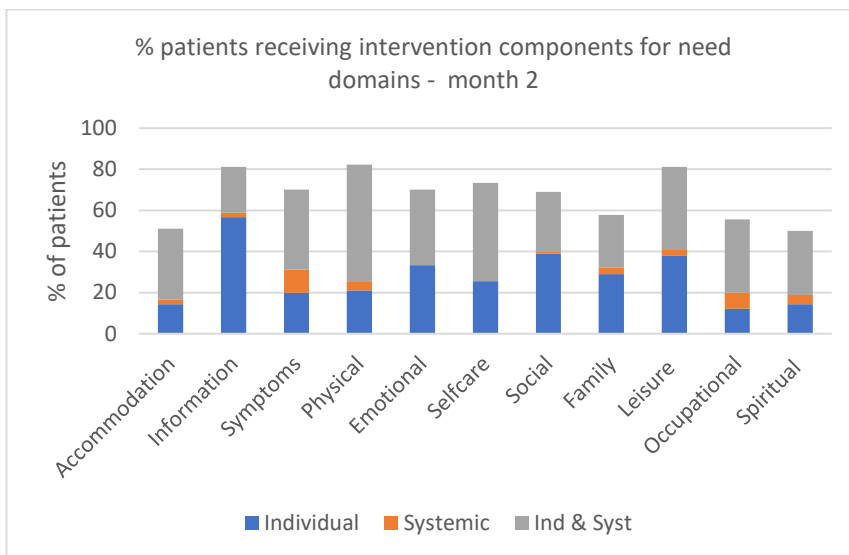


Figure 5-3: Type of intervention by need domain at month 2 of intervention

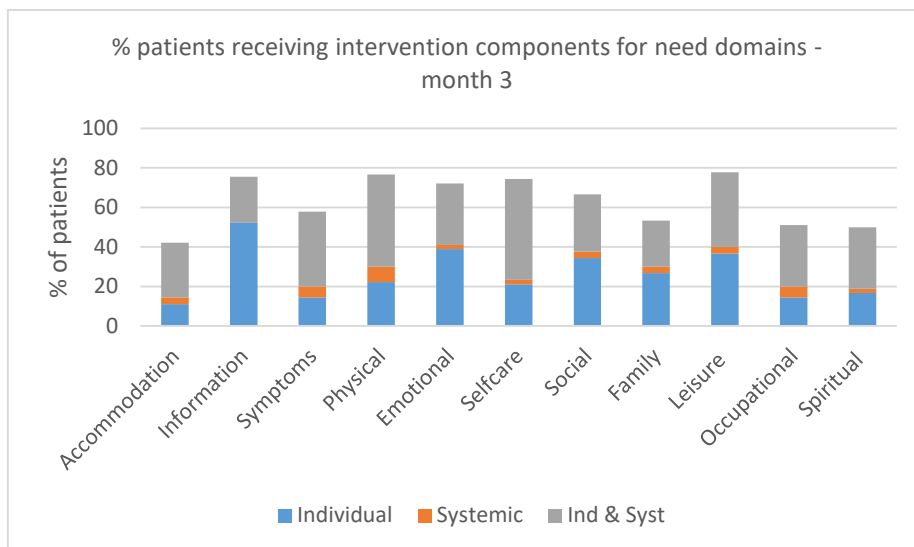


Figure 5-4: Type of intervention by need domain at month 3 of intervention

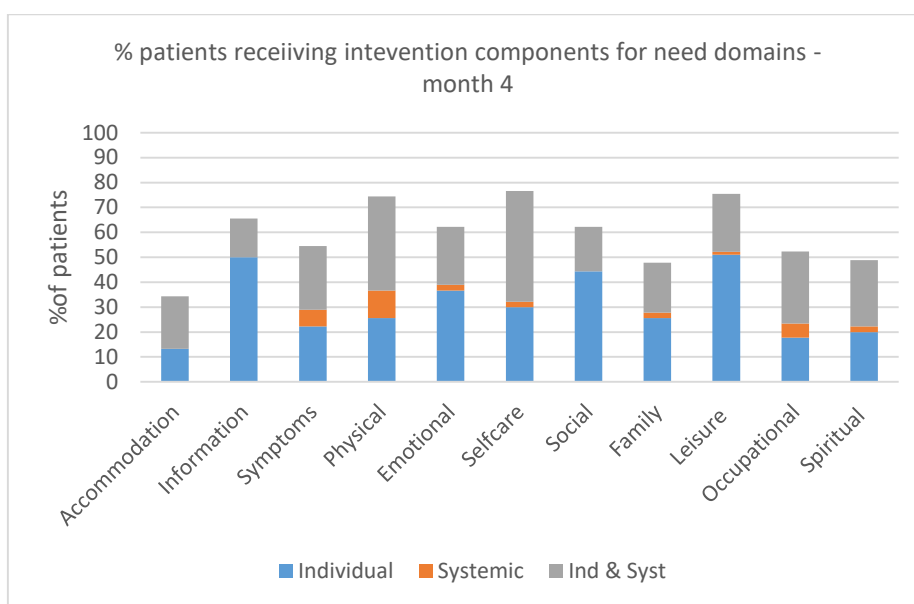


Figure 5-5: Type of intervention by need domain at month 4 of intervention

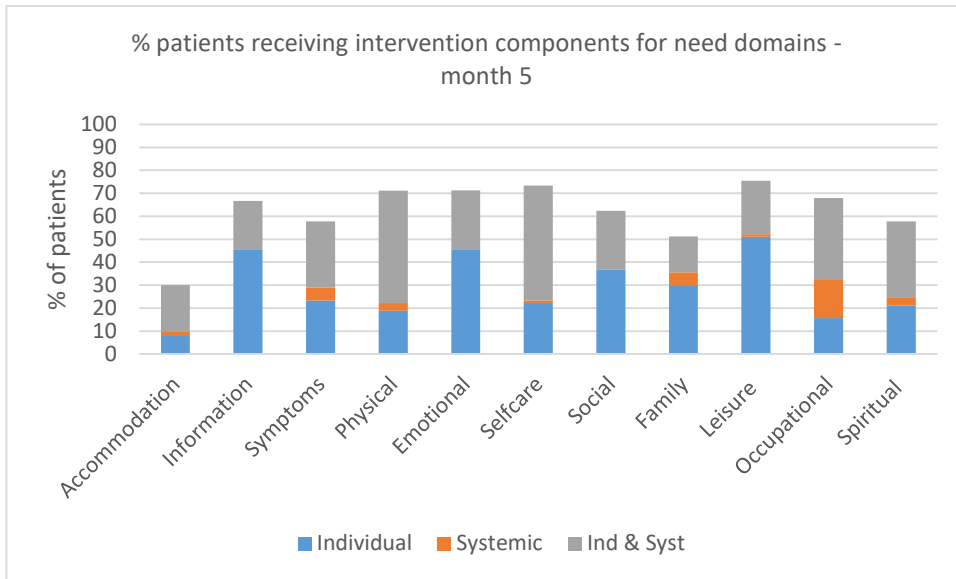


Figure 5-6: Type of intervention by need domain at month 5 of intervention

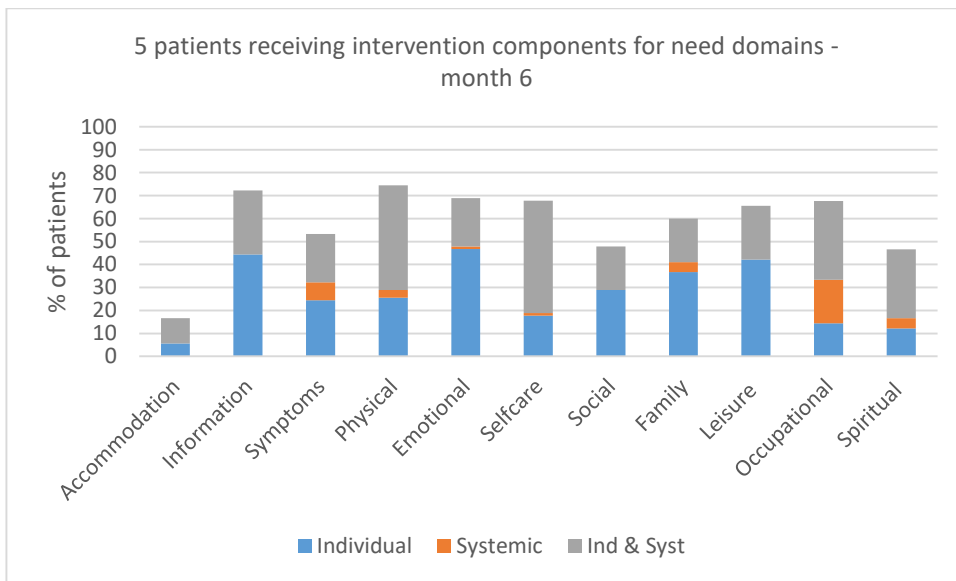


Figure 5-7: Type of intervention by need domain at month 6 of intervention

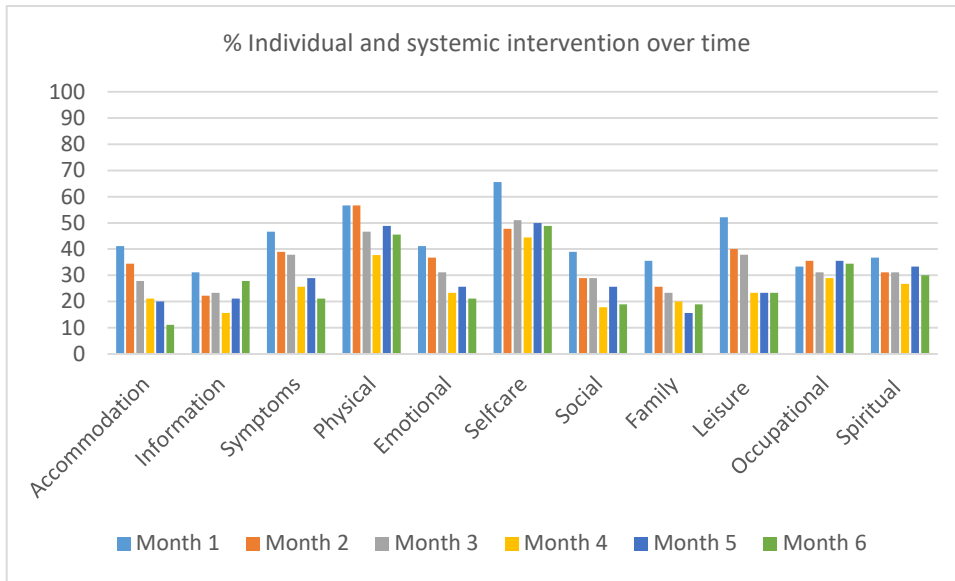


Figure 5-8: Individual and systemic interventions across the 11 components of NB-ICM

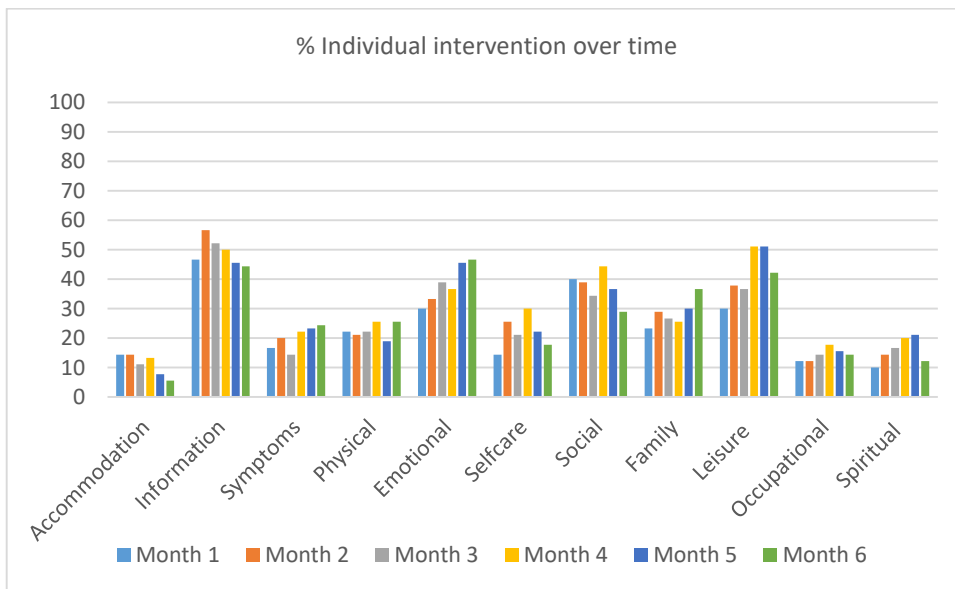


Figure 5-9: Individual interventions across 11 components of NB-ICM

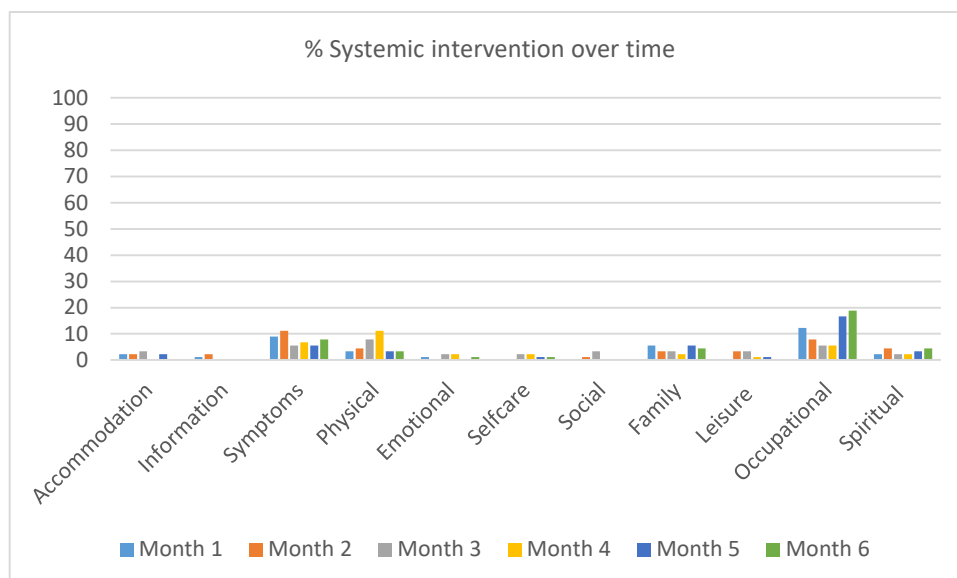


Figure 5-10: Systemic interventions across 11 domains of NB-ICM

Of the 90 people randomised to receive the intervention, 81 (90%) received the complete six months' intervention; 69 (77%) received the whole intervention in hospital, 12 (13%) were discharged during the intervention but continued to receive the service in the community (Table 5-3). The remaining 9 (10%) were discontinued from intervention before the end of six months; seven were discontinued due to discharge to geographies beyond Nagpur district, and two due to death within the six months. Of the nine people who did not complete the intervention, four were discontinued in the first month, two in the second month, one in the third month and two more were discontinued by month four of the intervention. Each session was recorded on the case management record form designed for the study included under Appendix 12.13.

Table 5-3: Completion of intervention

Completion of intervention by those randomised to intervention (n=90)		
	Frequency	Percent
In hospital	69	77
In community	12	13
Drop out	7	8
Death	2	2
Total	90	100

5.9 Needs assessment

Individual needs assessment was done through a standard form based on Camberwell Assessment of Need (CANSAS) (Slade, 1999). The adaptation draws from prior use of this measure in India through the formative study of needs (Balaji *et al.*, 2012) and need assessment formats used in community setting (Chatterjee *et al.*, 2014). The needs assessment form is included in Appendix 12.13.

The case manager assessed unmet needs of the service user at prefixed intervals of baseline, three, six, nine and 12 months, mapped across 11 domains.

Almost all the needs in each domain showed a change from being unmet to being met. Among the different needs under accommodation, food and safety, the unmet need for a clean-living space was 66% at month one and reduced to 17% at six months when the intervention was closed and continued to fall to a further 10% at month 12, which was six months after the close of intervention. The unmet need for access to enough nutritious food dropped from 12% at month one to 4% at the six-month time point and continued to remain at 4% at the 12-month time point. Episodes of verbal and physical violence dropped from 5% at month one to 2% at close of intervention and were at 4% at 12 months. Episodes of physical restraint went down from 3% at month one to 2% at six months and 1% at 12 months as shown in Figure 5-11.

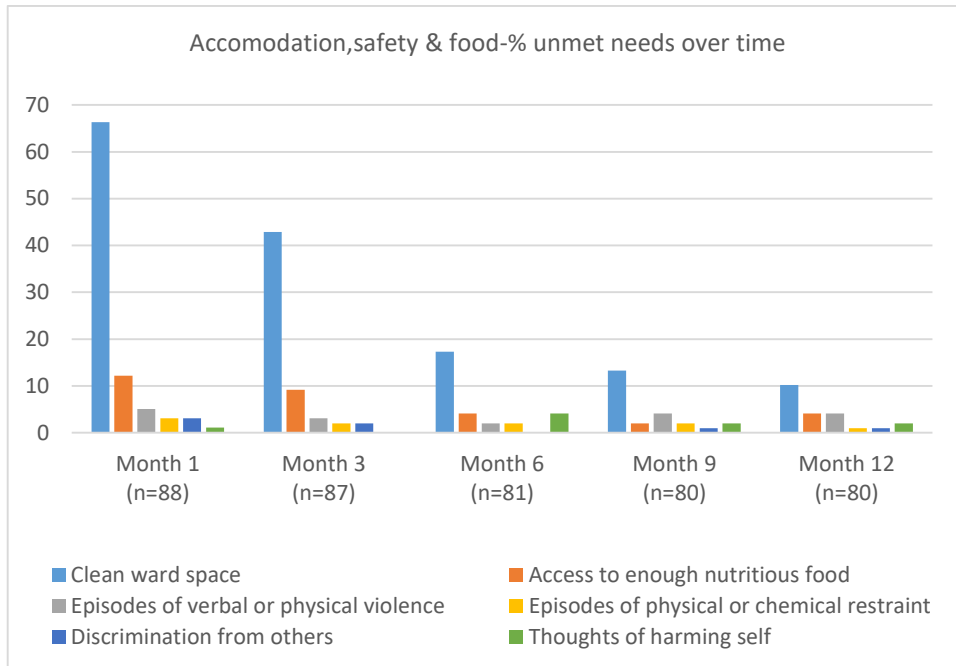


Figure 5-11: Unmet need- accommodation, safety and food

Most people had a high unmet need for psychoeducation — information on the nature of the illness and the treatment offered (77 % at month one, reduced to 64% at the close of intervention at six months) as shown in Figure 5-12.

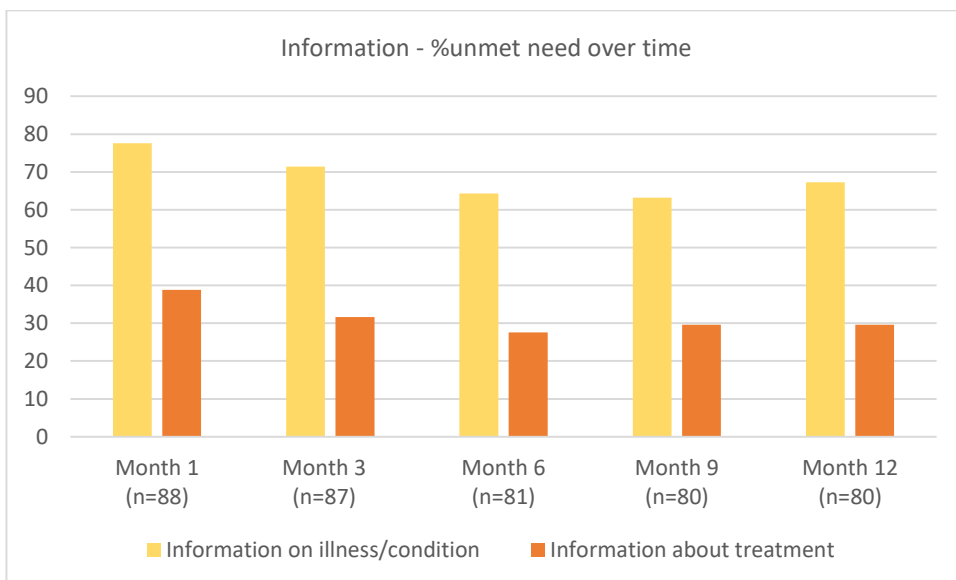


Figure 5-12: Unmet need - information about illness and treatment

Patients with psychosis often experience residual symptoms despite being on medication, with 10%-60% people experiencing psychotic symptoms being resistant to medication (Lieberman *et al.*, 2005; Patterson & Leeuwenkamp, 2008). Despite being on medication, a large percentage of service users had an unmet need of symptom control even for positive symptoms (44.9% at month one, reduced to 34.7% at the close of intervention at six months). Negative symptoms reduced from 34% to 21% at close of intervention and further to 17% at month 12. Symptoms due to medication reduced from 14% to 7% at close of intervention as shown in Figure 5-13.

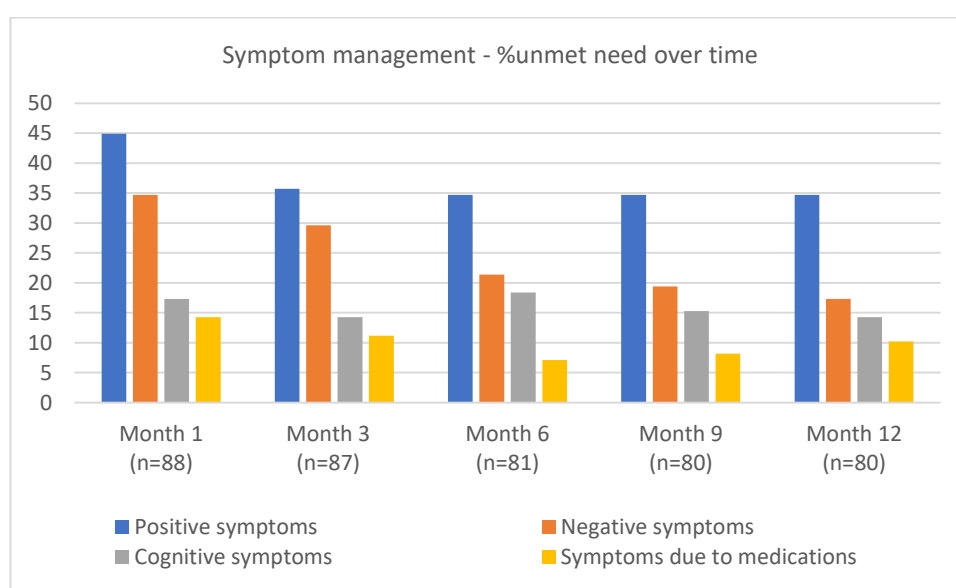


Figure 5-13: Unmet need - symptom management

Under physical health, the unmet need for health check-up reduced from 37% at month one to 21% at close of intervention and to a further 16% at month 12. Unmet need for regular dental care reduced from 46% to 39% at close of intervention and further to 33% at month 12. The need to bring down the use of tobacco showed an increase from 26% at month one to 31% at close of intervention which further fell marginally to 30% at six months after the close of intervention. We attribute this increase to the case manager's enhanced understanding of the behaviour and needs of service users. The unmet need for mobility reduced from 18% at month one to 13% at close of intervention and to a further 9% at month 12. The need for management of

other illness reduced from 30% at month one to 17% at close of intervention and to a further 12% at month 12. There was a large unmet need for physical activity which continued even at close of intervention and continued to remain high at 12 months (45% at month one, 44% at close of intervention and 49% at month 12). This can be seen in the context that all wards in the hospital are closed wards with little scope of movement (Figure 5-14).

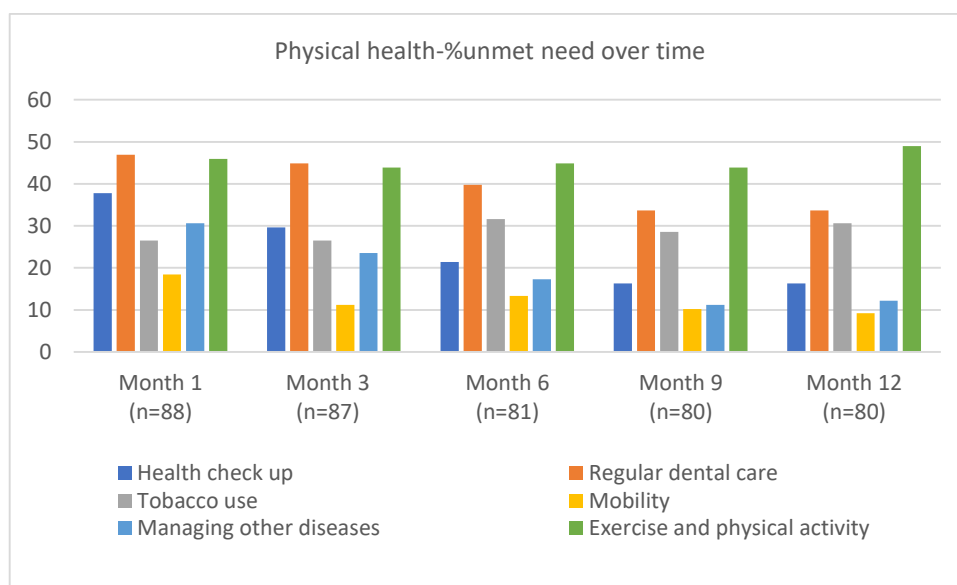


Figure 5-14: Unmet need - physical health

Having meaningful engagement and a sense of hope is also an unmet need. While the need for meaningful activity came down over the study period (50% at month one to 18% at the close of intervention further to 16% at month 12), the need for hope went down marginally at the close of intervention (53% at month one to 52% at close of intervention and to 57% at month 12). We attribute this to a deeper engagement with the service user which helped elicit this need, as shown in Figure 5-15.

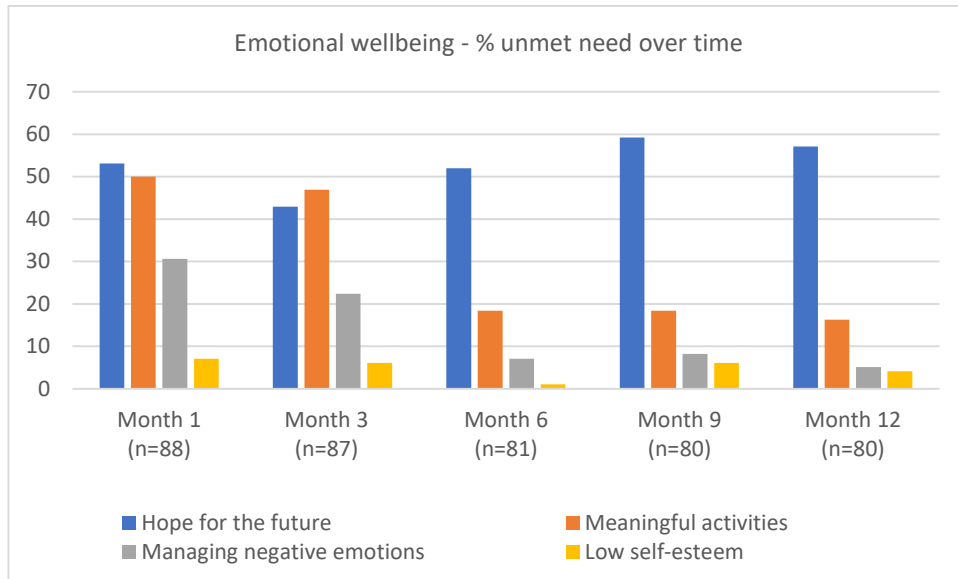


Figure 5-15: Unmet need - emotional wellbeing

All the four components on the self-care domain have shown a shift from being unmet at month one to being met at the close of intervention and further to six-month follow-up after the close of intervention. The unmet need for grooming fell from 72% at month one to 46% at close of intervention and further to 36% at 12 months, caring from personal utilities fell from 59% at month one to 31% at six months and further to 20% at 12 months. The unmet need for caring for one's clothes fell from 65% at month one to 39% at six months and further to 38% at 12 months. The unmet need for hygiene feel from 64% at month one to 58% at close of intervention and further to 49% at 12 months (Figure 5-16).

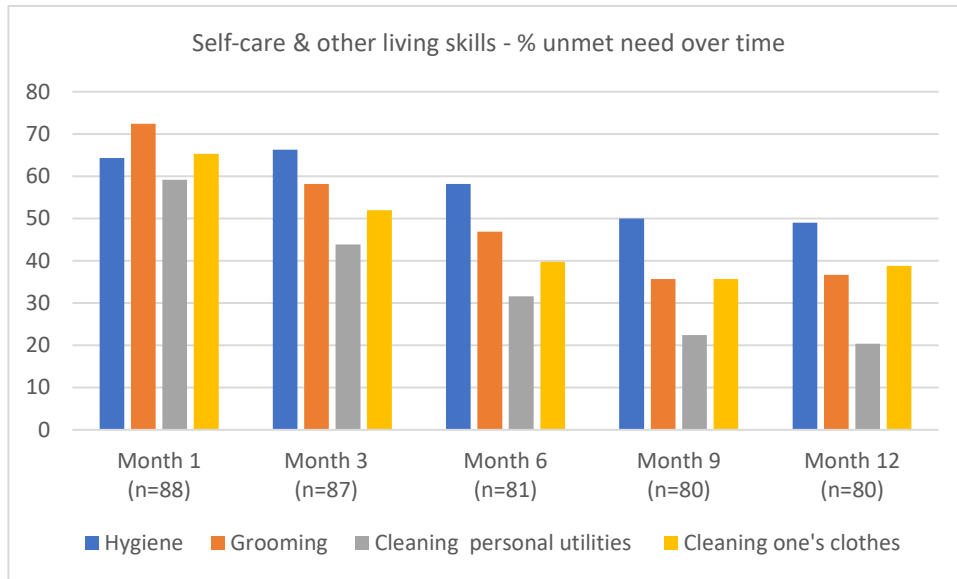


Figure 5-16: Unmet need - self-care and other living skills

Relationship with the case manager (60% at month one to 22% at close of intervention to a further 15% at 12 months) showed improvement over time as did involvement in group activities (49% at month one to 27 at close of intervention to a further 23% at 12 months) amongst elements of social relationships shown in Figure 5-17.

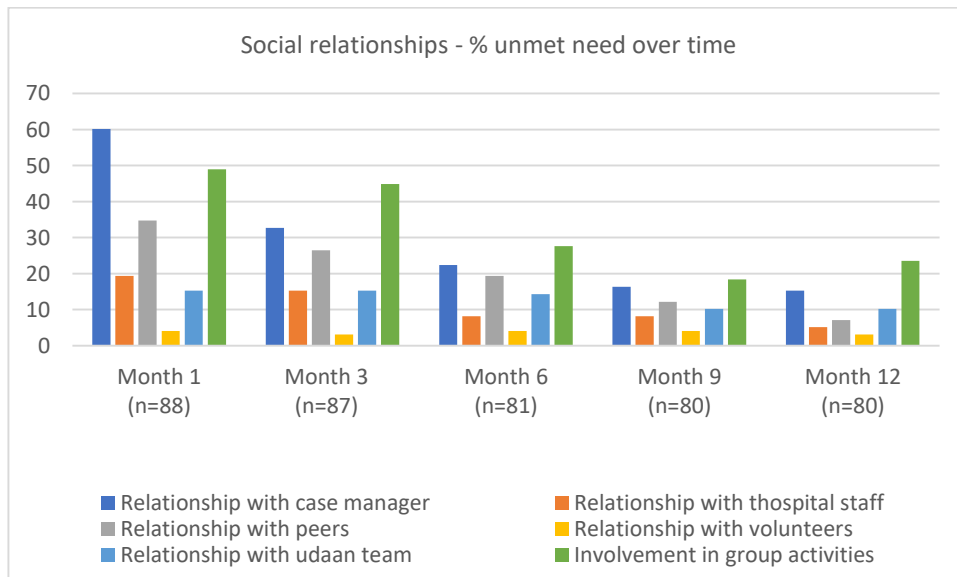


Figure 5-17: Unmet need - social relationships

In the domain of family relationships, there was a shift in tracing families who were not known at baseline (63% to 50% at close of intervention and further to 46% at 12 months). However, creating an engagement with the family was slightly difficult. Often family members refused to come visit the patient for fear of being made to take the person back home. The unmet need for engagement with family dropped from 37% to 29% at close of intervention and at 12 months was at 31%) shown in Figure 5-18.

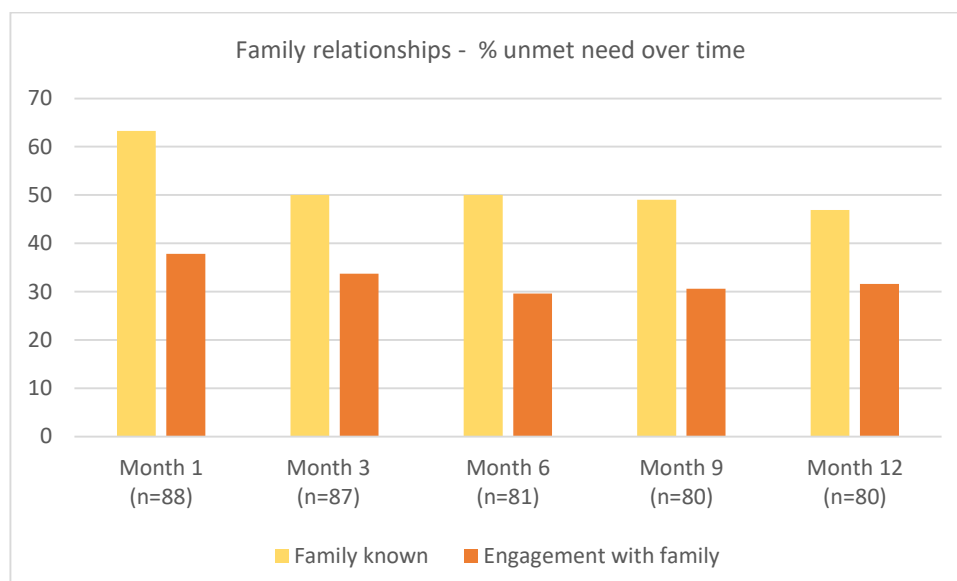


Figure 5-18: Unmet need - connecting with family

Activities of leisure showed a change over the study duration as patient engagement and activities in the hospital widened (hobbies 59% to 28% at close of intervention, sports 61% to 41% at close of intervention and further to 37% at 12 months, movies 64% to 35% at close of intervention and further to 32% at 12 months and outings from 26% to 13% at close of intervention) shown in Figure 5-19.

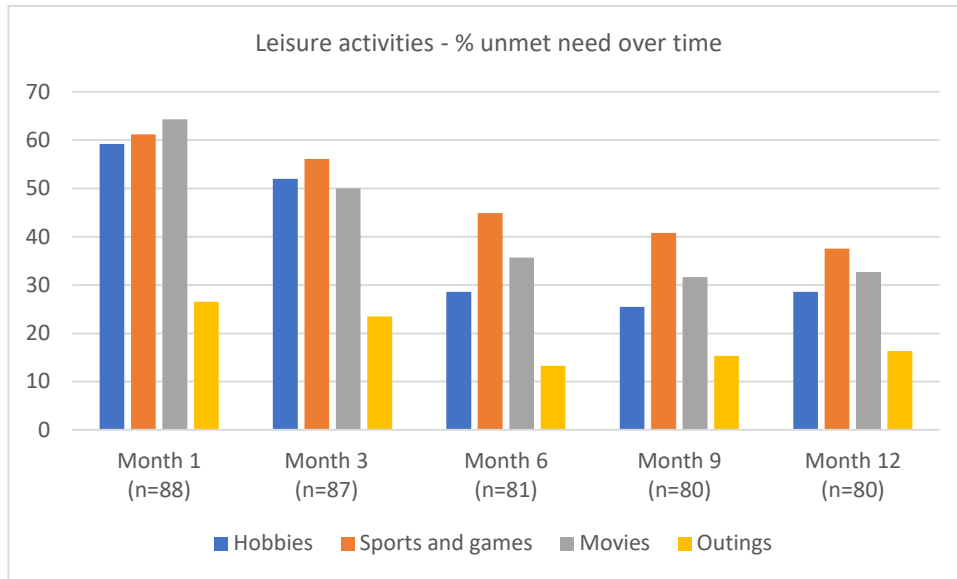


Figure 5-19: Unmet needs - leisure activity

Occupational and financial inclusion had elements of citizenship where the unmet need went up as the study progressed, we attribute this to better availability of information for the service user (43% at month one to 56% at close of intervention to 58% at month 12). All other needs on this domain showed a decline (skill building 51% at month one to 41% at month six and at 42% at month 12; employment 45 % at month one and 37% at six months to 38% at month 12; wages or stipend from 31% to 15% at close of intervention and at 12 months; bank accounts from 37% to 16% at close of intervention and opportunity to use earnings from 21% to 10% at close of intervention) shown in Figure 5-20.

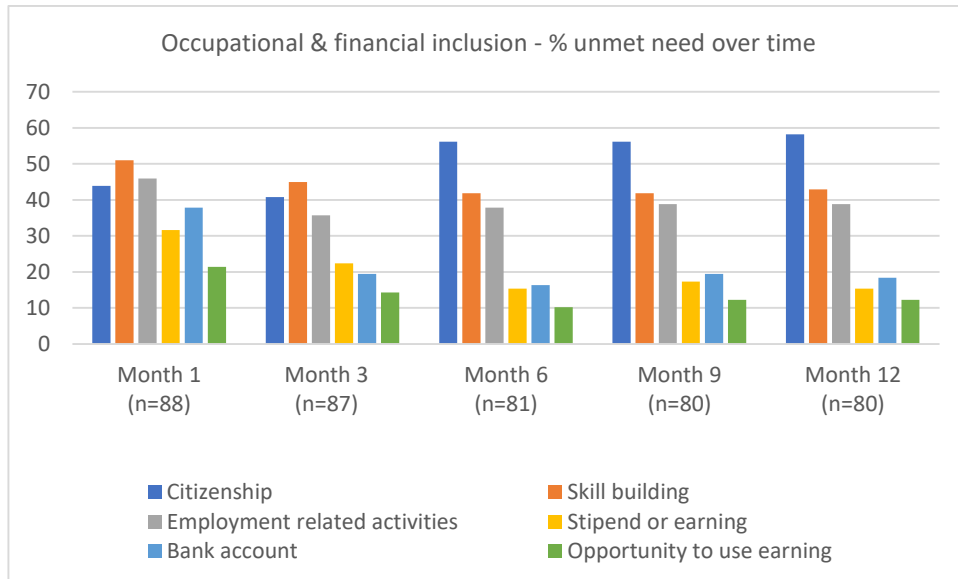


Figure 5-20: Unmet need - occupational and financial inclusion

The need for engaging in spiritual activities also went through a change as more opportunities were created through the hospital reform process (religious activities 53% at month one to 39% at close of intervention further reduced to 25% at month 12 and activities of yoga and meditation from 52% to 30% at the close of intervention and at month 12) shown in Figure 5-21.

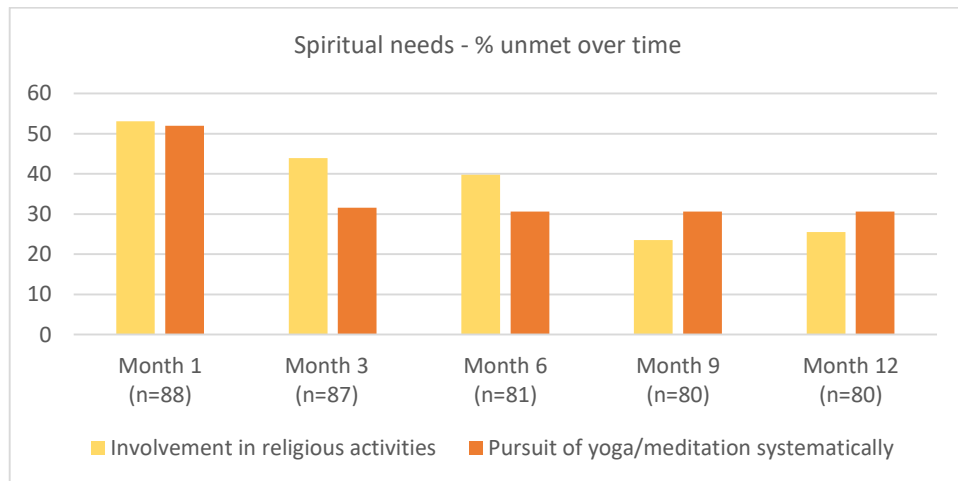


Figure 5-21: Unmet need - spiritual activities

5.10 Supervision

The student researcher conducted supervision through individual sessions with each case manager and joint monthly meetings with all the case managers. In total, 90 supervision sessions were conducted during the intervention period, 84 of these as individual supervision sessions and 6 as joint meetings of all case managers. The supervision checklist used is shown in Table 5-4.

Table 5-4: Supervision checklist

Supervision points	Means of verification
No of case management sessions per case completed	Review of case work record form
Needs identified	Review of needs assessment form completed at stipulated intervals
Planned intervention	Review of intervention plan drawn up at stipulated intervals. At least three inputs / actions per case per month initiated.
List of problems / barriers identified and their resolution	Case work record form

5.11 Withdrawal of NB-ICM

NB-ICM was systematically withdrawn after the six-month intervention period. For patients who continued in the long-stay wards of the hospital at the time of completion of intervention, sessions were gradually tapered off in the last four weeks of intervention. The case manager continued to maintain fortnightly patient contact for three months after withdrawal of intervention which was further reduced to monthly contact for the next three months. All other individual patient sessions were closed. The final, evolved intervention plan was included in the case file of the patient with a handover to the social workers / ward in-charge of the hospital (along with the patient where feasible). The patient's participation in all established group activities was continued. This included group sessions at the ward level, participation in celebrations and events, participation in employment training activities and participation in entertainment and recreational activities. In cases where details of the family have been elicited, the case management team continued to facilitate contact with the family and worked on the possibility of reintegration.

In cases where patients were discharged back to the family, the case manager made at least two visits to the family before the patient was

discharged, provided psychoeducation to the family and addressed concerns the family had. The case manager maintained a fortnightly follow-up for the first three months after discharge which was brought down to a monthly contact for the next three months. Special attention was paid to ensure that the patient did not miss follow-up visits to the OPD and that there were no medication stock-outs.

5.12 Conclusion

The clinical trial SITAR embedded within the Udaan programme of psychiatric hospital reform tested whether NB-ICM improves patient outcomes as compared to care as usual in long-stay psychotic patients in a psychiatric hospital undergoing larger structural and process reform. This comparison is valuable in policy decision making on how meagre resources should be used in low-resource settings. Case managers were effectively trained through a training programme specially designed for the intervention. The intervention was mapped to 11 need domains. Case managers assessed for unmet need at regular time points which in turn guided the development of the intervention plan. 90% of those randomly allocated to intervention received the complete intervention. The mean number of case management sessions held were 59.6 with a SD of 16 for each service user over a six-month period. The average number of sessions was higher than the anticipated 48 sessions per service user. For most domains, interventions intensified over the first three months and were tapered towards the end of intervention. For domains such as occupational engagement, interventions at all three levels continued till the end of the six-month period. Systemic intervention was also phasic and occurred only in certain months as opposed to individual and individual and systemic intervention which was continuous. Almost all the needs in each domain showed a change over the intervention period. Some of the needs that changed visibly were those of the need for a clean-living space, negative symptoms, regular health check-ups, management of negative emotions, grooming, relationship with peers and having a hobby. Intervention was systematically withdrawn, integrating it into care as usual in the hospital.

6 Impact of COVID 19 On the SITAR trial

6.1 Chapter Introduction

Corona viruses are enveloped RNA viruses found in mammals and in birds. Corona Viruses have seven known strains of which COVID 19 is the latest (Ghosh *et al.*, 2020) . This strain's emergence epi-cantered in the Hubei Province of the People's Republic of China in December 2019 and was declared a global emergency by WHO on 30th of January 2020 (Velavan & Meyer, 2020). This chapter discusses the pandemic and its impact on my research.

6.2 COVID 19 In India

India reported its first detected case of COVID 19 on the 30th of January 2020 from the state of Kerala. Maharashtra confirmed its first case on the 9th of March 2020 and the state declared an epidemic in five of its cities on 13th March 2020 and the closure of commercial and educational establishments (Kumar, 2020). Maharashtra announced a state wide lock down on the 23rd of March 2020 which was followed by the central Government's announcement of a nationwide lockdown on the 24th of March 2020 (Kumar, 2020).

6.3 India's lockdown

India, home to world's second largest population was the seat of the largest global lockdown due to COVID 19. India's complete lockdown was extended till 31st May and then lifted in phases up to the end of July 2020 (Kumar, 2020; Lancet, 2020).

The sudden enforcement of this lockdown disadvantaged highly vulnerable people leaving many stranded with loss of jobs and starvation. Regular public health services were disrupted, with all the government resources diverted to the management of the pandemic. implementation of public health measures was very difficult in places with overcrowded living conditions with inadequate hygiene and sanitation facilities (Lancet, 2020).

6.4 COVID 19 situation at RMHN and its impact on the SITAR trial

The Udaan program for psychiatric hospital reform is an MoU of technical support towards developing RMHN as a centre of excellence. The Udaan

team worked in close alliance with the hospital. As the COVID 19 situation worsened in Maharashtra, many members of hospital staff either fell ill or had to go through a 14-day quarantine due to exposure. RMHN, like many other mental hospitals already suffers from a huge paucity of staff (Murthy *et al.*, 2016) and COVID 19 related absenteeism caused further disruption in staff availability and patient services. Members from both the hospital reform team as well as from the District Mental Health Program (DMHP) under Udaan were deployed to help address some of the urgent service requirements of the hospital.

The hospital completely stopped visitors to the in-patient section which also included visits from family members. Personnel movement to the in-patient wards was also restricted. This impacted a range of regular activities as well as reform activities in the wards for almost three months.

Several reform components that were to be activated in the year 2020 such as the day care program, ensuring continuity of care for patients discharged from the hospital, systematic discharge of long-stay patients to community living activated through a collaborative civil society network and the activation of some skill building and employment pathways have been affected with timelines pushed to 2021.

Since the Udaan team was part of the personnel deployed to the in-patient wards, we could continue data collection as per originally set timelines.

We conducted Focus Group Discussions with patients on the intervention and control arms of the SITAR trial in August 2020. The impact of service disruption was clearly felt by the patients and is discussed in detail in chapter 8: Qualitative Analysis - Focus Group Discussions (FGDs); SITAR Trial.

6.5 Chapter conclusion

The COVID 19 situation has caused disruption in public health services across India. Reform activities at RMHN had to be down scaled to facilitate infection control. Since the Udaan team was part of service delivery at RMHN, we continued to have access to the In-patient wards. The SITAR trial and data collection thereof was not impacted.

7 Quantitative results of the SITAR trial

7.1 Chapter introduction

This chapter presents the quantitative results of the SITAR trial according to the CONSORT guidelines (CONSORT., 2010). We have also reported findings for the larger population of the Regional Mental Hospital of Nagpur (RMHN) that did not meet the inclusion criteria for the SITAR Trial to assess the overall impact of reform on the hospital population (Figure 4-1).

7.2 Data analysis and findings for SITAR

7.2.1 Sample

469 patients admitted to RMHN were assessed for inclusion in the SITAR trial. 182 patients met the inclusion criteria and were subsequently randomised to intervention (n=90) and control (n=92). The primary outcome was measured at the six-month time point. This time point was chosen due to the context of the research study and the feasibility of tracking patients long term. By this time, nine patients had dropped out of the intervention arm (seven patients discharged beyond Nagpur district and two deaths) and seven dropped out of the control arm (seven patients discharged beyond Nagpur district). By the nine-month time point, there had been an additional drop out of one patient (due to death) in the intervention arm and one patient (discharged beyond Nagpur district) in the control arm. By the 12-month time point, there was no additional drop out in the intervention arm and an additional drop out of one patient (discharged beyond Nagpur district) in the control arm. We thus analysed results for 166 patients at the six-month time point (81 interventions, 85 control), 164 patients at the nine-month time point (80 intervention, 84 control) and 163 patients at the 12-month time point (80 interventions, 83 control). The CONSORT flow chart is presented in Figure 7-1.

Consent was taken from patients, treating psychiatrists and the ward in-charge (psychiatrists and ward in-charge signed off for all patients included in the trial). While patients with severe mental illness living in an institution for a prolonged period may not be in a position to give consent, the study ensured maximum participation using pictorial tools to explain the study to small groups of patients at a time based on work done in prior research (Chatterjee *et al.*, 2015). Consent was recorded for patients who were in a

position to do so (10% across trial arms). Consent from the treating psychiatrist and ward in-charge was recorded for all patients, in keeping with Indian Government requirements. The proportion of consent from patients is presented in Figure 7-2.

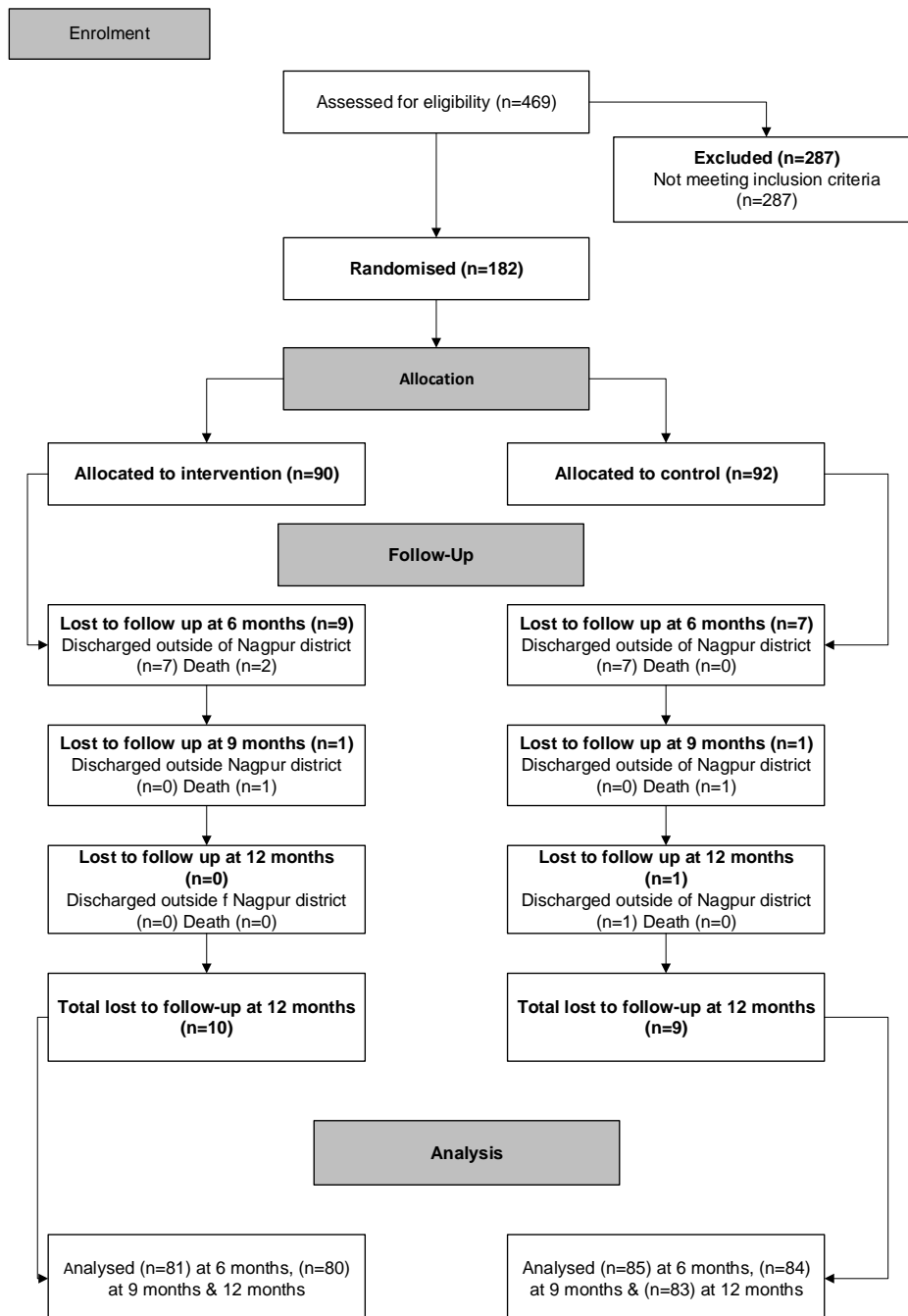


Figure 7-1: CONSORT flow chart for the SITAR trial

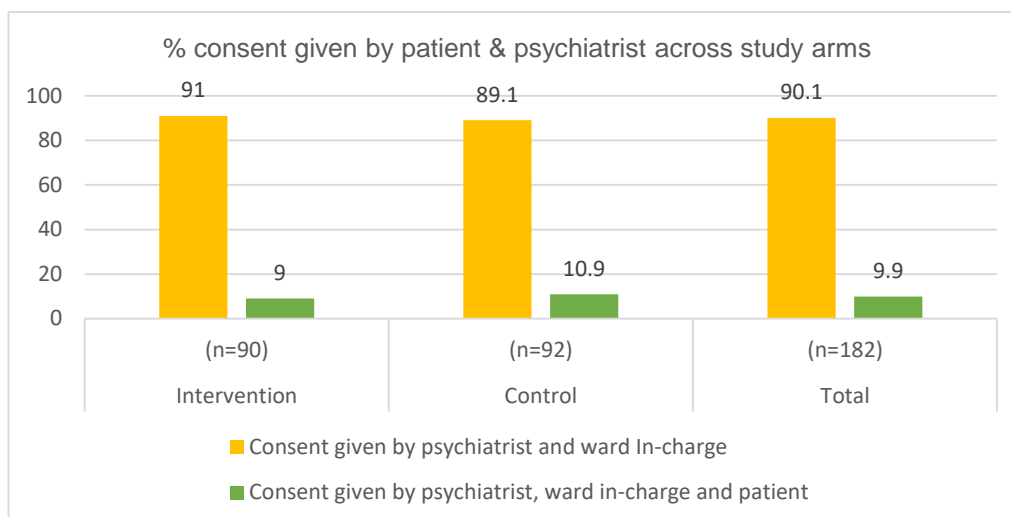


Figure 7-2: Consent given by patient, psychiatrists and ward in-charge across trial arms

7.2.2 Sample characteristics at baseline

Participant characteristics were summarised by trial arm using descriptive statistics. Mean and standard deviation (SD) were used for continuous variables and categorical variables were summarised using frequency and percentage and are presented in Table 7-1.

Table 7-1: Baseline sample characteristics of the SITAR trial sample

	Intervention (n=90)	Control (n=92)	Total (n=182)
Age mean (SD)	40.3 (10.6)	41.8 (11.5)	41.1 (11.1)
Age median (IQR)	41 (32-47.25)	41 (32.25-51)	41 (32-51)
Gender			
Female	54 (60%)	56 (60.9%)	110 (60.4%)
Male	36 (40%)	36 (39.1%)	72 (39.6%)
Religion			
Hindu	48 (53.3%)	37 (40.2%)	85 (46.7%)
Muslim	7 (7.8%)	8 (8.7%)	15 (8.2%)
Buddhist	7 (7.8%)	5 (5.4%)	12 (6.6%)
Not known	28 (31.1%)	42 (45.7%)	70 (38.5%)
Marital Status			
Married	24 (26.7%)	3 (3.3%)	27 (14.8%)
Unmarried	17 (18.9%)	12 (13%)	29 (15.9%)
Separated	2 (2.2%)	0 (0%)	2 (1.1%)
Not known	47 (52.2%)	77 (83.7%)	124 (68.1%)
Education			
Illiterate	6 (6.7%)	10 (10.9%)	16 (8.8%)
Partial schooling	39 (43.3%)	17 (18.4%)	56 (30.8%)

	Intervention (n=90)	Control (n=92)	Total (n=182)
Completed School	3 (3.3%)	6 (6.5%)	9 (4.9%)
Graduation	1 (1.1%)	0 (0 %)	1 (0.5%)
Post-Graduation	1 (1.1%)	0 (0%)	1 (0.5%)
Not known	40 (44.4%)	59 (64.1%)	99 (54.4%)
Domicile			
From Maharashtra	54 (60%)	52 (56.5%)	106 (58.2%)
Outside Maharashtra	12 (13.3%)	6 (6.5%)	18 (9.9%)
Not known	24 (26.7%)	34 (37%)	58 (31.9%)
Duration of stay in hospital at baseline reported in months Mean (SD)	52.90 (29.24%)	53.31 (26.61%)	53.11 (27.87%)
Duration of stay in months median (range)	40.98 (29.95-72.47)	43.86 (33.09-70.41)	43.36 (32.30-71.04)

Patients in both the intervention and control arm were in their early 40s (mean=40.3 for intervention and 41.8 for control). There were more women than men across both arms (60% in intervention and 61 % in control), In terms of religion, people were predominantly Hindu (53% intervention, 40% control). 43.3% in the intervention arm and 18.4% in the control arm, had partial schooling. Most patients were from the state of Maharashtra (60.5% in the intervention and 56.5% in the control arm).

Long-stay patients of mental hospitals in India are often homeless persons brought in through judicial intervention (Gowda *et al.*, 2017; Murthy *et al.*, 2016; Narasimhan *et al.*, 2019; Tripathi *et al.*, 2013) and are often unable to provide information about themselves, even on variables of personal identity. This is reflected in the SITAR trial sample (31.1% in the intervention and 45.7% in the control arm had no information on their religion).

The mean length of stay in hospital across trial arms was between four to five years (52.9 months for intervention and 53.1 months for control).

7.3 Outcomes

The primary outcome was disability levels at the six-month point after initiation of intervention measured through WHODAS. Secondary outcomes comprised disability measures at nine and 12 months as well as measurement of symptoms (measured through CGI), social and

occupational functioning (SOFAS) and quality of life (EQ-5D) at the six-, nine- and 12-month time points.

7.3.1 Disability (main effects)

We used the 36 item proxy version of WHODAS 2.0 (Üstün, 2010) to assess disability levels of patients participating in the SITAR trial at baseline, six, nine and 12 months. WHODAS 2.0 provides a total disability score as well as scores for six domains of functioning: cognition, mobility, self-care, getting along, life activities and participation.

Raw scores were converted to normalised scores using methods specified in the WHODAS manual, on a scale of 0-100 with higher scores indicating higher disability (Üstün, 2010). We plotted the disability score for each study arm in a line graph to examine trends of disability scores over time shown in Figure 7-3

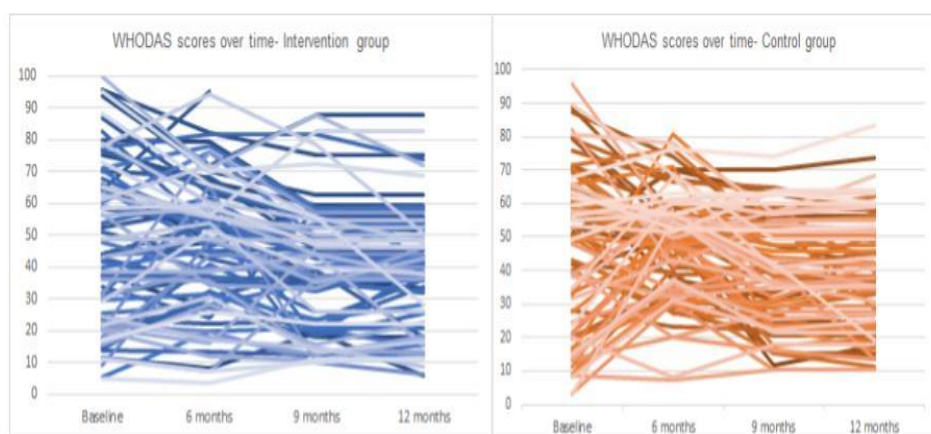
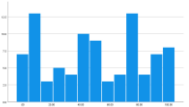
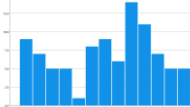
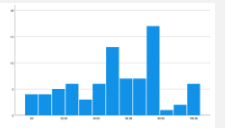
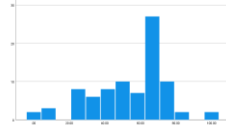
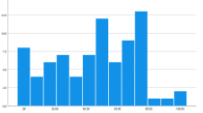
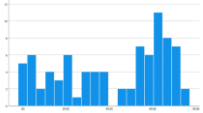
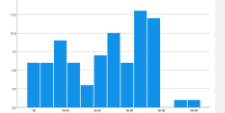







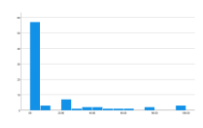
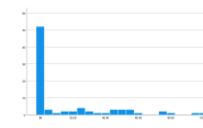

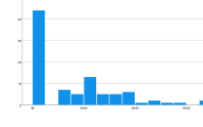



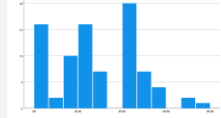
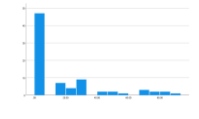



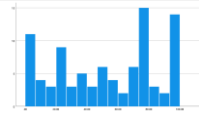
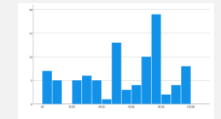
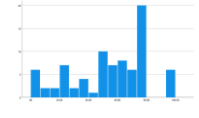
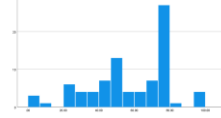
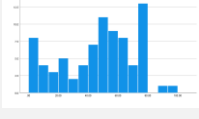
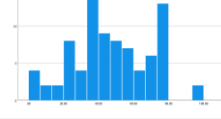
Figure 7-3: WHODAS scores over time in the intervention and control arms of SITAR

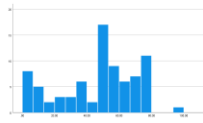
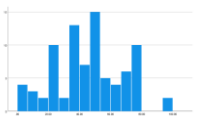

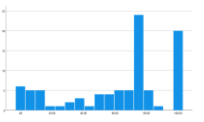

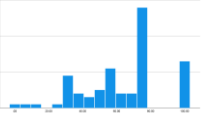




Histograms were plotted for each of the six domains and for the total score at each time point across trial arms to assess if the data were normally distributed. Based on this assessment, non-parametric statistical tests were used to compare trial arms on domain scores and total disability score. The data from this analysis are presented in Table 7-2.

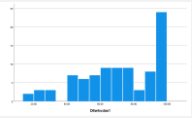
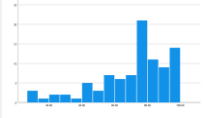
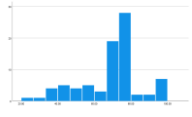
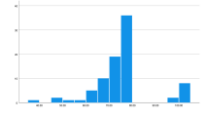


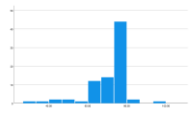

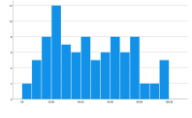
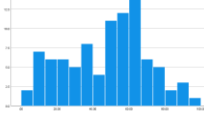
Table 7-2: Domain and total WHODAS scores in intervention and control arms – descriptive statistics and significance values across arms

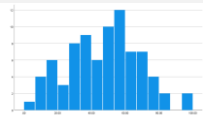
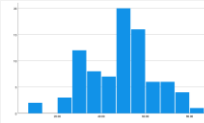
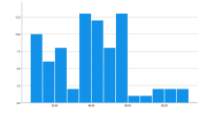
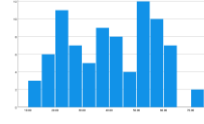
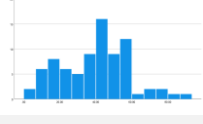
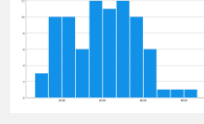
	Intervention				Control				p-value
	N	Mean (SD)	Median (Inter quartile range)	Distribution	N	Mean (SD)	Median (range)	Distribution	
Domain 1: Cognition									
Baseline	90	48.28 (32.15)	45.83 (15.62-75)		92	50.09 (30.02)	58.33 (25-73.95)		0.77
6 months	81	52.16 (26.82)	54.16 (33.33-70.83)		85	52.79 (20.43)	58.33 (39.48 66.66)		0.88
9 months	80	44.47 (26.60)	47.91 (21.87-66.66)		84	41.41 (24,38)	50 (20.83-62.5)		0.47
12 months	80	43.12 (26.14)	47.91 (16.66-66.66)		83	40.56 (24.14)	41.66 (20.83-62.5)		0.54

	Intervention				Control				p-value
	N	Mean (SD)	Median (Inter quartile range)	Distribution	N	Mean (SD)	Median (range)	Distribution	
Domain 2: Mobility									
Baseline	90	26.27 (31.55)	10 (0-46.25)		92	26.84 (29.76)	10 (0-50)		0.76
6 months	81	17.03 (27.52)	0 (0-30)		85	15.05 (25.54)	0 (0-25)		0.59
9 months	80	15.43 (27.92)	0 (0-123.75)		84	14.10 (25.24)	0 (0-18.75)		0.72
12 months	80	12.87 (24.58)	0 (0-21.25)		83	15.24 (25.22)	0 (0-25)		0.53
Domain 3: Self-care									
Baseline	90	14.77 (19.77)	0 (0-29.1)		92	14.56 (17.21)	10.41 (0-24.82)		0.75

	Intervention				Control				p-value
	N	Mean (SD)	Median (Inter quartile range)	Distribution	N	Mean (SD)	Median (range)	Distribution	
6 months	81	31.49 (25.90)	32.63 (0-50)		85	28.61 (19.13)	25 (16.66-41.66)		0.51
9 months	80	16.97 (25)	0 (0-32.63)		84	19.19 (19.64)	16.66 (0-32.63)		0.11
12 months	80	16.88 (23.44)	0 (0-32.63)		83	17.32 (20.61)	16.66 (0-32.63)		0.50
Domain 4: Getting along									
Baseline	90	52.67 (32.2)	55.7 (25-75)		92	55.31 (27.53)	62 (32.27-75)		0.65
6 months	81	54.30 (26)	55.7 (37-75)		85	57.14 (22)	62 (43.7-75)		0.53
9 months	80	46.74 (24.24)	50 (26.42-62)		84	47.18 (21.69)	43.7 (37-67.02)		0.72

	Intervention				Control				p-value
	N	Mean (SD)	Median (Inter quartile range)	Distribution	N	Mean (SD)	Median (range)	Distribution	
12 months	80	46.43 (23.64)	50 (30.7-62)		83	45.90 (21.65)	50 (30.7-62)		0.48
Domain 5: Life activities									
Baseline	90	58.33 (34.66)	65.62 (25-100)		92	61.34 (32.55)	73.43 (39.06-78.12)		0.70
6 months	81	59.33 (29.31)	68.75 (37.5-75)		85	62.57 (24.35)	68.75 (48.43-75)		0.67
9 months	80	49.29 (31.49)	64.06 (22.65-75)		84	49.55 (27.90)	56.25 (22.65-75)		0.83
12 months	80	50.15 (28.31)	56.25 (22.65-75)		83	48.87 (28.32)	56.25 (18.75-75)		0.91

	Intervention				Control				p-value
	N	Mean (SD)	Median (Inter quartile range)	Distribution	N	Mean (SD)	Median (range)	Distribution	
Domain 6: Participation									
Baseline	90	71.65 (23.69)	71.56 (53.43-96.25)		92	70.92 (22.96)	75 (57.18-87.89)		0.85
6 months	81	68.88 (16.48)	71.25 (59.21-75)		85	74.08 (11.43)	75 (71.25-75)		0.13
9 months	80	70.41 (9.56)	71.87 (64.53-75)		84	70.36 (8.91)	71.2 (43.7-100)		0.73
12 months	80	70.09 (10.16)	75 (67.5-75)		83	70.53 (8.58)	71.25 (65-75)		0.22
WHODAS Total									
Baseline	90	46.57 (25.88)	43.95 (22.30-68.19)		92	47.70 (23)	51.34 (29.05-64.19)		0.69

	Intervention				Control				p-value
	N	Mean (SD)	Median (Inter quartile range)	Distribution	N	Mean (SD)	Median (range)	Distribution	
6 months	81	47.20 (21.19))	48.76 (31.07-62.52)		85	48.37 (15.44)	50.75 (36.64-57.94)		0.74
9 months	80	40.55 (19.83)	41.35 (22.29-54.57)		84	40.30 (16.29)	40.71 (25.32-54.44)		0.78
12 months	80	39.92 (18.46)	41.64 (25.46-52.89)		83	39.74 (16.85)	40.38 (24.54-52.34)		0.95
<p>Mann Whitney u tests have been used for assessing the difference in scores between the intervention and control group for each domain at each time point. Higher values indicate higher disability</p>									

No statistical difference was seen across the total disability scores at the six-month time point which was the primary outcome of the trial (p=0.74).

We also did not find a statistical difference in total disability scores between the randomised arms at nine- and 12-months' time point (p=0.78 and 0.95 respectively). The domain scores on disability measures comprising cognition, mobility, self-care, getting along, life activities and participation showed similar results with no statistical difference identified at the six-, nine- or the 12-month time points.

We then used linear regression to assess for difference for the total disability score at six, nine and 12 months across study arms, adjusting for clinically relevant variables of age, gender and duration of stay in the hospital. The randomised arm was not found predictive of disability scores at any of the time points (p for randomised arm 0.72, 0.86 and 0.84, at six, nine and 12 months respectively) as shown in Table 7-3.

Of the three variables of clinical interest (age, gender and duration of stay), only gender appeared predictive of disability scores at six months (p=0.01) although this result was not apparent at the nine- or 12-month time point (p=0.41 and 0.61 at nine and 12 months respectively). Regardless of randomization, women had higher levels of disability than men (WHODAS scores at six months: Mean (SD) male- 43.19 (18.63) female- 50.92 (17.70).

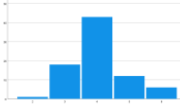







Table 7-3: Multivariate linear regression for WHODAS scores at six, nine and 12 months

Multivariate linear regression for WHODAS scores at 6 months				
	Estimate	SE	T	P
Randomised arms	-1.02	2.84	-0.36	0.72
Age	0.07	0.13	0.55	0.58
Duration of Stay	-0.01	0.05	-0.25	0.80
Gender	7.92	2.91	2.71	0.01
Multivariate linear regression for WHODAS scores at 9 months				
Randomised arms	0.50	2.83	0.18	0.86
Age	0.16	0.13	1.25	0.21
Duration of Stay	-0.06	0.05	-1.22	0.22
Gender	2.38	2.90	0.82	0.41
Multivariate linear regression for WHODAS scores at 12 months				
Randomised arms	0.54	2.76	0.20	0.84
Age	0.23	0.13	1.81	0.71
Duration of Stay	-0.05	0.05	-1.10	0.27
Gender	1.42	2.84	0.50	0.61

7.3.2 Symptoms

We used CGI scores to measure symptoms over time across study arms. Histograms were plotted for the total CGI score at each time point across study arms to assess if the data were normally distributed. Based on this assessment, non-parametric statistical tests were used to compare study arms on the CGI scores. The data from this analysis are presented in Table 7-4.

Table 7-4: CGI scores – descriptive statistics and significance values across arms

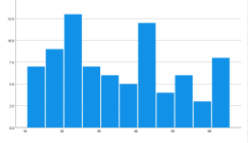
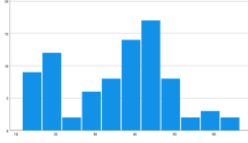
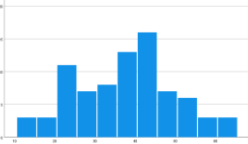
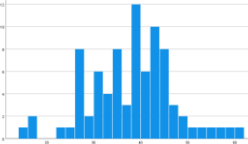
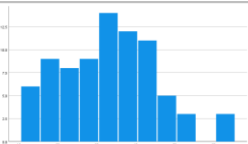

	Intervention				Control				p-value
	N	Mean (SD)	Median (Inter quartile range)	Distribution	N	Mean (SD)	Median (range)	Distribution	
CGI									
Baseline	90	4.01 (0.84)	4.00 (3.00-4.00)		92	4.03 (0.70)	4.00 (4.00-4.00)		0.67
6 months	81	3.62 (1.04)	3.00 (3.00-4.00)		85	3.61 (1.05)	4.00 (3.00-4.00)		0.93
9 months	80	3.41 (1.01)	3.00 (3.00-4.00)		84	3.45 (1.10)	3.00 (3.00-4.00)		0.99
12 months	80	3.38 (1.01)	3.00 (3.00-4.00)		83	3.42 (1.08)	3.00 (3.00-4.00)		0.95
<p>Mann Whitney u tests have been used for assessing the difference in scores between the intervention and control group at each time point.</p> <p>Lower values indicate improvement in symptoms</p>									

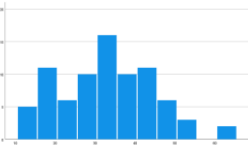
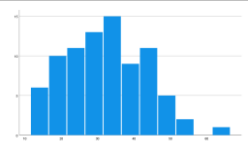
No statistical difference was seen across study arms in the CGI scores at the six ($p=0.93$)-, nine ($p=0.99$)- and 12-month ($p=0.95$) time points.

7.3.3 Social and occupational functioning

Social and occupational functioning was measured through the SOFAS at baseline, six, nine and 12 months across trial arms. We plotted histograms for scores at each time point to assess for normal distribution of data. Non-parametric tests were used for statistical analysis and are presented in Table 7-5.

Table 7-5: SOFAS scores- descriptive statistics and significance values across trial arms

	Intervention				Control				p-value
	N	Mean (SD)	Median (Inter quartile range)	Distribution	N	Mean (SD)	Median (range)	Distribution	
Baseline	90	35.21 (15.49)	33 (22-48.35)		92	35.68 (13.00)	38 (25.5-44)		0.74
At 6 months	81	37.70 (12.53)	39.00 (27.50-45.50)		85	37.35 (9.01)	39 (31.00-43.00)		0.77
At 9 months	80	33.14 (12.18)	33.50 (23.25-41.00)		84	32.69 (10.35)	32.5 (23.00-41.00)		0.97

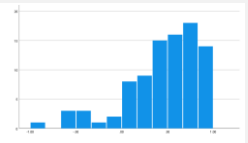


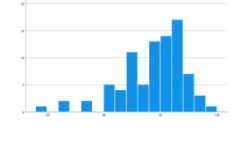

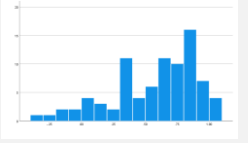
	Intervention				Control				p-value
	N	Mean (SD)	Median (Inter quartile range)	Distribution	N	Mean (SD)	Median (range)	Distribution	
At 12 months	80	32.94 (11.81)	33 (24-41.75)		83	32.11 (10.79)	32 (23-40)		0.72
<p>Mann Whitney u tests have been used for assessing the difference in scores between the intervention and control group at each time point. Lower scores indicate better social and occupational functioning</p>									

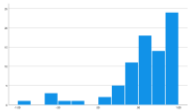
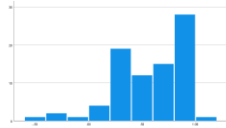
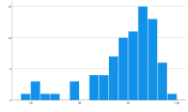
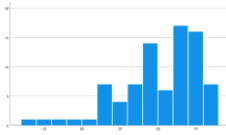
No statistical difference was seen across trial arms in the social and occupational functioning scores at six ($p=0.77$), nine ($p=0.97$) and 12-month ($p=0.72$) time points.

7.3.4 Quality of life

We used EQ-5D to measure quality of life. Raw scores on the five dimensions were combined into a health state score as defined in the EQ-5D manual which were then converted into a single index value or utility value. We used country index values for Indonesia since those for India are not available. QALY was computed using EQ-5D utility values and are presented in Table 7-6. The EQ-5D utility value and the QALY did not show a statistical difference at any of the time points ($p=0.29$, 0.89 and 0.87 at six, nine and 12 months respectively). No statistical difference was noted in the QALY across trial arms ($p=0.79$).

Table 7-6: EQ5D scores and QALY— descriptive statistics and significance values across study arms

Utility score	Intervention				Control				p-value
	N	Mean (SD)	Median (Inter quartile range)	Distribution	N	Mean (SD)	Median (range)	Distribution	
Baseline	90	0.45 (0.41)	0.51 (0.24-0.70)		92	0.48 (0.32)	0.52 (0.19-0.76)		0.97
6 months	81	0.38 (0.34)	0.47 (0.15-0.59)		85	0.44 (0.28)	0.47 (0.28-0.64)		0.29
9 months	80	0.55 (0.39)	0.65 (0.43-0.86)		84	0.57 (0.32)	0.66 (0.37-0.86)		0.89

Utility score	Intervention				Control				p-value
	N	Mean (SD)	Median (Inter quartile range)	Distribution	N	Mean (SD)	Median (range)	Distribution	
12 months	80	0.56 (0.39)	0.65 (0.40-0.86)		83	0.57 (0.32)	0.61 (0.36-0.86)		0.87
QALY	80	0.46 (0.32)	0.54 (0.36-0.70)		83	0.50 (0.26)	0.54 (0.35-0.71)		0.79`

Higher values indicate a better quality of life.
Mann Whitney u tests have been used for assessing the difference in scores between the intervention and control group at each time point.

Table 7-7: Multivariate – Linear regression for CGI, SOFAS and EQ5D at six, nine and 12 months

CGI scores at 6 months				
	Estimate	SE	T	P
Randomised arms	0.01	0.17	0.04	0.96
Age	0.00	0.01	0.18	0.85
Duration of Stay	0.00	0.00	0.57	0.57
Gender	-0.06	0.17	-0.33	0.74
CGI scores at 9 months				
Randomised arms	-0.04	0.17	-0.26	0.79
Age	-0.00	0.00	-0.28	0.78
Duration of Stay	0.00	0.01	-0.28	0.78
Gender	-0.11	0.17	-0.66	0.50
CGI scores at 12 months				
Randomised arms	-0.05	0.16	-0.30	0.76
Age	-0.00	0.00	-0.11	0.91
Duration of Stay	0.01	0.00	1.82	0.07
Gender	-0.09	0.17	-0.51	0.61
SOFAS score at 6 months				
Randomised arms	0.44	1.64	0.27	0.78
Age	0.03	0.07	0.44	0.66
Duration of Stay	-0.00	0.03	-0.09	0.92
Gender	6.07	1.68	3.60	P < 0.01
SOFAS score at 9 months				
Randomised arms	0.55	1.76	0.31	0.75
Age	0.05	0.08	0.65	0.51
Duration of Stay	-0.03	0.03	-1.08	0.28
Gender	3.28	1.80	1.81	0.07
SOFAS score at 12 months				
Randomised arms	1.00	1.77	0.57	0.57
Age	0.09	0.08	1.11	0.26
Duration of Stay	-0.04	0.03	-1.11	0.26
Gender	3.00	1.81	1.65	0.10
EQ5D at 6 months				
Randomised arms	-0.06	0.05	-1.13	0.26
Age	-0.00	0.00	-0.50	0.61
Duration of Stay	0.00	0.00	1.16	0.24
Gender	-0.02	0.05	-0.35	0.73
EQ5D at 9 months				
Randomised arms	-0.03	0.06	-0.45	0.65
Age	-0.00	0.00	-1.74	0.08
Duration of Stay	0.00	0.00	1.19	0.23
Gender	0.09	0.06	1.48	0.14
EQ5D at 12 months				
Randomised arms	-0.01	0.06	-0.22	0.82
Age	-0.00	0.00	-1.38	0.17
Duration of Stay	0.00	0.00	1.55	0.12
Gender	0.11	0.06	1.91	0.058
QALY				
Randomised arms	-0.04	0.05	-0.86	0.39
Age	-0.00	0.00	-1.49	0.13
Duration of Stay	0.00	0.00	1.14	0.26
Gender	0.06	0.05	1.15	0.25

For the multivariate analysis we used linear regression to assess for difference across trial arms in CGI, SOFAS and EQ-5D scores at the six, nine and 12-month time points adjusting for clinically relevant variables of age, gender and duration of stay. The results are presented in Table 7-7. Randomised arms were not predictive of CGI, SOFAS or EQ-5D scores at any of the time points, however gender was predictive of SOFAS scores at the six-month time point which was not apparent at the nine- or 12-month time points. Men had better social and occupational functioning at six months than women (SOFAS score: Mean (SD) at six months – male-33.94 (9.83) female-39.95 (10.87)).

7.3.5 Change in disability, symptoms, social and occupational functioning and quality of life at baseline six, nine and 12 months of hospital reform

One of the objectives of the SITAR trial was 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 (Raja *et al.*, 2020). In this section, we examine the effect of structural and process reform without the individual intervention. Changes in WHODAS scores from baseline to six, nine & 12 months are shown in Table 7-8, split by trial arm.

Table 7-8: Changes in WHODAS scores from baseline to six, nine and 12 months

		N	Mean	SD	Min	Max	Percentiles			P value
							25th	50th	75th	
Intervention	Baseline to 6 months difference	81	0.08	15.68	-45.08	30.69	-8.42	0.69	8.99	0.596
	Baseline to 9 months difference	80	6.51	15.80	-27.69	56.51	-4.19	7.78	17.03	< 0.01
	Baseline to 12 months difference	90	7.14	16.95	-27.69	59.93	-6.70	6.58	19.52	0.001
Control	Baseline to 6 months difference	85	-1.31	20.35	-52.11	40.99	-15.63	2.17	12.79	0.818
	Baseline to 9 months difference	84	6.90	20.61	-50.59	53.97	-6.34	8.36	20.52	0.003
	Baseline to 12 months difference	83	7.70	20.91	-35.37	60.44	-6.63	8.42	21.80	0.002
Wilcoxon Signed Rank test was used to assess the within group difference across time points Higher scores indicate higher levels of disability										

In both trial arms, WHODAS scores show a significant change from baseline at the nine-month time point (intervention $p < 0.01$, control $p=0.03$) which remain apparent at the 12-month time point (intervention $p=0.001$, control $p=0.002$). There was a decrease of six points in mean disability scores in both trial arms from baseline to the nine-month mark and continued to drop to a difference of seven points at 12 months.

We also categorised disability scores across trial arms as no disability, mild, moderate, severe and extreme disability based on a prior study (Hanga et al., 2016). Figure 7-4 shows the categorisation of disability across study arms. Intervention and control groups showed a shift from severe to moderate and mild disability at the nine-month time point which continued to remain apparent at the 12-month time point.

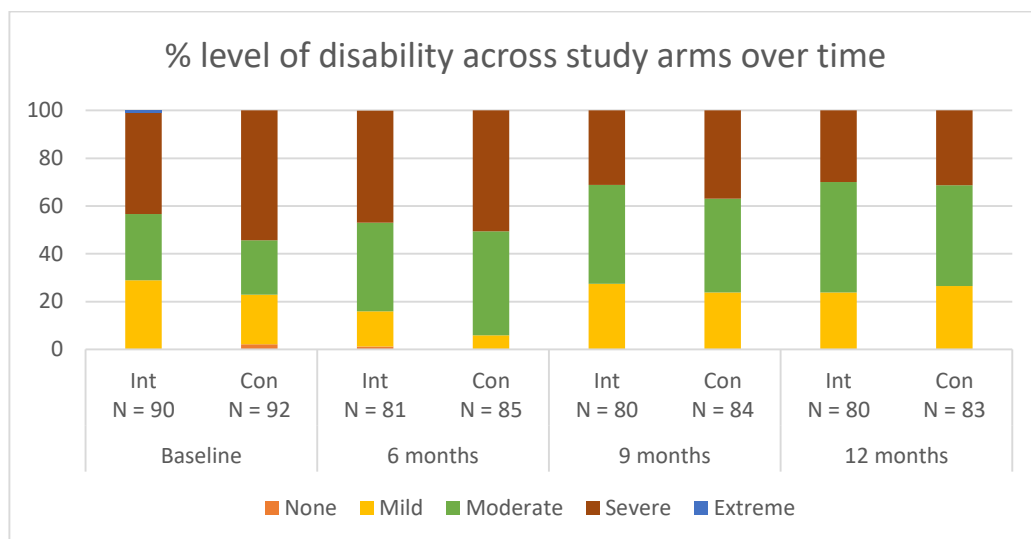


Figure 7-4: Categorization of disability across study arms

Symptoms showed a significant improvement at the six-month time point and remained apparent at the nine- and 12-month time points (intervention $p < 0.01$ at six, nine and 12 months. Control $p < 0.01$ at six, nine and 12 months). A difference of 0.43, 0.63 and 0.67 from baseline was noted at six, nine and 12

months respectively for the intervention arm and a difference of 0.41, 0.57 and 0.60 at six, nine and 12 months from baseline for the control arm. (The maximum score on CGI is seven with lower scores indicating an improvement in symptoms).

We categorised symptoms into seven levels ranging from ‘not at all ill’ to ‘extremely ill’ based on the CGI scoring system. For both arms, there is a clear / distinctive shift from ‘moderately ill’ to ‘mildly ill’ over time (Figure 7-5).

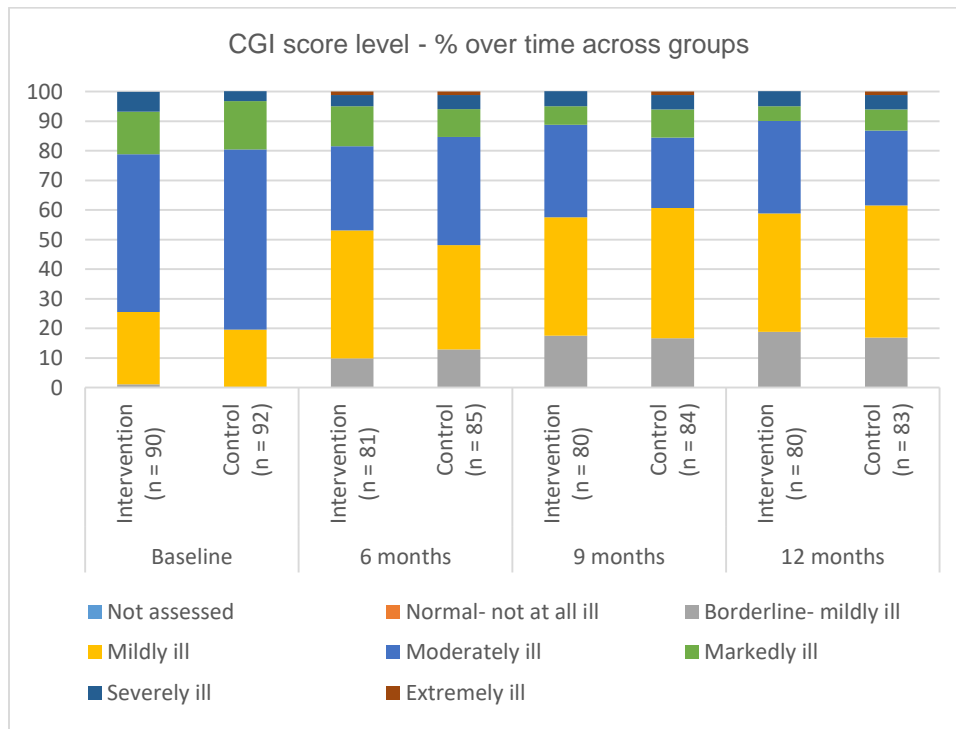


Figure 7-5: Categorization of symptoms across study arms

Table 7-9: Changes in CGI, SOFAS and EQ-5D scores from baseline to 6, 9 & 12 months

		N	Mean	SD	Min	Max	Percentile			P value
							25th	50th	75th	
Intervention	CGI Baseline to 6 months difference	81	0.43	0.87	-2.00	2.00	0.00	1.00	1.00	p < 0.001
	CGI Baseline to 9 months difference	80	0.63	0.93	-2.00	2.00	0.00	1.00	1.00	p < 0.001
	CGI Baseline to 12 months difference	80	0.67	0.92	-2.00	2.00	0.00	1.00	1.00	p < 0.001
	SOFAS Baseline to 6 months difference	81	-2.01	10.49	-31.00	22.00	-8.00	-3.00	4.5	0.080
	SOFAS Baseline to 9 months difference	80	2.41	9.94	-23.00	28.00	-4.00	2.00	9.00	0.039
	SOFAS Baseline to 12 months difference	80	2.61	10.67	-23.00	37.00	-5.00	2.00	9.00	0.051
	EQ5D Baseline to 6 months difference	81	0.05	0.30	-1.01	0.75	-0.13	0.06	0.22	0.081
	EQ5D Baseline to 9 months difference	80	-0.10	0.28	-0.87	0.56	-0.33	-0.11	0.11	0.002
	EQ5D Baseline to 12 months difference	80	-0.11	0.28	-0.91	0.56	-0.31	-0.08	0.06	0.001
Control	CGI Baseline to 6 months difference	85	0.41	0.83	-2.00	2.00	0.00	1.00	1.00	p < 0.001
	CGI Baseline to 9 months difference	84	0.57	0.92	-3.00	2.00	0.00	1.00	1.00	p < 0.001
	CGI Baseline to 12 months difference	83	0.60	0.94	-3.00	2.00	0.00	1.00	1.00	p < 0.001
	SOFAS Baseline to 6 months difference	85	-1.96	12.56	-33.00	23.00	-12.00	1.00	5.00	0.358
	SOFAS Baseline to 9 months difference	84	2.70	12.54	-27.00	36.00	-4.75	1.00	10.75	0.062
	SOFAS Baseline to 12 months difference	83	3.36	12.72	-29.00	34.00	-4.00	1.00	12.00	0.024
	EQ5D Baseline to 6 months difference	85	0.05	0.31	-0.66	1.17	-0.14	0.00	0.26	0.220
	EQ5D Baseline to 9 months difference	84	-0.08	0.29	-0.71	0.92	-0.25	-0.09	0.11	0.005
	EQ5D Baseline to 12 months difference	83	-0.08	0.30	-0.80	0.82	-0.32	-0.09	0.07	0.006

Social functioning largely comprises the ability to look after oneself and maintain daily activities, along with social and instrumental skills of living in the community and is an important requisite for occupational functioning (Saraswat et al., 2006). Social and occupational functioning measured through SOFAS showed a change from baseline of 2.4 and 2.6 points for the intervention arm at the nine- and 12-month time point (p=0.04 & 0.05 respectively). However, the difference in SOFAS scores in the control arm is significant only at the 12-month time point (p=0.02) as shown in Table 7-9.

Quality of life measured by EQ5D showed a marked improvement at the nine-month time point which continued to remain apparent at the 12 months (intervention $p=0.002$ and 0.001 at nine and 12 months, respectively. Control $p=0.005$ and 0.006 at nine and 12 months respectively) as shown in Table 7-9.

7.4 Outcomes in patients admitted to the mental hospital (not included in SITAR)

In keeping with the study design of SITAR, we assessed all patients admitted to the hospital (barring patients in the acute and forensic wards) at baseline. Patients assessed at baseline and continuing to remain in hospital were also assessed at the six-, nine- and 12-month time points. This section provides a summary of findings for this cohort. The tables for this section are presented in Appendix 12.16.

469 patients admitted to RMHN were assessed at baseline of which 182 were included in the SITAR study. Of the 287 non-SITAR patients, 166 were still in hospital and assessed at six months, 164 were assessed at nine months and 153 were assessed at 12 months. Patient characteristics at baseline were summarised using descriptive statistics. Mean and standard deviation were used for continuous data and categorical data were summarised using frequency and percentages and are presented in Appendix 12.16.1.

7.4.1 Sample characteristics

Patients admitted to RMHN and not included in the SITAR study were in their mid-40s (mean = 46.59) and had a median duration of stay of four years at baseline in the hospital. A majority had psychosis as their primary diagnosis (74%) of these 3% had psychosis with a comorbid mental disorder. Those with a diagnosis of intellectual disability constituted 20% of the patients and 5% had a primary diagnosis of epilepsy. Women made up 49% of the patients, while 51% were men. Religion, marital status, education level and place of origin was unknown for 32%, 57%, 47% and 22% of the patients respectively included as Appendix 12.16.1.

Of the 287 patients assessed at baseline, 153 (53%) continued to remain in hospital at the time of the 12-month assessment while 134 (47%) did not complete all assessments as they were absent at the 12-month time point. We have analysed these two groups separately while presenting data for the total cohort of 287 patients.

Of the 134 patients who did not complete four assessments, 10 patients (7.5%) died in hospital. The remaining 124 patients (92.5%) had been discharged. Of these, 75% were discharged back to families and 25% were discharged through the visitors' committee (a body that has monitoring oversight of the hospital) to various entities like community-based organisations and to prison (if the patient was originally transferred from there) (Appendix 12.16.2).

Baseline characteristics of the cohort of 153 patients who continued to remain in hospital at the 12-month time point (referred to as the hospital cohort) differed from those who were not in hospital at 12 months (referred to as the discharged cohort). Patients in the discharged cohort were younger with a mean age of 40 years as compared to the hospital cohort with a mean age of 52 years. The hospital cohort had more women compared to the discharged cohort Appendix 12.16.1.

In terms of basic characteristics of identity, the discharged cohort had lesser 'not known(s)' as compared to the hospital cohort (religion 10% unknown in the discharged cohort compared to 52% in the hospital cohort; education 24.6% unknown in the discharged cohort and 52.3% in the hospital cohort and, details of their origin 9% unknown in discharged cohort and 34% in the hospital cohort). While 90% of the discharged cohort had a primary diagnosis of psychosis, the hospital cohort had 59%. The duration of stay in hospital at baseline for the two groups was also very different. The discharged cohort had a median stay of 1.5 years compared to the hospital cohort with a median stay of 21 years (Appendix 12.16.1).

7.4.2 Analysis of outcomes

We have presented outcome measures on disability scores (WHODAS), symptoms (CGI), social and occupational functioning (SOFAS) and quality of life (EQ-5D utility scores) for the entire non-SITAR cohort (Appendix 12.16.3). However, the group that continued to remain in hospital is inherently different to the group that was discharged. Hence, we have analysed these two groups separately.

The hospital cohort (n=153) had a mean disability score of 52.84 at baseline, 50.79 at six months, 48.24 at nine months and 48.18 at 12 months (Appendix 12.16.4). There was no significant difference in scores from baseline to six months ($p=0.098$). At the nine-month time point, there was a significant difference (improvement) in disability scores to baseline which continued to remain apparent at the 12-month time point ($p=0.002$ at both the nine- and 12-month time points) presented in Appendix 12.16.5.

The mean CGI (symptoms) score was 4.18 at baseline dropping to 3.65 at six-months, which further reduced to 3.5 at nine and 12 months (Appendix 12.16.4). The baseline to six months' score showed a significant difference which continued to remain apparent at the nine- and 12-month time point ($p < 0.001$ at six, nine and 12 months) presented in Appendix 12.16.5.

The mean social and occupational functioning (SOFAS) score was 39.14 at baseline, 38.44 at six months, 38.12 at nine months and 37.55 at 12 months (Appendix 12.16.4). SOFAS scores did not show a significant difference at any of the post measures of six, nine and 12 months ($p=0.202$, 0.176 and 0.113 at six, nine and 12 months respectively) presented in Appendix 12.16.5.

The mean quality of life score (EQ-5D) and utility score at baseline and six-months is 0.38 and 0.43 at the nine- and 12-month time point (Appendix 12.16.4). We did not see a significant change in quality-of-life scores at the six- and nine-month time points ($p=0.966$ and 0.088 at six and nine months respectively), however there is a significant difference in the scores at the 12-month time point ($p=0.052$) presented in Appendix 12.16.5

Of the 134 patients in the discharged cohort, 121 (90%) patients had only one assessment at baseline. We have presented the baseline scores for the disability, symptoms, social and occupational functioning and quality of life measures as a comparison to the baseline measures of patients who continued to remain in hospital at the 12-month point (Appendix 12.16.6).

In comparison to the hospital cohort (n=153), the discharged cohort (n=134) had a lesser level of disability at baseline with a mean WHODAS score of 37.48. Symptom scores for the discharged cohort were similar to the hospital cohort with a mean of 4.16 at baseline. The discharged group also showed lesser disruption in social and occupational functioning (mean SOFAS score = 30.58 at baseline) and a better quality of life (mean EQ-5D score 0.57 at baseline) presented in (Appendix 12.16.6).

7.5 Summary of results

In summary, 469 patients admitted to RMHN were assessed at baseline and 182 allocated to the SITAR trial. Results were analysed for 166, 164 and 163 patients across the intervention and control arms of the trial at six, nine and 12 months to baseline, respectively. Data for the 287 patients who were not included in the SITAR trial was analysed separately.

In terms of socio-demography, patients allocated to the SITAR trial were in their early 40s with a higher number of women and were predominantly Hindu. Most patients hailed from the State of Maharashtra and had at least partial schooling. The mean length of stay in hospital at baseline, across trial arms was between four to five years.

No significant difference was seen in outcome measures of disability, symptoms, social and occupational functioning and quality of life, between the intervention and control arms of SITAR at six, nine or 12 months after adjusting for clinically relevant variables of age, gender and duration of stay in hospital at baseline.

We examined changes in outcome measures at baseline and at six, nine and 12 months across all patients of the SITAR trial to assess the impact of hospital reform on disability, symptoms, social and occupational functioning and quality

of life. There was significant reduction in disability levels, by six points, at nine months to baseline which, further dropped to seven points at 12 months. Patients in the intervention and control arms showed a shift from severe to mild disability at nine months and it continued to remain apparent at 12 months. Across trial arms, symptoms showed a significant improvement at six months and remained apparent at nine and 12 months. Social and occupational functioning significantly improved in the intervention arm at nine months and at 12 months for the control arm. There was a significant improvement in quality of life across both trial arms at nine months which continued to remain apparent at 12 months.

Data for 287 patients admitted to RMHN, not included in the SITAR trial was analysed separately. Of these, 153 patients continued to remain in hospital at the 12-month time point (referred to as the hospital cohort) while 124 patients were discharged and did not complete the outcome and follow-up assessments (referred to as the discharged cohort). Patients in the discharged cohort were younger with a mean age of 40 years as compared to the hospital cohort with a mean age of 52 years. The hospital cohort had more women compared to the discharged cohort. The hospital cohort, like patients in the SITAR trial, showed a significant improvement in disability levels at nine months which remained apparent at 12 months. Similar to patients in the SITAR trial, the hospital cohort showed a significant improvement in symptoms at six months continuing to remain apparent at nine and 12 months. The hospital cohort did not show a significant improvement in social and occupational functioning scores at six, nine or 12 months. Quality of life in the hospital cohort showed a significant improvement only at 12 months. In comparison to the hospital cohort, the discharged cohort had a lesser level of disability, lesser disruption in social and occupational functioning and a better quality of life at baseline.

8 Qualitative analysis - focus group discussions (FGDs); SITAR trial

8.1 Chapter introduction

The qualitative component of the SITAR study aimed at documenting patient perceptions on the overall reform process, the individual intervention and its perceived impact. We used FGDs to elicit service user's lived experiences through a phenomenological epistemological lens. The mental hospital environment fostered the context for natural groups with a shared experience of living in the same environment that could be elicited through FGDs (Kitzinger, 1995). A thematic analysis was done using NVivo (Denardo, 2002; Krzyzanowski, 2008). Verbatim quotes have been used to substantiate findings. We have also discussed the challenges of using a qualitative research technique that involves participant interaction in context with a group whose autonomy and voice are diminished and nearly absent by virtue of living in an institution (Goffman, 1961; Payne, 2009).

8.2 Method

8.2.1 Sample

The sampling approach used was purposive. We chose patients based on availability in hospital at the time of the FGD, severity of illness & those who could engage in verbal conversation. Four focus group discussions were held with a total of 39 patients. Two groups comprised of patients assigned to the intervention arm and two groups were drawn from the control arm. The composition of patients in each focus group is listed in Table 8-1, below.

Table 8-1: Patients included in focus group discussions

	Intervention Arm		Control Arm	
	Group 1	Group 2	Group 3	Group 4
Number of female participants	6	4	9	-
Number of male participants	4	6	-	10
Total participants	10	10	9	10
Total interaction time in minutes	24.38	15.37	11.34	12.56
Average interaction time	19.86		11.95	
No of words in the transcript	1178	423	294	299
Average word count	800.5		296.5	
Number of people who knew of Tata Trusts work or Udaan	9 (90%)	3 (30%)	5 (55%)	4 (40%)

8.2.2 Procedure

We developed a comprehensive protocol for the focus group discussions and a guide for themes of enquiry included as Appendix 12.12. The protocol also detailed the logistical plan for conducting the FGDs. Each FGD was conducted on a different day between 10.00 am and 12.00 pm in a large hall within the mental hospital premises. Since the FGDs were conducted in August 2020, after the COVID-19 pandemic hit, a safety protocol that included sanitization, distancing and masking was implemented. Each patient was equipped with a mask and seated 6 feet apart. Microphones were used to ensure clarity in communication. Multiple audio recorders were placed in the room. The student PI was the primary facilitator, assisted by a team of researchers who took independent notes.

Each session was transcribed independently by the PI and another researcher. Notes were compared and compiled into a single transcript per session. The FGDs were bilingual, and conducted in Hindi and Marathi, Subsequently, the PI translated it into English. In the absence of authentic equivalent words/phrases (*such as names of festivals*) the original Hindi or Marathi words have been retained. The transcripts were shared with the research assistants to check for accuracy. Upon finalising, the transcript was read multiple times for familiarization of content. Elements such as number of participants were drawn out. The narrative content of the FGD was coded using NVivo.

8.3 Observations

Despite purposive selection to ensure participation, verbal responses and patient engagement was limited. The maximum interaction was seen with the first group of patients. This progressively declined with subsequent groups (interaction time reported in table 8-1). Patients generally kept their heads bent and were seen fidgeting with their clothes and or the tablecloth. Occasionally they would get up, wander away and would need to be escorted back to their seat (to ensure adherence to COVID safety protocols). Often patients had to be addressed directly and asked specific questions to elicit even a brief response. In situations when patients indicated agreement or disagreement by nodding/shaking their heads, researchers verbally reconfirmed. These behaviours are not uncommon when viewed in the context of chronic psychosis, and institutionalisation (median time in institution was between four to five years for the intervention and control groups) (Goffman, 1961; Palmier-Claus *et al.*, 2019).

Predominantly, patients enrolled in the intervention arm were more interactive than those in the control arm. This was determined by two proxy indicators - interaction time and number of words in the transcript. The average interaction time within the intervention group was 20 minutes as compared to 12 minutes within the control group. The word counts from transcripts reveal an average of 800 and 296 words in the intervention and control groups respectively. Participants in the intervention group received an average of 59.6 individual intervention sessions during the SITAR trial. Those in the control arm did not receive any individual intervention. We posit that the continued one-on-one engagement with patients in the intervention arm facilitated improved communication in the FGDs. In a care as usual environment within a LMIC mental hospital, there are limited opportunities to engage and communicate amongst one another (Murthy *et al.*, 2016). As was reflected in the FGDs, patients in the control arm, on the other hand were not used to expressing their feelings and opinions.

8.4 Analysis

Thirteen and nine people from the intervention and control arm respectively, said they were aware of Tata Trusts or Udaan (colloquially referred to as 'Tata-wale' or the "Tata people" by staff and patients of the hospital).

The four themes that emerged through our analysis were (1) engagement and communication; (2) restoration of dignity (3) patient role shifts - passive to active (4) recognition of rights and needs. Each theme is discussed in detail below:

8.4.1 Engagement and communication

Patient engagement activities could broadly be divided into activities that were initiated at the ward level for all patients. This included facilities such as making radios available in the ward, starting movie clubs for all the wards, facilities of a library, meditation room and a male & female salon. There was also a specific focus on ensuring systemic cleanliness in the wards. These reforms have been described in chapter 3: Psychiatric Hospital Reform at The Regional Mental Hospital of Nagpur (RMHN) - Udaan, A Case Study. Individual engagement with patients through the Needs Based Intensive Case Management (NB-ICM) was aimed at meeting unmet patient needs through the bouquet of services created through the reform process. This included training on activities of daily living, vocational skill building and employment opportunities amongst others. The NB-ICM is described in detail in the chapter 5: Need Based Intensive Case Management (NB-ICM).

Enhanced engagement was the most common perception of reform amongst patients. The most reported component of patient engagement was that they were "being spoken to". Patients recognised and mentioned names of case managers who went to the wards to engage with them. Nine patients (seven from the intervention arm and two from the control arm) said that being spoken stood out for them. Evidence also indicates that being spoken to by service providers is important to the experience of receiving care for patients with psychosis (McCabe & Priebe, 2008). This interaction between service user and provider is crucial towards fostering social inclusion - a multidimensional construct linked to a sense of belongingness and has considerable significance

in the context of personal recovery (Brennaman & Lobo, 2011; Morgan *et al.*, 2007).

“They come to our wards and seek us out- talk to us- makes me feel good”.

Female patient (53263)- intervention arm, group 1

“Talk to us, show movies- give chiwda²”.

Female patient (54577) control arm- group 3

Patient’s experiences of engagement and communication reflect the nature of reform activities conducted in the hospital. Patients in both the intervention and control arms expressed their liking and use of services like the radio, television and movie clubs. In addition to providing entertainment, these offer a link to the world outside the mental hospital and have been used extensively as mechanisms to promote wellbeing (Geretsegger *et al.*, 2017; Grocke *et al.*, 2014; Thompson, 1955; Van de Wall, 1946).

“Now we got one radio- our ward sister got it for us”.

Female patient (52410)- intervention arm, group 1

“Our TV is not working- please can we get that started- we really miss it, since so many days it is not working”.

Female patient (52410) intervention arm, group 1

“Come to wards and talk to us- take to library- show movies- give chiwda- I like movie most- now no movie”.

Male patient (53168)- control arm, group 4

Patients enrolled in the intervention arm appeared to have much wider engagement with the reform activities as compared to patients in the control arm. This was particularly related to the range of skill building and employment reform activities initiated at the hospital. This included, working at the Tata Trusts’ office and food truck; learning to make brooms; making paper envelopes; operating a

² An Indian snack much like a trail mix.

photocopy machine and working at the tailoring unit. Participation in these activities enhanced mobility around the hospital, and external world, much more than was possible for other patients who lived in a closed ward situation prevalent in most mental hospitals in India (Murthy *et al.*, 2016).

“I work on the food truck and also in the wards. I clean plates and attend to the customers. I get to go all the way to the Truck”.

Male patient (54747)-intervention arm, group 1

“I used to go to the Tata office- I like it”.

Female patient (53201)- intervention arm, group 1

8.4.2 Restoration of dignity

Erosion of dignity is a common experience for patients with severe mental illness. This increases many folds when a person lives in an institutional setting like a mental hospital (Capri & Buckle, 2015; Letendre, 1997; Pereira *et al.*, 2005; Skorpen *et al.*, 2015; Skorpen *et al.*, 2014). The restoration of dignity through the reform process was an important experience for patients in the intervention arm. We explored the restoration of dignity through multiple individual constructs. Patients expressed *“being heard”* or *“listened to”* which was a stark contrast to the feeling of invalidation often experienced by patients (Hagen & Nixon, 2011).

“Our hospital never used to have any new people- now so many people come to visit us- we get to talk to them- they listen to us- people from different countries.”

Female patient (52410)- Intervention arm, group 1

Long stay patients in the intervention arm reflected on their opportunity to dress-up as a result of being engaged in a range of skill training pathways. They recalled having access to well fitted, coloured clothes as opposed to the ill-fitting hospital gowns they had worn for years. Patients also emphasised the increase in autonomy and choice. Increased autonomy and choice has been associated

with patients having a better experience of treatment even when the treatment was compulsory (Andreasson & Skärsäter, 2012).

“and you know we only got coloured clothes after Tata wale came”.

Female patient (50208)- intervention arm, group 1

“We got clothes of our own size- first we had to wear gowns that would all fall off- now we get to choose”.

Female patient (52410) intervention arm, group 1

Another key facet related to promotion of dignity highlighted by patients in the intervention arm was the shift in power dynamic between staff and patients brought about by the reform process. When Udaan was initiated, we noticed that chairs were reserved for staff - patients were not allowed to sit on them. While seemingly simple, denying access to formal seating is rife with complex undertones of the hierarchy and power dynamic between caregiver and patient, the inherent caste divide that has been present in mental hospitals in India and the stigma people with mental illness regularly experience (Laugharne *et al.*, 2012; Pinto, 2018; Wahl, 1999).

“I can sit on the chair like you do”.

Female patient (52410) intervention arm, group 1

Another important aspect in the restoration of dignity was the sense of “*being cared for*” shared by patients in the intervention arm. Feeling “*cared for*” has been associated with dignity particularly in people with experiences of institutionalised mental health care (Skorpen *et al.*, 2015; Skorpen *et al.*, 2014).

“I used to go to the Tata Office- I used to dress up for that- I learnt how to work in the office- I learnt how to make tea- I learnt stitching and to run the machine and make bags- I got so much help from there- I really liked it- I felt there was something to look forward to- For the first time I felt there was someone for me- I could meet new people and get to talk to them- I know everybody by their name”.

Female patient (52410) intervention arm, group 1

8.4.3 Patient role shifts: passive to active

The enhanced engagement with patients was reflected in the changing roles that patients had in the hospital. Patients from the intervention arm were engaged in a range of activities throughout the day across a variety of skill building programmes ranging from caretaking at the half-way home/ step-down ward to manning the food truck, or working at the tailoring unit. However, patients in the control arm were involved only in ward bound activities. Hospital reform and associated changes in roles have also been emphasised in other studies of hospital reform (Jin & Li, 1994).

“Priti³Didi⁴ comes make pouches (Paper envelopes)

Female patient (51411)- Control arm, group 1

“yes yes I know Tata- I go to food truck- I used to stay in ward no 9 (half way home). In the ward I would clean the ward, clean bathroom, also make brooms I know we have to take 50 Rs and give one broom”.

Male patient (51299)-intervention arm, group 2

8.4.4 Recognition of rights and needs

Patients were aware of the enhanced services made available through the reform process. They recognised their right to these services and expressed their needs. This became apparent when the services were absent for a short period as a result of the COVID-19 pandemic, and the need to ensure patient safety. The FGDs were conducted in August 2020 when the hospital re-initiated operations and routine functioning was limping back. Patients explicitly requested a re-commencement of services that had been temporarily discontinued due to “corona” as they referred to it. Patients also wanted the restoration of cleanliness and hygiene standards in their wards which was hampered by reduced staff availability due to quarantine protocols. They also wanted their television sets repaired and a clock to be brought into their wards. Male patients asked for the halfway home or “stepdown” ward to be reopened.

³ Priti is one of the case managers on the Udaan team.

⁴ Didi means sister in Hindi.

Patients also expressed that they had missed the presence of the case managers and other members of the Udaan team in the wards. They also missed the many visitors who visited the hospital prior to the pandemic. In essence, patients asked for what they had experienced through the reform process to be restored. Many patients asked to be sent home to their families. Overall, patients in the intervention arm had more requests than patients in the control arm.

“I am a ‘numberdaar’⁵ patient- I have lived in this hospital for 20 years. I really like the work of Tata wale, but now with this corona our work is at standstill, barely anybody comes to our ward. I want the tailoring unit to start again. I used to stitch till five in the evening- I really want that to start again- please I request you to start”.

Female patient (50208)- intervention arm, group 1

“We miss you people would come back inside- we really miss you- when will this corona go”.

Female patient (52410) intervention arm, group 1

“And one more thing our toilets are not working- we only have one working toilet for so many people- no one has come to the wards- we wanted to tell you this”.

Female patient (50208)- intervention arm, group 1

“Our TV is spoilt- please fix it”.

Female patient (55250) control arm, group 1

Patients in the intervention arm had personal experiences of how the reform had impacted their lives. Patients in the control arm did not report reform as having any personal impact.

“Madam they are the ones who brought new things- they brought movies- they did so much- they did the fashion show- I dressed up- wore jewellery and makeup and every day we would practice with them”.

Female patient (52410) intervention arm, group 1

⁵ A numbardaar patient is one that has stayed in the hospital for a fair amount of time and is given responsibilities as well as privileges that are slightly more than most patients. This concept is akin to a kind of pecking order that is formed in institutional set-ups such as prisons.

“I can say from my experience that things happened for me because you people were there- I was discharged- I was having a rough time outside- could not sleep- was fighting- but hospital was not willing to take me back- you called Dr Praveen- you got me admitted- I know that”.

Female patient (50208)- intervention arm, group 1

Largely patients in the intervention arm voiced the substantial shifts that the hospital had undergone since the Tata Trusts - Udaan programme was initiated. Changes were substantial enough for them to feel that they were better off living inside the hospital than outside it.

“Lots of change- as different as the earth and the sky (Zameen aasman ka fark hai)”

“And I want to tell you one thing clearly- after staying here on Tata wale work- I do not want to go anywhere- please do not send me out”.

Female patient (50208)- intervention arm, group 1

8.5 Methodological challenges and limitations

Focus group discussions are widely used as a qualitative research method in mental health particularly in the context of understanding lived experiences of illness, recovery and service usage and perceptions associated with it (Chernomas *et al.*, 2000; Ng *et al.*, 2008; Whitley & Campbell, 2014). People with severe mental illness typically are a population with diminished contractual power with scant legitimization of their lived experience and knowledge thereof (Onocko-Campos *et al.*, 2017). Our experience of conducting FGDs for the SITAR trial was that the group setting created an environment of mutual support. It made participants feel more comfortable, and even offered gentle peer led prompts for those who had difficulty speaking to express themselves (Onocko-Campos *et al.*, 2017). Apart from the logistical challenge of conducting an FGD in a mental hospital where patients had to be moved to the meeting room from the long-stay wards, there were added safety protocols to adhere to in view of the COVID 19 pandemic. All service users were familiar with the Udaan team members offering logistical support and this was clearly an advantage. Patients in the intervention arm were familiar with case managers and had spent several

hours with them through the individual intervention. However, this was the first interaction for the participants in the control group. We did not involve hospital staff in the FG, this was done in order to create an environment where patients could talk freely. In different circumstances, with greater resources, warm up group sessions prior to the actual FGDs may have facilitated improved interaction. The presence of hospital staff in the FG may have helped patients talk more freely. We did not explore this possibility.

8.6 Chapter conclusion

Four focus group discussions, two comprising patients from the intervention arm (n = 20) and two from the control arm (n =19) respectively, were conducted by the student PI. The aim was to investigate patient perceptions on the reform process and their experiences associated with reform. Despite purposive sampling, verbal articulation in patients was limited. We attribute this to the extended duration of stay in mental hospital environments. Patients in the intervention arm had a wider experience of reform. They were involved in activities across the 52-acre hospital campus and had extensive interactions with Udaan case managers. In comparison, patients in the control group were only involved in reform activities conducted in their wards. Engagement with patients was reported across all groups.

“Being spoken to” stood out as an important point for the patients. Other facilities that were initiated at the ward level through the reform process were also highlighted by patients. These included improved sanitation protocols, access to a library & movie club.

Patients in the intervention arm had a personalized experience of reform that was instrumental in enhancing mobility beyond the confines of their wards. This resulted in wider and more enriched social interaction and networks, access to skill building and meaningful engagement through the day.

Patients in the intervention arm also experienced enhanced autonomy and a restoration of dignity emerging from the reform process along with a subtle shift in the power dynamic in the staff-patient relationship within the mental hospital.

Patients in both the intervention and control arms keenly felt the disruption of services caused by the COVID 19 pandemic.

There were several methodological challenges in conducting FGDs with the long stay cohort of the mental hospital. Insight into their experience brings a vital perspective to the findings of the SITAR trial.

9 Health economic analysis of Udaan and SITAR

9.1 Chapter introduction

The previous two chapters presented the qualitative and quantitative evidence of the SITAR trial. This chapter presents an evaluation of the costs involved in generating this impact and explores whether those costs are affordable and worthwhile.

The World Health Organization has asserted the criticality of adequate mental health financing to turn policy into tangible, on ground programmes (Raja *et al.*, 2010; WHO., 2003). Mental health interventions encompass a wide range of actions such as legislation, policy framework, prevention and promotion of mental health, treatment and rehabilitation services. Currently, the best cost effectiveness data is available for a range of pharmacological treatments, with scant research on the health economic evaluation of other interventions in mental health (WHO., 2006). Though mental hospitals remain a key provider of services in many parts of the world, they are in need of reform that would ensure high quality services mainlining human rights and dignity of its service users (WHO, 2018). The hospital reform programme under Udaan is a unique initiative seeking to address an important area of scientific investigation in terms of evidence based reforms of psychiatric hospitals and their impact on patient outcomes (Raja *et al.*, 2021). The SITAR trial is an evaluation of the Udaan programme (Raja *et al.*, 2020). This chapter describes the health economic evaluation of the Udaan programme and the embedded SITAR trial. This evaluation was undertaken to determine the overall investment involved in a hospital reform programme and the additional costs of an individualised patient service package in the form of SITAR from a health systems perspective. We sought to understand the additional costs of Udaan and SITAR in comparison to costs of care as usual and determine the affordability of such a reform program. The per person month costs of Udaan and SITAR were derived and compared with 1) the existing cost of care as usual 2) benefits of participation measured by QALYs (cost utility) and presented using conventional approaches of

economic evaluation through a cost-utility and cost effectiveness analysis (Razzouk, 2017).

9.2 Methods

9.2.1 Costing Udaan and SITAR

We conducted a retrospective micro-costing, bottom-up cost analysis of the Udaan programme and the Need-Based Intensive Case Management (NB-ICM). We mapped the resources or inputs required for Udaan and SITAR as follows: human resources, development costs of training material, cost of training, costs of delivering the intervention which included people, facilities, equipment and supplies. Udaan represents the larger hospital reform programme (control arm of the SITAR trial) and the addition of SITAR; the NB-ICM intervention represents the intervention arm of the SITAR trial. The costing framework for Udaan and SITAR is presented as Appendix 12.17.1. The costing was based on actual expenditure incurred through the Udaan programme as well as cost components derived through collaborations, which includes costs of items received in kind such as clothes, soaps and shampoos directly linked to patient care and costs incurred for structural and process reform. Costing was appropriately apportioned to the SITAR trial in terms of time allocation of staff based on an analysis of case management records. We also mapped costs of care as usual through the hospital spend on patient care by the hospital.

Based on the costing framework, a costing spreadsheet was developed using the CHEERS guidelines for reporting economic evaluations (Husereau *et al.*, 2013). Costs for current prices were considered as of January 1, 2020, as the base or reference year. The time horizon adopted for baseline economic evaluation was the duration of the project (four years). Costs were adjusted for inflation to capture change in the value of the currency arriving at the constant or real costs incurred for the program. For the purpose of this study, we have used Consumer Price Index (CPI) as a measure of inflation. We converted local currency to US\$ and then adjusted for inflation at US inflation rates and then converted it back to local currency INR as per market exchange rate of January 1, 2020 (BLS, 2016; Husereau *et al.*, 2013; Xe.). We further amortised one-time

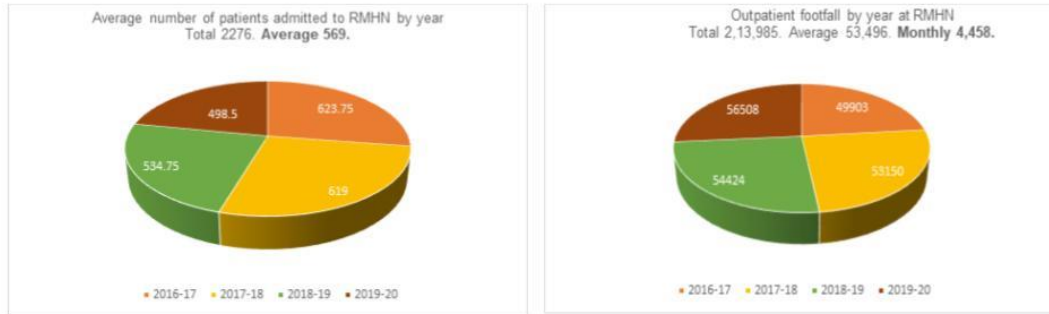
costs (refurbishment for structural reform) to the four-year period of the program using an annual discount rate of 3%. We conducted a sensitivity analysis varying the discount rate to 6 % as well as varying the amortisation period to 10 years (Adam, 2003).

To contextualise the additional costs of Udaan and SITAR, we estimated costs of care as usual based on the expenditure statements of the hospital for the four years of the programme. Costs of care as usual were adjusted for inflation in a similar manner to costs of Udaan. The costs of care as usual are presented in Table 9-2 in the appendix. All adjusted costs have been reported in ₹ INR and in \$ USD at market exchange rate on March 1, 2021 (Xe.).

9.2.2 Calculating the number of Beneficiaries

We estimated the total number of people served by the hospital to convert the total cost of the programme to a cost per person month benefitting from it. Since the Regional Mental Hospital Nagpur (RMHN) comprises a moving population of patients with continuous admissions and discharges we calculated programme reach (no. of patients benefitted by the programme) by taking the in-patient count on the last day of every quarter of the four programme years of Udaan for the number of patients admitted to the hospital (average yearly in-patient count shown in figure 9-1) The detailed calculation is included in Appendix 12.17. 3.. For the out-patient count we took the four-year average of the out-patient foot fall shown in figure 9-1.

Total patient count per day at RMHN



Total daily patient count for RMHN		
Department	Monthly count	Daily count
IPD	569	569
OPD	4458	148.6
Total patient count	5027	736.56

Figure 9-1: Total patient count per day at RMHN

9.3 Results

A summary of the adjusted costs of Udaan, Udaan+SITAR and SITAR for all four variations of the sensitivity analysis are presented in Table 9-1. The detailed costs of Udaan and SITAR by component for all four variations of the sensitivity analysis are presented as Figure 9.2 and as a table in Appendix 12.17.2.

Table 9-1: Monthly and daily adjusted costs of Udaan and SITAR; all sources reported in INR and USD

	Udaan	Daily per patient cost	SITAR	Daily per patient cost	Udaan + SITAR	Daily per patient cost
Costs amortised for four years with an annual	₹ 24,49,741	₹ 16.24	₹ 2,45,083.	₹ 1.63	₹ 26,94,824	₹ 17.87
	\$38,122.33	\$ 0.25	\$3,813.93	\$ 0.03	\$41,936.27	\$ 0.28

discount rate of 3%						
Costs amortised for ten years with an annual discount rate of 3%	₹ 16,89,018	₹ 11.20	₹ 2,45,083	₹ 1.63	₹ 19,34,102	₹ 12.82
	\$26,284.14	\$ 0.17	\$3,813.93	\$ 0.03	\$30,098.07	\$ 0.20
Costs amortised for four years with annual discount rate of 6%	₹ 24,06,100	₹ 15.95	₹ 1,05,291	₹ 0.70	₹ 25,11,392	₹ 16.65
	\$37,443.21	\$ 0.25	\$1,638.53	\$ 0.01	\$39,081.74	\$ 0.26
Costs amortised for ten years with annual discount rate of 6%	₹ 15,73,883	₹ 10.44	₹ 1,05,291	₹ 0.70	₹ 16,79,175	₹ 11.13
	\$24,492.43	\$ 0.16	\$1,638.53	\$ 0.01	\$26,130.96	\$ 0.17

Given a four-year amortisation period and an annual discount rate of 3%, 42% of Udaan's total costs were on structural reform. Human resource costs for reform and training combined were at 36%. The additional costs of NB-ICM (SITAR) were at 9% (Figure 9-2). When we varied the amortisation period to 10 years, the costs of structural reform dropped to 23% and the combined costs of staff and training rose to 49% and the costs of SITAR were at 13%. When we adjusted the annual discount rate to 6% with an amortisation period of four years, the costs of structural reform were at 47% with staff and training costs at 37% while the costs of research dropped to 4%. When we further adjusted the amortisation period to 10 years with an annual discount rate of 6%, costs of refurbishment were at 26% while staff and training expense was at 56%. Cost of SITAR was 6% of total costs.



Figure 9-2: Percent Adjusted costs of Udaan and SITAR by component

Table 9-2: Adjusted costs of care as usual in INR and USD

Year	Costs / number
2016-17	₹19,81,75,743 \$3,083,967
2017-18	₹18,91,35,926 \$2,943,292
2018-19	₹16,40,17,949 \$2,552,411
2019-20	₹19,99,63,719 \$3,111,791
Total	₹75,12,93,337 \$11,691,462
Average yearly expenditure	₹18,78,23,334 \$2,922,865
Average monthly expenditure	₹1,56,51,945 \$243,572
Number of patients	5,027
Cost per person per month	₹3,114 \$48
Cost per person per day	₹103.79 \$2

9.3.1 Costs per patient of Udaan and SITAR in INR and USD

The per patient day costs for Udaan+SITAR (total costs of programme) varied from ₹11 to ₹18, costs of SITAR ranged from ₹1 to ₹2 and the costs of Udaan ranged from ₹10 to ₹16 based on the sensitivity analysis. Since hospital reform is possible without large scale structural reform, we have also presented the monthly and daily per patient costs of Udaan + SITAR without the costs of structural reform (table 9-3). The per patient costs vary from ₹8.23 (\$0.13) to 10.46 (\$0.16) across the four variants of the sensitivity analysis.

Table 9-3 Monthly and daily costs of Udaan + SITAR without the costs of structural reform in INR and USD

	Udaan + SITAR		Structural reform	Udaan + SITAR without structural reform	
	Monthly costs	Costs per patient day	Monthly costs	Monthly costs	Costs per patient day
Costs amortised for four years with an annual discount rate of 3%	₹26,94,824	₹17.87	₹11,17,616	₹1577207	₹10.46
	\$41,936	\$0.27	\$17,392	\$24544	\$0.16
Costs amortised for ten years with an annual discount rate of 3%	₹19,34,102	₹12.82	₹4,37,729	₹1496372	₹9.92
	\$30,098	\$0.19	\$6,811	\$23293	\$0.15
Costs amortised for four years with annual discount rate of 6%	₹25,11,392	₹16.65	₹11,81,534	₹1329857	₹8.82
	\$39,081	\$0.25	\$18,386	\$20694	\$0.14
Costs amortised for ten years with annual discount rate of 6%	₹16,79,175	₹11.13	₹4,37,729	₹1241445	₹8.23
	\$26,130	\$0.17	\$6,811	\$19319	\$0.13

9.4 Cost Utility Analysis (CUA)

We used EQ-5D to measure quality of life. QALYs were calculated for the 12-month follow-up period based on EQ-5D responses at six, nine and 12 months, and then assumed to continue at the 12-month level over the time horizon of the economic evaluation. The mean utility value at baseline for the control arm (0.48) was assumed as the base QALY before the start of the intervention. The QALY for the first 12-month period for Udaan (control arm) was calculated as the difference between the mean QALY (0.50) and the utility value at baseline (0.50-0.48=0.02). The QALY for each year post the first 12 months for Udaan, was

assumed as the difference in utility value at 12 months to utility value at baseline or the incremental QALY ($0.57-0.48=0.09$). This calculation was based on the assumption that in the absence of any reform, utility values would remain at the values measured at baseline. The QALY for the first 12-month period for Udaan+SITAR (intervention arm) was calculated as the difference between QALY for intervention (0.46) and mean QALY (0.50) ($0.50-0.46=-0.04$). Since Udaan+SITAR did not show an effect at 12 months, no further analysis was computed.

Mean EQ-5D utility values for care as usual, the intervention and control arm at baseline, six , nine and 12 months and up to 10 years are shown in figure 1-3 and represent the 'Area Under the Utility-Time Curve', which is the formula used for calculating the QALY (Whitehead & Ali, 2010).

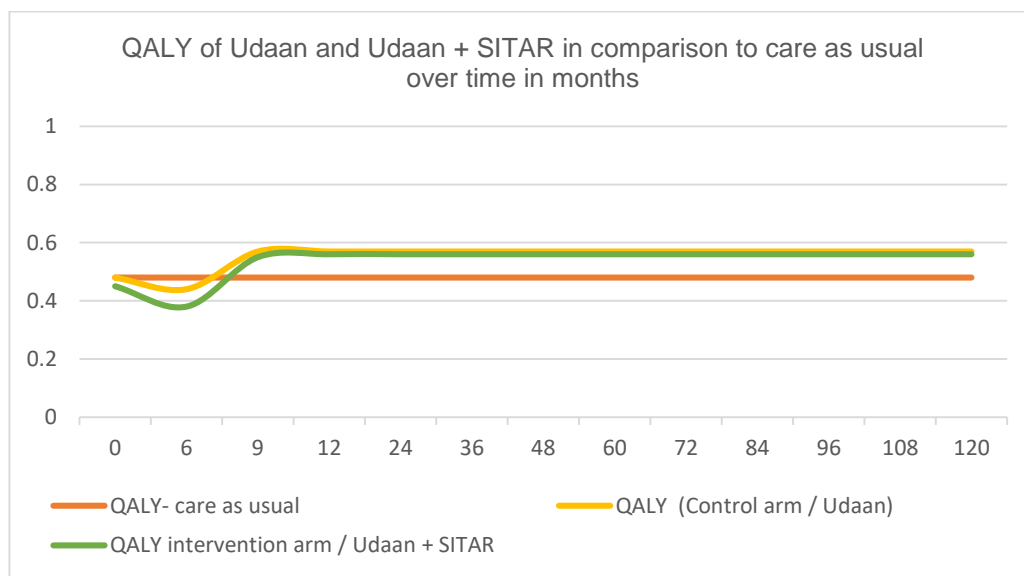


Figure 9-3: Mean EQ-5D scores of care as usual and trial arms over time

We further applied a discount factor of 0.97 and 0.94 based on the discount % used in the sensitivity analysis and applied it to the incremental QALY and costs (Gravelle & Smith, 2001).

We calculated incremental costs of UDAAN vs care as usual and UDAAN+SITAR vs UDAAN, plotting the Incremental Cost Utility Ratio (ICUR)

for all the four variations based on the sensitivity analysis. The ICURs are shown in Table 9-4 and the detailed calculation is in Appendix 12.17.4.

The highest ICUR value for the incremental costs of Udaan vs care as usual at a 3% annual discount rate and a four-year amortisation period was ₹81,561 or \$1,269.25.

Table 9-4: Incremental Cost Utility Ratio (ICER) for Udaan vs costs of care as usual reported in INR and USD

Incremental costs, QALY and ICUR based on sensitivity analysis	INR	USD
Discounted incremental Costs of Udaan for four years at 3%	₹22,021.69	\$342.70
Discounted incremental QALY of Udaan for four years		0.27
ICUR	₹81,561.81	\$1,269.25
Discounted incremental Costs of Udaan for ten years at 3%	₹34,756.81	\$540.88
Discounted incremental QALY of Udaan for ten years		0.83
ICUR	₹41,875.67	\$651.66
Discounted incremental Costs of Udaan for four years at 6%	₹20,348.88	\$316.66
Discounted incremental QALY of Udaan for four years		0.25
ICUR	₹81,395.52	\$1,266.66
Discounted incremental Costs of Udaan for ten years at 6%	₹28,010.51	\$435.89
Discounted incremental QALY of Udaan for ten years		0.6
ICUR	₹46,684.18	\$726.49

Ideally an ICUR would be compared to the Willingness to Pay Threshold (WTP). Since we do not have a computation of WTP for health for the Indian context, we have used the older WHO guideline on cost-effectiveness based on the per capita Gross Domestic Product (GDP) (Marseille *et al.*, 2014). Indian GDP per capita for 2020 is US\$2,100. (Macrotrends.). The ICUR for Udaan is at US\$1,269.25. This intervention costs less than 1X GDP per capita and would be considered highly cost effective as per WHO cost-effectiveness guidelines. It is important to note that the 1X to GDP guideline is in the context of DALY.

We did not analyse the cost utility of the Udaan+SITAR intervention versus Udaan because no effects of intervention were seen on the QALY of the intervention arm. There is very little evidence on quality-of-life measures for people living in institutions (Megens & Van Meijel, 2006). Subjective quality of life for people with severe mental illness is also determined by the social network

of a person and feelings of anxiety and depression. It is mediated by factors such as social support the individual has, self-esteem mastery, autonomy and self-efficacy (Hansson, 2006). Long-stay patients in mental hospitals have high unmet needs, poor self-esteem, low autonomy and poor social support (2015). Higher intervention and follow-up time than was possible in the SITAR trial might be needed to determine a discernible difference in quality-of-life measures.

We did not see any main effects on the primary outcome of WHODAS (Disability) scores at six months, hence a Cost Effectiveness Analysis (CEA) was not undertaken based on this primary outcome.

9.5 Strengths and limitations of the cost benefit analysis for Udaan and SITAR

Psychiatric hospital reform in LMICs has happened in an unplanned manner with no evidence of the associated costs of reform or the outcomes there of (Raja *et al.*, 2021). The economic evaluation of Udaan and SITAR provides important information not previously available. Understanding total costs involved in reform, the per person costs of reform in comparison to per person costs of care as usual adds valuable information that could help in critical decisions on the nature and setting of care provided to people with severe mental illness who have high care needs.

Cost estimation was done using a bottom-up retrospective costing exercise, which had the advantage of accurate estimation on each component of the programme, by individuals directly responsible for executing the program. Many elements of the Udaan programme and SITAR intervention were drawn on the basis of market value of the material received in kind for running the program. The bottom-up analysis was a time-consuming process with multiple discussions covering a long implementation period and took several months to complete.

For the structural component of the Udaan programme, which included large infrastructure refurbishment, we have used an amortisation period of four years and 10 years. Per person costs of reform are sensitive to utilisation rates and to

programme durations and has been captured effectively in this economic evaluation.

Hospital care or costs of care as usual have been estimated on expenditure statements provided by the hospital for four years of the Udaan programme. These costs may not include expenditure that may have been incurred by the state government and hence may be an underreporting of costs of care as usual.

There is very little published research on comprehensive hospital reform and costs thereof, thus comparative data on costs was not available for analysis. We also did not find data on comprehensive costs of community mental health programs to compare costs of hospital-based interventions with other interventions in the community.

Several assumptions have been made in the calculation of QALYs. In the absence of an 'ideal' control group, utility value of the control group at baseline was assumed as the Baseline QALY. We have also assumed that incremental QALY gains for the intervention and control arm will remain as they have been in the first 12 months of the trial period. As this was a pragmatic trial, where we could not follow-up with patients beyond a 12-month period, these assumptions are reasonable. These economic evaluation findings need to be substantiated by further studies on quality of life for people who are long-stay in mental hospitals. Refined research is also needed in capturing indices such as empowerment and dignity that may not be captured by traditional quality of life measures and are important from a patient perspective. The WHO guideline on cost effectiveness of interventions is a DALY based guideline. Applying this in the context of QALYs is therefore a weak indicator used in the absence of an available, robust measure.

9.6 Chapter conclusion

The cost of Udaan and SITAR intervention indicates a small increase in the costs of care. The costs of Udaan, represent costs of systematic hospital reform and the cost utility analysis suggests that this increase is cost effective. This is however, challenging to establish definitively. This finding has significance

considering that hospital-based reforms are a key area of intervention in the light of the fact that almost all mental health care services in LMICs are currently provided by mental hospitals. Deinstitutionalisation, as it happened in high income countries, may not be a possibility for LMICs. At less than 20% of costs of care as usual, systematic reform has the potential to offer high quality services, minimise human rights violations and impact clinical and social outcomes. The added intervention of SITAR costs less than ₹1.00 per person per day. As an intervention addressing unmet patient needs, SITAR was perceived as valuable by patients for restoring a sense of dignity, increasing autonomy and widening their social network and support system. These value additions may not be effectively captured by traditional measures on outcomes. SITAR might thus appear as an intervention that adds costs to the overall reform process of Udaan without adding any benefits. However, this might be an inappropriate conclusion to draw in view of gaps in scientific research and evidence on appropriate patient centric measures that capture changes in dignity, autonomy and empowerment inherent to the journey of recovery in SMDs. Long-stay patients in mental hospitals constitute a very vulnerable group of people with high support needs. There is an urgent need of understanding costs of care of such patients in comparative settings in the context of LMICs. where the costs of care and the effects thereof might be different to those established for High Income Country settings. There is also a need for further research on the value a society places on mental health and wellbeing and its preferences for a robust cost utility analysis.

10 Discussion

10.1 Chapter overview

This chapter reflects on the research undertaken for this thesis. SITAR was a two-arm pragmatic randomised controlled trial embedded in a larger program (Udaan) on systematic reform of one psychiatric hospital in India (RMHN). The research comprised the following distinct phases planned to answer the primary research question-

- A systematic review of literature on psychiatric hospital reform in LMICs.
- Development of the evaluation of (Udaan) in the form of SITAR trial.
 - Documentation of systematic reform of the Regional Mental Hospital Nagpur (Udaan) as a case study.
 - Development of the methodology and methods for SITAR trial and its execution
 - Development of the Needs Based-Intensive Case Management (NB-ICM). This formed the intervention component of the SITAR trial.
 - Development of NB-ICM training manual for case managers
- Economic evaluation of Udaan and SITAR.

10.2 Scientific evidence on psychiatric hospital reform in LMICs

Around the world, mental hospitals continue to remain critical care pathways for people with severe mental illness, especially so in Low, Lower-Middle and Upper Middle-Income Countries (Morris *et al.*, 2012; WHO, 2018). For the past 200 years, psychiatry has been struggling with reform of mental hospitals, the living conditions, and human rights violations. Abuse of people with SMD continue to remain areas of significant concern (Lin *et al.*, 2009; Mills & Jain, 2010; Murthy *et al.*, 2016). Mental hospitals, however, are not static entities. They are evolving and finding renewed relevance in the global mental health care landscape.

10.2.1 Reform of psychiatric hospitals in the last four decades

There have been several efforts of reforming psychiatric hospitals in many LMICs, triggered by poor quality of care and lack of dignity especially for patients who live there for longer periods of time (Fan *et al.*, 1994; Ganesan, 2017; Jin & Li, 1994; Kruger & Lewis, 2011; Uys *et al.*, 1996). Reform was also triggered by judicial intervention as was the case in India and Argentina (Hillman, 2007; Murthy *et al.*, 2017; Murthy *et al.*, 2016; Nagaraja & Murthy, 2008; Varma, 2016).

10.2.1.1 Structural reform

Since most psychiatric hospitals were established during the colonial period, their infrastructure is old and in need of urgent refurbishment. In many countries, infrastructural changes have been done to improve living conditions for patients such as across hospitals in India (Murthy *et al.*, 2016). The vast and sprawling acreage often associated with psychiatric hospitals has been used in creating facilities relevant to the needs of current patients such as starting half way homes as in the case of Argentina (Hillman, 2007).

10.2.1.2 Process reforms

There have been several attempts to reform clinical and non-clinical processes of mental hospitals pushing forward better quality of care, protection of human rights and dignity and autonomy in patients such as that in Argentina, China, Sri Lanka, India, South Africa, Brazil and Grenada (Fan *et al.*, 1994; Fisher *et al.*, 1988; Ganesan, 2017; Hillman, 2007; Huf *et al.*, 2012; Jin & Li, 1994; Kruger & Lewis, 2011; Murthy *et al.*, 2016).

10.2.1.3 Capacity building of hospital staff

Though there is a large paucity of human resource in mental health with less than 1 professional for every 10,000 people, a bulk of this human resource is concentrated in hospitals with seven out of 10 mental health professionals working in mental hospitals (Lora *et al.*, 2017; WHO, 2018). In several countries, staff of mental hospitals have been a critical stakeholder and conduit of the reform process, being involved through, engagement, training and joint decision

making in changing practise and policy within these institutions (Fisher *et al.*, 1988; Ganesan, 2017; Kruger & Lewis, 2011).

10.2.2 Gap in knowledge and evidence

Mental hospitals remain at the centre of global mental health dialogue and the redirection of public mental health policy, albeit in the context of deinstitutionalization and closure. They, however, have slowly disappeared from scientific literature over the past several decades (Cohen & Minas, 2017; Collins *et al.*, 2011; Patel *et al.*, 2016).

We found very little evidence of mental hospital reform in our systematic review of literature spanning a forty-year period and covering 137 countries classified as Lower, Lower-Middle or Upper-Middle income countries by the World Bank. Of the 16 studies identified, only one was rated as being of high quality.

Largely driven by a need to improve the living conditions and quality of care for long stay patients, these reforms are sporadic and unplanned. Reforms have not been linked to patient outcomes. There is also no evidence of the associated costs of reform and the comparative costs and effectiveness of other modalities of care in LMICs for patients with SMD who have high care needs.(Raja *et al.*, 2021).

10.3 Premise of the SITAR trial- the research question

The absence of effective and scaled comprehensive community mental health programs and the impracticability of closing down mental hospitals in most LMICs place an urgency on the need for a pragmatic approach to implementing mental hospital reform based on high quality care promoting human rights and dignity, repurposing them to meet current service user needs. The absence of reform of these psychiatric hospitals places very vulnerable people, looked after by them at risk of homelessness and criminalisation as countries try to comply with downscaling of these hospitals in the wake of deinstitutionalisation modelled on the lines of mental health care in high income countries (Bachrach, 1984; Barnagarwala, 2020; Dear & Wolch, 2014; Hopper *et al.*, 1997; Krupinski *et al.*,

1984; Lamb, 2001; Mechanic & Rochefort, 1990; Padmakar *et al.*, 2020; Thornicroft & Bebbington, 1989).

The SITAR trial aimed to bridge a critical gap in scientific evidence by studying the impact of reform on individual patient outcomes of reducing disability, improving symptoms, improved social and occupational functioning and a better quality of life. We also aimed to study the modality in which reform would reach the patient. Different approaches to case management have been used as a service approach for people with severe mental illness in a range of different settings (Dieterich *et al.*, 2017; Knight & Carter, 1990; Lamb & Weinberger, 2005; Okin *et al.*, 2000).

SITAR used Need-Based Intensive Case Management (NB-ICM) within the context of the hospital, seeking to answer the research question- *‘whether larger structural and process reform of a mental hospital brings about change in patient outcomes or a case management based individual service package is needed to effectively translate larger hospital reform into discernible difference in patient outcomes especially for those who are long-stay often living in closed hospital wards.’*

NB-ICM comprised of eleven components – accommodation, safety and food, psychoeducation, symptom management, physical health, emotional wellbeing, self-care and other living skills, social relationships, connecting with family, leisure activities, occupational and financial inclusion, and spiritual needs. Intervention elements were broadly divided into individual and systemic level interventions under each of the 11 need-based components. The intervention plan was developed for each patient based on an assessment of unmet needs by the case managers.

10.4 The reform of the Regional Mental Hospital of Nagpur; The Udaan program

Udaan initiated the reform process through a baseline facility assessment using the WHO’ QualityRights framework (WHO, 2012).The living conditions for patients along with psychosocial care needed improvement on several fronts.

Hygiene needed improvement with more and better facilities such as toilets and bathrooms for both patients and staff. Treatment provided by the hospital was largely medical and there were no opportunities for staff training. These findings of the baseline facility assessment echoed with the findings of the Human Rights Commission and are similar to the situation in other mental hospitals in India (et.al, 1946; Murthy *et al.*, 2016; Nagaraja & Murthy, 2008).

Based on the learning of the INCENSE program and of the QualityRights program in psychiatric hospitals of Gujarat in India (Parivartan, 2015; Pathare *et al.*, 2019) , Udaan took forward psychiatric hospital reform combining various evidence based elements of reform into a single, clearly described package of services comprising of structural and process reform along with training of hospital staff. Political will played a critical role for a program like Udaan to be implemented in the confines of a hospital setting otherwise largely devoid of external influences (Murthy *et al.*, 2016; Nagaraja & Murthy, 2008; Narasimhan *et al.*, 2019). Political will is fundamental in directing reform as well as translating evidence based mental health care into policies and programs at scale (Hann *et al.*, 2015; Lancet Global Mental Health Group, 2007; Rathod *et al.*, 2017; Saraceno *et al.*, 2007).

10.5 The hospital population

Psychiatric hospitals in India comprise patients seeking acute or short-term care and those that remain in hospitals over long periods of time. Most patients in mental hospitals have a diagnosis of psychosis, psychosis with co morbid developmental disorders such as intellectual disability and neurological conditions such as epilepsy (Narasimhan *et al.*, 2019).

We mapped socio-demographic and clinical variables of all patients admitted to RMHN at the start of the SITAR trial. This mapping showed that the hospital population is not a homogeneous group. Three distinct groups emerged and we analysed them separately. 1) The first set of people were patients with a primary diagnosis of psychosis having a hospital stay between 1 and 10 years at baseline, this group formed the SITAR cohort comprising the intervention and

control arms of the trial (n = 182). Patients not included in the SITAR trial (non-SITAR group) comprised two distinct cohorts: 2) patients who continued to remain in hospital at the time of our second follow-up measure which was at 12 months to baseline called the hospital cohort with n = 153. These patients were distinct to the SITAR cohort either by a longer duration of stay or having a comorbid neurological or developmental disorder and 3) patients who were no longer in hospital at the 12-month time point to baseline called the discharged cohort (n=124).

Patients in the hospital cohort were different to those included in the SITAR trial as well as to those in the discharged cohort and were older with much longer length of hospital stay at baseline (median 21 years as compared to median 4 to 5 years of hospital stay in patients on the SITAR trial). Patients in the discharged cohort were younger with a mean age of 40 years, they were more connected to their families and had a much shorter duration of hospital stay (median length of stay at baseline was 1.5 years).

10.5.1 The socio-demographic profile of long stay patients at RMHN

Most people who end up becoming long-stay patients are in the productive age group of under 60 years (Narasimhan *et al.*, 2019). While there were a higher number of men at admission, seen in the Non-SITAR discharged cohort, there were a higher number of women in the long stay cohort of the SITAR trial as well as in that of the hospital cohort. This trend of higher abandonment of women has been seen in mental health services in India and is reflective of the status of women in the Indian social framework with the added disadvantage of a severe mental illness (Moorkath *et al.*, 2018; Narasimhan *et al.*, 2019; Thara *et al.*, 2003).

The distribution of religion in the long stay cohort largely reflects religious distribution of the wider population (Narasimhan *et al.*, 2019; Sreenivasan & Hoenig, 1960). However, as many people admitted to mental hospitals in India are homeless, this along with the course of the illness often impacts their understanding and information on basic variables of identity such as religion and

place of origin which remain unknown even after many years of stay in the mental hospital (Gowda *et al.*, 2017; Murthy *et al.*, 2016).

The median length of stay for the SITAR cohort was between 4 and 5 years echoing the general trend of mental hospitals in India where 32% of all patients admitted to mental hospitals have a stay longer than a year and for the hospitals of Maharashtra, this is at 36% (Murthy *et al.*, 2016; Narasimhan *et al.*, 2019).

10.6 Findings of the SITAR Trial- A summary

10.6.1 Difference between intervention and control arms of SITAR

We hypothesised that there would be a difference in outcomes (disability, symptoms, social and occupational functioning and quality of life) for patients who received the additional service package of Need Based Intensive Case Management (NB-ICM) which formed the intervention arm (Udaan + SITAR) in comparison to overall reform of the psychiatric hospital (Udaan) forming the control arm in the SITAR trial. The trial was powered at 90% to detect a difference in the primary outcome of disability (WHODAS) scores at 6 months (Raja *et al.*, 2020).

One of the hallmark features of psychosis is the presence of functional deficits and associated disability (Bowie *et al.*, 2018; Green *et al.*, 2000; Griffiths *et al.*, 2019; Harvey, 2010). Studies have found disability increases further with duration of illness and that patients who continue to remain long-stay in psychiatric hospitals tend to have higher disability levels than do those discharged to community settings (Johnstone *et al.*, 1981; Narasimhan *et al.*, 2019). Other studies have also indicated that patients who stay in hospital for longer have higher levels of dependency and as such are difficult to discharge to situations with lower support (Farmer *et al.*, 1990; Narayan & Kumar, 2012; Taiwo *et al.*, 2008).

Long stay patients (the SITAR trial and the hospital cohort) had higher levels of disability than the discharged cohort at baseline. Except for the discharged cohort, all other groups of patients fell under the category of 'severe disability'. We found no significant difference in disability levels measured through

WHODAS scores between the intervention and control arms of the SITAR trial. Patients receiving NB-ICM were not significantly different in terms of disability to those who did not receive NB-ICM at 6, 9 and 12 months. We also found no difference in disability scores between the intervention and the control arm adjusting for age, gender and duration of stay in hospital at baseline. Gender however was independently predictive of disability scores at the 6-month time point, this though was not seen at 9- and 12-months. These results have been reported in Chapter 7. Other studies have also shown that women in psychiatric institutions tend to be more disabled than men (Narasimhan *et al.*, 2019; Pryce *et al.*, 1991). Assertive Community Treatment and other forms of case management also show mixed results on reduction of disability, although these results are largely from high income countries where standard care tends to be comprehensive (Burns *et al.*, 1999; Smith & Newton, 2007).

Most long-stay patients in psychiatric hospitals continue to have behavioural problems and symptoms of psychosis despite being on treatment (Elis *et al.*, 2013; Narasimhan *et al.*, 2019; ODEJIDE, 1985). Our findings indicate that patients in the intervention and control arms of SITAR were moderately ill at baseline. We found no significant difference in symptom levels between intervention and control arms at 6, 9 or 12 months of the trial.

Remission in symptoms in psychosis is closely associated to social and occupational functioning of patients with chronic psychosis (Cardenas *et al.*, 2008; San *et al.*, 2007; Tandberg *et al.*, 2013). We found a high deficit in social and occupational functioning across both the intervention as well as the control arms of SITAR at baseline. This finding is in keeping with the profile of long-stay patients with psychosis in institutions (Harvey *et al.*, 2000). We did not find a significant difference in social and occupational functioning scores in the intervention and control arm of the trial at 6, 9 and 12 months.

Health Related Quality of Life (HRQoL) for people living with severe mental illness, has been an area of increasing scientific interest and inquiry in terms of both clinical outcomes as also in economic evaluations (Awad & Voruganti, 2000). Assessment of quality of life in mental health grew with

deinstitutionalisation and the need to determine patient satisfaction with their new living arrangements in community settings (Basu, 2004). People with chronic psychosis moved to the community report better quality of life than do those living within an institutional set-up (Fleck *et al.*, 2007; Hobbs *et al.*, 2002; McInerney *et al.*, 2018; Megens & Van Meijel, 2006; Padmakar *et al.*, 2020; Rossetto, 2009).

Health related quality of life for long-stay patients at RMHN participating in the SITAR trial was poor at baseline for both the intervention and control arm. We did not see a significant change in quality-of-life scores at six, nine and 12 months. We also found no significant difference in median QALY for the intervention and control arm at 12 months. There are several issues in the measurement of quality of life of people living with a severe mental illness (Chaudhury *et al.*, 2018; Katschnig, 2006). Subjective variables linked to a better quality of life for people with SMD are a feeling of being in control, particularly distressing symptoms, autonomy and choice, a positive self-image, a sense of belonging, engagement in meaningful and enjoyable activities, a sense of hope (Connell *et al.*, 2012). These variables of subjective wellbeing and perceived quality of life for severe mental illness may not be well captured by instruments currently used in measuring quality of life especially in context to severe mental disorders (Brazier, 2010).

10.6.1.1 Need Based Intensive Case Management (NB-ICM)

Case management as an approach to care for people with severe mental illness largely grew with deinstitutionalisation, to meet the support needs for people placed in the community. Standard and Intensive case management is used in most parts of the high-income world as an approach to care for people living with SMD in the community. Its efficacy has often been measured in terms of reduction in number of days spent in hospital, clinical and social outcomes (Dieterich *et al.*, 2017; Marshall *et al.*, 1998; Marshall & Lockwood, 1998).

Amongst the different models of case management is the Assertive Community Treatment (ACT) characterised by lower caseloads, active outreach, a team

approach to intervention that is directly provided rather than being a referral pathway. ACT has evolved differently in different service contexts and studies have shown that just lower caseloads for intensive case management does not show any change in clinical or social outcomes and attention needs to be paid to content of treatment (Burns *et al.*, 1999; Marshall & Lockwood, 1998).

Almost five decades since its origin in a hospital, the SITAR trial used the principals of ACT / intensive case management in a structured individualised patient service package for severely disabled patients in a psychiatric hospital in India. Most patients with psychosis, especially those who have been living in an institution over long periods of time have no access to psychosocial or rehabilitative interventions (2015; Murthy *et al.*, 2016; Varma, 2016). We thus sought to use NB-ICM as a service package to provide long-stay patients' equitable opportunity to benefit from the larger structural and process reform of the hospital. The intervention comprised of eleven components. These were accommodation, safety & food, psychoeducation, symptom management, physical health, emotional wellbeing, self-care and other living skills, social relationships, connecting with family, leisure activities, occupational and financial inclusion and spiritual needs. Intervention elements were broadly divided into individual and systemic level interventions. The individual intervention package was based on a regular mapping of unmet needs of the patient. The intervention is described in chapter 5.

The use of NB-ICM did not show significant change on any of the four outcome measures of disability, symptoms, social and occupational functioning and quality of life at the six-, nine- or 12-month time point between the intervention and control arms of the SITAR trial. Further, adjusting for clinically relevant variables of age, gender and length of stay, we did not find the intervention arm to be predictive of any of the four outcome measures at 6, 9 and 12 months.

We assessed unmet patients' needs as part of the process of NB-ICM (described in chapter 5). There was a reduction in unmet needs on almost all of the 11 need domains addressed through the intervention. There was a visible difference in variables such as reduction in negative symptoms, management of

negative emotions, improvement in personal grooming. improvement in relationship with peers and participation in activities including developing a hobby. Improvement was also seen in the individual's ability to use systemic resources being developed through the reform process in tasks such as keeping their own living space clean. Systemic improvement through the reform process also reduced the unmet need for health check-ups and attending to needs such as dental, gynaecological and ophthalmic care. However, we did not measure unmet needs in the control arm not receiving NB-ICM. Data from the INCENSE program that mapped unmet needs in long-stay patients at the Regional Mental Hospital Pune has shown that a large proportion of basic needs of long-stay patients in hospital remain unmet or partially met; this has also been seen in other settings in low-income as well as high-income countries (Chopra & Herrman, 2011; O'Brien, 1992; Parivartan, 2015; Zhong *et al.*, 2019).

We also collated treatment data from patient files. We did not note any difference in prescription patterns between the intervention and control arm patients of SITAR.

Though several patients in the intervention arm were discharged to families, often associated to work done through case managers, we did not include discharge from hospital as a trial outcome. This is because discharge from hospital in Indian settings is governed by several factors beyond the immediate scope of Udaan and SITAR, including lack of feasible options for discharge as has been witnessed for long-stay patients in special hospital settings in Low-income and high-income countries (Maden *et al.*, 1993; Murthy *et al.*, 2016; Narasimhan *et al.*, 2019; Parivartan, 2015; Sayal & Maden, 2002).

10.6.1.2 Difference in Patient' experience of the reform process between the intervention and control arms of SITAR

Patients with severe mental illness commonly experience an erosion of dignity. This increases a great deal when the person is living in an institutional set up (Letendre, 1997; Skorpen *et al.*, 2015; Skorpen *et al.*, 2014). We sought to study

patients' perception and experience of changes in care in a hospital undergoing reform using a series of Focus Groups (FGs) (chapter 8).

In terms of subjective experience of reform, patients in the intervention arm had a much wider and deeper engagement with the reform process. They had more personalised experiences of reform and related instances of services that stood out for them such as the ability to pick out coloured clothes for themselves as opposed to wearing ill-fitting hospital gowns, access to ophthalmic services and ability to negotiate their stay in the hospital mediated through case management. The control group's experience of reform was limited to changes on their respective wards such as changes in sanitation, hygiene and patient engagement services. In contrast, the intervention group experienced expanded mobility across the hospital, enhanced social interaction and the forming of a social network along with access to learning a range of skills and meaningful engagement throughout the day. Patients in the intervention arm also experienced enhanced autonomy and reported a restoration of dignity arising out of the reform process along with a subtle change in the power dynamics of the staff patient relationship within the mental hospital. The patients who participated in the FGs were those that continued to remain in hospital in August 2020 when the group discussions were held. Seven people in intervention arm and eight people in the control arm had been discharged to the community. We could not include them given the pandemic situation and the limited resources of the trial. It would have been very valuable to include their experience of the reform process and its impact on their life in the community.

Thus, while conventional, proxy based, quantitative measures on functionality, symptom improvement, social and occupational functioning and quality of life, did not show a significant difference between the intervention and control arms of SITAR, there was a change in patient's subjective experience of care. Prior studies on the effectiveness of ACT also report a sense of subjective wellbeing for patients receiving the intervention (Nordén *et al.*, 2012). Patients' perception of social support attributable in part to ACT has an important bearing on patients' experience of subjective wellbeing (Prince & Gerber, 2005).

10.6.2 Outcomes of psychiatric hospital reform- Difference in outcomes at baseline, six, nine and 12 months for all hospital patients

We additionally hypothesised that psychiatric hospital reform would lead to an improvement in functionality that is a reduction of disability, improvement in symptoms, social and occupational functioning and quality of life. We assessed this by comparing the scores of quantitative measures at baseline to scores at six, nine and 12 months.

10.6.2.1 A summary of the findings

We did not see a significant change in disability scores at 6 months when compared to baseline scores. There was a marginal improvement in WHODAS scores of less than 1 point in the intervention arm and a marginal increase in disability by a little over 1 point in the control arm. Long-stay patients not included in the SITAR trial (hospital cohort) showed a marginal decrease in disability by 2 points at the 6-month time point which was not significantly different to baseline WHODAS scores. All three groups, SITAR intervention, SITAR control and the hospital cohort, showed a significant improvement in WHODAS scores at 9 months in comparison to baseline scores. These results have been reported in chapter 7 of the thesis.

Disability in psychosis is a persistent phenomenon and its severity, especially in institutionalised patients with poor social networks, increases over time (Evert *et al.*, 2003; Harvey *et al.*, 2013; Narasimhan *et al.*, 2019; Wiersma *et al.*, 2000). Longer duration of untreated illness and homelessness is also associated with higher levels of disability (Murthy *et al.*, 2016; Padmakar, 2018), (Cannon, 2012; Farooq *et al.*, 2009).

Symptom scores at six months showed a significant improvement to baseline scores in the intervention and the control arms of SITAR which continued to remain apparent at nine and 12 months. A similar pattern of significant improvement in symptom scores at six months to baseline was seen in the hospital cohort which continued to remain apparent at 9 and 12 months. We attribute this change in symptoms to two factors, 1. A better medication supply

mechanism was developed with the government that ensured regular availability. 2. Structured patient engagement and ward based reform work helped address negative symptoms (Aleman *et al.*, 2017; Lutgens *et al.*, 2017).

Social and occupational functioning scores measured through SOFAS showed a significant improvement to baseline scores at nine months and continued to remain apparent at 12 months in the intervention arm of SITAR. SOFAS scores showed a significant change to baseline scores in the control arm only at 12 months. However, we did not see a significant difference in SOFAS at six, nine or 12 months to baseline in the hospital cohort. Social and occupational functioning constitutes a core area of deficit in chronic psychosis and probably requires a longer intervention time frame to show improvement (Bellack *et al.*, 1994; Gorwood *et al.*, 2013; Harvey *et al.*, 2004).

Health Related Quality of Life scores showed a significant difference to baseline scores at nine months which remained apparent at 12 months in the intervention and control arms of SITAR. The hospital cohort showed a significant change in quality-of-life scores only at 12 months to baseline. Psychosis impacts health related quality of life in people and is associated to symptoms of the illness, unmet needs, autonomy and choice. Patients living in mental hospitals have reduced autonomy and high unmet needs which would have a bearing on their quality of life (Connell *et al.*, 2012; Hansson, 2006; Murthy *et al.*, 2016; Parivartan, 2015).

10.7 Implications of the SITAR trial and its original contribution to knowledge

10.7.1 Outcomes of reform

Our findings show that systematic hospital reform has the potential to make a significant difference to important clinical and social outcomes for patients, especially those who have been long-stay at the hospital. Despite being on pharmacological intervention by virtue of being in hospital, there was further improvement in symptoms within the first six months of systematic reform. Improvement in functionality and overall disability took at least nine months to significantly change. There is also some indication that in the absence of

systematic reform, there was a possibility of increasing disability and further deterioration in social and occupational functioning over time. Improvement in social and occupational functioning took at least nine months before significant change was noted first in the intervention arm of SITAR and at 12 months in the control arm of SITAR which represents 'care as usual' in a hospital in transition. Long-stay patients with comorbid conditions such as epilepsy and intellectual disability took longer to show significant change in social and occupational functioning with significant change only being visible at 12 months. There was significant improvement in quality of life for long-stay patients, however benefits of improving quality of life were seen earlier in patients with psychosis as compared to those who had psychiatric and neurological comorbidity.

The baseline situation of most psychiatric hospitals in India are characterised by closed wards. Long-stay patients living in them have no meaningful activity or engagement, completely unmet social needs, no worthwhile opportunity for a hobby, recreational activity or paid employment. There is no effort to address independent living skills and the continued legacy of custodial care and negative discrimination further reiterates feelings of low self-esteem and shame. Most long-stay patients thus experience continued deterioration in symptoms, cognitive impairment and very high dependency needs (Padmakar *et al.*, 2020; Padmakar, 2018; Parivartan, 2015). Given this, there is a possibility that a longer intervention and follow-up time was needed to detect a discernible change in patient outcomes (Leff & Trieman, 2000; Newman *et al.*, 2012)

There is little evidence of systematic and comprehensive reform of mental hospitals in LMICs in scientific literature (Raja *et al.*, 2021). The only other documentation of reform of a comparable mental hospital, measuring outcomes in long-stay patients, was that undertaken by the INCENSE program in one hospital each in Maharashtra and Assam. The program report, included in our systematic review of literature, found no significant change in outcomes for long-stay patients and noted that additional psychosocial intervention in the absence of larger systemic hospital reform does not translate into any meaningful change for people living in these settings (Parivartan, 2015). Many patients with SMD

continue to have high care needs and are not able to exit institutionalised systems of care for a varied set of reasons that include not having any family to go back to (Murthy *et al.*, 2016; Narasimhan *et al.*, 2019; Padmakar *et al.*, 2020). In such a situation, reformed hospital care that has an impact on patient outcomes such as that demonstrated by SITAR may constitute a viable and affordable care pathway in countries like India and other LMICs with limited options of care (Dartnall *et al.*, 1999; Gururaj *et al.*, 2016; Murthy *et al.*, 2016).

The use of case management based individually tailored service package for patients in the form of NB-ICM makes a significant difference to the patient's subjective experience of care in the mental hospital and has an important role to play in meeting un-met patient needs. However, the use of this service package did not show any difference in quantitative measures on the SITAR trial. There could be multiple reasons for this; 1) a longer duration of intervention time might be needed than the 6 months provided under SITAR. 2) the underlying hospital reform via Udaan influenced both groups. Systemic elements of the reform process occurred throughout the hospital and would have influenced all the patients in the hospital. Since much of this reform focused on meeting basic needs for patients, this could be a reason for patients in intervention and control groups both showing a uniform significant change in outcomes at 9 months to baseline. 3) the instruments measuring change might not have been able to pick up change occurring through intervention which were brought out through the focused group discussion.

10.7.2 Cost of reform

The incremental adjusted costs of reform (UDAAN) ranged between 10% and 16% of the costs of care as usual based on the sensitivity analysis. The additional costs of SITAR to costs of Udaan ranged from 7% to 10% based on sensitivity analysis. Health economic evaluations are an emerging field of enquiry in India with limited evaluations in mental health especially in context to severe mental disorders (Mishra & Nair, 2015; Prinja *et al.*, 2015). Improving the quality of life for people living with a severe mental illness is increasingly being researched, however given the complex and multidimensional nature of severe

mental illness, evaluating outcomes of psychiatric rehabilitation is particularly difficult (Iyer *et al.*, 2005). The economic evaluation of Udaan and SITAR sheds important light, though preliminary, on the costs of care for people with severe mental illness who are long stay in a mental hospital. The costing exercise for Udaan and SITAR captured nuanced costs of a complex intervention in the chaotic setting of a mental hospital and as such provides important insights into the kind of infrastructural and operational resources that are called for in putting up a reform intervention in a psychiatric hospital. The cost utility analysis indicates a potentially cost-effective reform intervention. Qualitative data on patients' subjective perceptions place value on the intervention provided through SITAR, though it did not translate into a discernible effect on conventionally measured outcomes, perhaps indicating the need for more sensitive data collection methods and tools that better capture the increased sense of autonomy, empowerment and dignity that patients experienced with intensive case management. New measures have been developed but further research and evidence is needed to discern their utility in measuring outcomes for people living with a severe mental illness (Keetharuth *et al.*, 2018; Vergunst *et al.*, 2017).

10.8 Strengths and limitations of the SITAR trial

SITAR is the first methodologically robust trial to test the impact of reform in a psychiatric hospital on patient outcomes. It delivers evidence on the effectiveness of reform in the real and chaotic everyday world of a large psychiatric hospital in an LMIC.

The use of mixed methods was another strength of the study. Qualitative research provided important insight into the patient's experience of reform and the differences between the two groups.

The economic evaluation of Udaan and SITAR provide very important insights into the costs of a complex intervention comparing it to the costs of care as usual for a group of very vulnerable people with high dependency needs.

The SITAR trial was an evaluation of a complex intervention and had several challenges and limitations. The findings of the trial are primarily limited by the

fact that we did not have an ideal 'control group' of patients in a comparable hospital not undergoing reform. The measures used for the trial may not have been able to capture the nuanced patient experience of the transition process. The fact that many Udaan team members would be present in the wards, where no outsider was allowed earlier, may have altered the dynamics of the ward and staff and patient behaviour. We did not have the resources to use trained and neutral observers to capture this. The economic evaluation of Udaan and SITAR is based on several assumptions which mean that the findings are indicative at best. While inclusion of patient's experience of reform brought valuable insight into how the reform process influenced their lives, long-stay patients are not used to articulating their opinions and feelings. Preparatory warm-up sessions prior to the focus group discussions would perhaps have facilitated a better interaction especially with patients from the control group.

10.9 Impact on service reform

The Udaan program and SITAR trial have a range of products that will inform and aid the process of hospital reform in LMICs. These include the training manual for case managers working in hospital settings, the manual on the NB-ICM service package, training modules for hospital staff on clinical and psychosocial care, Standard Operating Procedures (SOPs) of process reform and a process document that describes the journey of reform and our learnings thereof.

10.10 Recommendations

The SITAR trial emerged from other work on hospital reform such as that of INCENSE. Apart from its findings, Udaan and SITAR give an extremely important message that systematic reform of psychiatric hospitals in LMICs is possible. Research is needed to distil out the elements of Udaan and SITAR that are scalable. Further work is needed in determining if the NB-ICM can be scaled up through lay health workers and consumer / peer providers. Though nascent, community mental health services are slowly beginning to emerge in various parts of India. Further research is needed to study the combined impact of reforming psychiatric hospitals in tandem with development of community based

mental health care services, especially in terms of new long-stay patients and care for the severely mentally ill.

10.10.1 Policy recommendations

- Structural and process reform of mental hospitals in LMICs like India commensurate with capacity building of staff has the potential to improve symptoms and functioning for long-stay patients.
- Structured and intensive case management provided in the context of larger hospital reform helps in meeting unmet patient needs for long-stay patients.
- In the absence of options for community living for people with high care needs, mental hospital can be reformed through the protocols developed in Udaan to offer a better living environment.
- Udaan also offers a pragmatic set of protocols to implement the changes brought about in the Mental Health Care Act of 2018 passed by the Government of India.
- Using the large infrastructure of mental hospitals to develop linked community services for people with severe mental illness may serve as a pragmatic model of care in the context of LMICs.

10.10.2 Research recommendations

There is a need for further research in the following areas:

- Understanding pathways of care that can address the reduction of a continually developing pool of long-stay patients and approaches to offering structured rehabilitation services in LMICs.
- Measures and methodology that can capture nuanced and relevant functional outcomes and lived experience in patients with SMD.
- The effectiveness of task shifting and task sharing in the care of patients with high dependency needs in mental hospitals through peer patients.
- Long-term follow-up of patients in psychiatric hospitals undergoing reform versus those that are yet to initiate transition in the context of LMICs.

- Economic evaluation of comparative care in the community for SMD patients with high dependency needs in LMICs.
- Scalability of reforms, especially process reforms and reforms in patient services carried out under Udaan in other hospital settings in India.

10.11 Personal reflection

The Tata Trusts have supported the INCENSE program and several other programs for the severely mentally ill across the length and breadth of India and I have had the privilege of being intricately involved with the running of these programmes for the past 14 years. The MoU for Udaan had been signed between Tata Trusts and the Government of Maharashtra prior to my PhD's initiation. Designing and executing the evaluation through the PhD helped me build a whole new set of skills, think critically in terms of program design and its evaluation and bring precision and quality in measurement and data management. I undertook five different modules on quantitative research, qualitative research and health economics and deliberately opted to complete assignments on all the modules using parts of my protocol for each of them. This allowed me access to a wide set of expertise in the form of my course teachers and directors who gave me time and discussed aspects of my protocol. Small pointers set me on the right course to undertake such a complex evaluation. A simple example was- " Do your CONSORT every week", this helped me efficiently track patients in the very large and dynamic world of the mental hospital. I have done some elements of qualitative and quantitative research through my career, doing a randomised trial was a completely new experience. It was both joy at the new learning and at times feelings of being very overwhelmed. It was challenging to explain the reality of a mental hospital in an LMIC to the University Ethics Committee. I also had no prior training in health economics and despite training and handholding through supervision, this is an area I have struggled with. The most heartening part of the journey has been the experiences patients shared with me throughout the journey of reform, some of their sharing was new learning for me and I would not have noticed it had they not pointed it out. When I have the opportunity to do a similar trial again, I would

like to explore methodologies that will allow for better exploration of patients' experiences and include measures relevant to their lives.

10.12 Conclusion

As deinstitutionalisation became the norm in psychiatric care in many parts of the high-income world, scientific attention to psychiatric hospitals and the people living in them declined. Mental hospitals remain the primary providers of care in LMICs and look after a group of very vulnerable people who otherwise would be trans-institutionalised to places such as a prison and beggars' home without access to psychiatric care. For the past 200 years, psychiatry has struggled with the reform of these institutions which, continue to function in much the same way they did when they were set up in the colonial world. Global mental health is predominantly focused on community-based care and is disconnected to the reality of the seriously mentally ill, especially those living in the closed wards of institutions. Though mental hospitals are not static entities and are constantly evolving, changes in them appear unplanned and de-linked to evidence. LMICs urgently need a pragmatic approach to implementing mental health, with evidence-based reforms of psychiatric institutions to meet the needs of service users today whilst developing care pathways in the community.

Udaan is an attempt at systematic hospital reform combining structural reform, process reform, capacity building of staff and an individual patient service package. The SITAR Trial was an evaluation of the effectiveness of this psychiatric hospital reform program and also assessed the value of a Needs Based Intensive Case Management (NB-ICM) intervention for long-stay patients in hospital likely to have high care needs.

The findings of SITAR provide preliminary evidence on the effectiveness of psychiatric hospital reform and point to the significance of a needs-based service package for patients that provides equitable access to services created through the reform process. There is indicative evidence on the cost utility of hospital reform. Reform of mental hospitals in LMIC settings may provide affordable pathways of care for SMD patients with high care needs.

Directive research is needed to build further evidence on the outcomes of reform, the change that reform entails for service users and the comparison of costs of reformed care in mental hospitals to that of comprehensive community care and the outcomes thereof.

The global mental health narrative needs to incorporate evidence on psychiatric hospital reform and re-examine its relevance as a viable mental health care pathway for thousands of vulnerable people living with severe mental illness.

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12 Appendix

12.1 Publication on the systematic review of literature

Social Psychiatry and Psychiatric Epidemiology
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REVIEW



Psychiatric hospital reform in low- and middle-income countries: a systematic review of literature

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Abstract

Purpose Psychiatric hospitals or mental asylums grew across the world in the colonial era. Despite concerns over quality of care and human rights violations, these hospitals continue to provide the majority of mental health care in most low- and middle-income countries (LMICs). We sought to review the evidence of reform of mental hospitals and associated patient outcomes.

Methods We adopted an integrative review methodology by including experimental and non-experimental research. The review protocol was registered on PROSPERO (CRD42019130399). A range of databases and systematic hand searches were conducted by two independent reviewers. Research conducted between 1980 and May 2019, that focused on any aspect of reform in mental hospitals for adults (age 18 and upwards) with severe mental illness and published in English, were considered.

Results 16 studies were included in the review. 12 studies met inclusion criteria, and four additional reports emerged from the hand search. Studies covered—India, China, South Africa, Grenada, Georgia, Sri Lanka, Argentina and Brazil. Key findings emphasise the role of judicial intervention as a critical trigger of reform. Structural reform composed of optimisation of resources and renovations of colonial structures to cater to diverse patient needs. Process reforms include changes in medical management, admission processes and a move from closed to open wards. Staff engagement and capacity building have also been used as a modality of reform in mental hospital settings.

Conclusion There is some documentation of reform in psychiatric hospitals. However, poor methodological quality and variation in approach and outcomes measured, make it challenging to extrapolate specific findings on process or outcomes of reform. Despite being integral service providers, psychiatric hospitals still do not adopt patient centric, recovery-oriented processes. Hence, there is an urgent need to generate robust evidence on psychiatric reform and its effect on patient outcomes.

Keywords Psychiatric hospitals · Low- and middle-income countries · Transforming psychiatric hospitals · Reform of mental hospitals

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12.2 Publication of the trial protocol

Open access Protocol

BMJ Open Psychiatric hospital reform in low-income and middle-income countries Structured Individualised Intervention And Recovery (SITAR): a two-arm pragmatic randomised controlled trial study protocol

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ABSTRACT

Introduction Low-income and middle-income settings like India have large treatment gaps in mental healthcare. 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 psychiatric 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 psychiatric hospital in India.

Methods and analysis Structured Individualised Intervention And Recovery (SITAR) is a two-arm pragmatic randomised controlled trial, focusing on patients aged 18–60 years with a hospital stay of 12–120 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 WHO Disability Assessment Scale), symptom severity, social and occupational functioning and quality of life. A computer-generated permuted block randomisation 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 December 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

Strengths and limitations of this study

- This is the first ever methodologically robust study in low-income 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 healthcare policy across the country.
- There is a strong component of government involvement that adds to the potential of sustainability and scaling up across other psychiatric 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.

(CTR/2019/01/017267). Trial results will be published in accordance to CONSORT guidelines.

INTRODUCTION

People living with severe mental disorders (SMD) (psychosis, bipolar and affective disorders and severe-to-moderate depression) in low-income and middle-income countries (LMICs) face impediments to their clinical and functional recovery, and have large unmet needs associated with poverty, protection of human rights, social inclusion and participatory citizenship.^{1–6} A range of cost-effective and evidence-based interventions

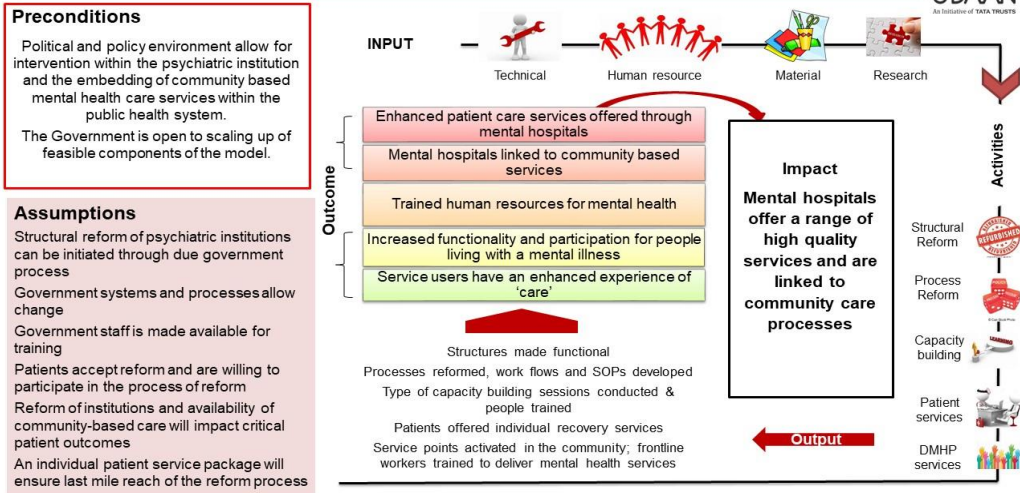
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12.3 Theory of change for Udaan and SITAR

A Theory of Change



12.4 Case vignette

The stories of long-stay patients with SMD living in mental hospitals, are replete with instances of abandonment, violation of human rights and dignity. The case of Sameera, ID 52410, is one such example, and is presented for the purpose of this vignette. The name and identification details of the institutions except for RMHN have been anonymised.

12.4.1 Early life

Sameera recalls being told she was left at the gates of the Nagpur orphanage she grew up in when she was barely six months old. Sameera attended a local government-run school. During her early years, Sameera's closest ally and friend was Namrata, an older girl living at the same orphanage. Namrata cared for Sameera and looked after her needs. When Namrata reached puberty, she was married against her will by the orphanage management. Sameera recalls being extremely unhappy during that time. The orphanage manager raped Sameera for months. Her teacher noticed a change in Sameera's behaviour and during a discussion, she told her everything. Sameera's case was reported to Childline and she was moved to another government institution in Nagpur. This institution, however, was only for adult women and Sameera was a minor. Within 15 days of her arrival, she was moved to a 'home' for intellectually disabled women in Amravati, 157 kilometres away from Nagpur.

12.4.2 Sameera's journey to Regional Mental Hospital, Nagpur

Sameera recalls feeling lonely, despondent and losing her appetite at the 'home'. She spent most of her time sleeping. When the 'home' staff intervened, Sameera reacted violently. Due to this repeated behaviour, the institution in Amravati procured a judicial order to transfer Sameera to the RMHN. Sameera was first admitted in 2000 with a diagnosis of "schizophrenia with mania". Since she was first admitted, Sameera has been discharged and re-admitted multiple times to the hospital through judicial orders. Her last admission was on October 23, 2016 and Sameera has been at RMHN since then.

12.4.3 Case management

Sameera was randomised to the intervention arm of the SITAR trial. Her case manager's preliminary assessment and reports suggest Sameera was one of the most functional patients in her ward. The case manager reported Sameera not having any friends and keeping to herself. Over the six months of case management, Sameera slowly began participating in skill building and reform activities. She picked out clothes for herself from the clothes storage created by the Udaan programme. She then set about refitting the clothes to her size, showing her seamstress skills. Sameera was one of the patients who worked at the Tata Trusts' office on the hospital campus. She steadily progressed to sitting at the staff lunch table with everyone else and began holding longer conversations. Sameera's progress however, was not a linear process and had several ups and downs revealing various triggers that would set her back. Sameera's case manager continued to work through her needs collaboratively. Sameera was not only a member of the planning team, but was also a participant in the fashion show that was put up by the women case managers and their patients. Sameera went shopping for clothes and jewellery with the team. She has begun participating in discussions of a life outside the hospital – something she refused to engage in earlier. Udaan helped her procure citizenship and identity documents through the reform process. Sameera's name is also on the list of patients to be rehabilitated in partnership with a local NGO and The Banyan's Home Again programme of community rehabilitation. Once government permissions are granted, the next steps in the process of community integration will be initiated.

Sameera's story reflects the story of many long-stay female patients in mental hospitals. Consulting them, creating the space for their opinion and facilitating their participation in planning their care is an extremely important element of the reform programme and the NB-ICM service package.

12.5 SPIRIT protocol for SITAR

Section/item	Item No	Description
Administrative information		
Title	1	Psychiatric Hospital Reform in Low and Middle-Income Countries Structured Individualised 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>31st Dec 2018</i>
Funding	4	Tata Trusts
Roles and responsibilities	5a	Tasneem Raja
	5b	Tata Trusts World Trade Centre -1, 26 th Floor, Cuffe Parade, Mumbai – 400 005 Tel: +91 - 22 - 6665 8282
	5c	<i>Funder- (pg 15)</i> <ul style="list-style-type: none"> • <i>MoU with the Government of Maharashtra for the Psychiatric hospital reform (Tata Trusts)</i> • <i>Part funding of the program with other donors (R.G Marudhane Motivation for Excellence Foundation and part funding by the Government of Maharashtra)</i> • <i>The Donors do not have a direct say in the design, data analysis and interpretation / publication of the study findings</i>

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

6a 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 programme 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 centre 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 modernising it. This does not include individual recovery plans for patients.

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

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 (three and six 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 minimise the risk of bias.

1. Standardising 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. Randomisation 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.

Eligibility criteria 10

Key Inclusion	Exclusion Criteria
A primary diagnosis of psychosis** Continuous length of stay in the hospital ≥ 12 to 120 months Over the age of 18 years	Service users over the age of 60 years* Service users with neuro-developmental disorders such as epilepsy** 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.

- 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 into 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 psychosocial 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.

- 12 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 -
The primary measure is disability levels.
Disability Measure - WHO Disability Assessment Scale 2.0 (WHODAS 2.0) (primary outcome) is a generic assessment instrument for health and disability and produces standardised 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.
Symptom measure - The Clinical Global Improvement Scale (CGI) 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 *et al.*, 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 & Steven D. Targum, July 2007 JOAN BUSNER & STEVEN D. TARGUM, July 2007).
Social and Occupational Functioning Scale (SOFS)
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 *et al.*, 2000). In the study, it will be used to rate functionality over a three-month period.
Health related quality of life measure EuroQol-5D (EQ-5D)
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.
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 in-patient 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
- Intervention plan
- Symptoms checklist
- Self-care and other living skills checklist

Participant
 timeline (PG 14-
 15)

1 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 eight 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 ±50 n) 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 randomised 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 σ of 20.</p> <p>The effect size and variance were 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 randomisation 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>

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 randomisation 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
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 MS Word files. The MS Excel, MS 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 anonymised

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 summarise 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 McNemar'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 (eg. 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

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 required? 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>The following has been done</p> <ul style="list-style-type: none"> • 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). • Permission sought from Hospital administration to initiate the individual intervention package, baseline and outcome measures as defined in the protocol (completed). • Ethics clearance sought from a registered ethics committee in India. • Ethics clearance sought from the University of Warwick ethics committee. • Trial registry on the Central Trials Registry of India.
Protocol amendments	25	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.
Consent assent (Pg 8)	or 26a	<p>The PI will obtain all informed consent using the pictorial information sheet and set of cards attached with the protocol.</p> <p>Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32).</p>
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable.
Confidentiality (Pg 12- 14)	27	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 MS 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.

Declaration of interests (Pg 15)	28	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.
Access to data (Pg 14)	29	The PI, statistician and university supervisor will have access to the data.
Ancillary and post-trial care	30	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.
Dissemination of policy (Pg 14)	31a	The following modalities will be used for dissemination of results - <ul style="list-style-type: none"> • Part of the yearly process dissemination of the larger Udaan program. • Scientific publications as part of the PhD. • PhD thesis made available in the public domain. • Policy brief for the Government based on the findings of the study. • Tool kit of the final tools and manuals used for the study made available in the public domain.
	31b	Primary authorship will be with the PI. Supervisors will be invited to be co-authors on all publications. No professional writers will be used.
	31c	NA
Appendices		
Informed consent materials	32	Informed Consent and Participant Information Sheet in pictorial format enclosed with the protocol. Model consent form and other related documentation given to participants and authorised surrogates.
Biological specimens	33	NA

12.6 Approvals

12.6.1 Hospital permission letter



Outward No: 250
Date : 02.07.2018

To,
The Medical Superintendent,
Regional Mental Hospital,
Nagpur

SUB: Requesting approval for service user measurement and initiating individual service packages

Dear Sir,

I am glad to inform you that Udaan has stepped into the third year of its implementation. In retrospect, Udaan has been working towards bringing about positive changes by rendering services to the hospital users as a whole.

Over the last two years, Udaan has worked with the staff of RMHN and prepared the groundwork for initiating the individual service package. The aim of this component of work is to provide a set of psychosocial rehabilitation services to patients of the hospital. In the first phase of this work, we will provide services to people who have been in the hospital for a long duration.

As with everything else on the Udaan program, the individual service packages will be initiated with baseline measurement (disability level, symptom severity, social and occupational functioning and quality of life). We have designed the intervention package to be for a duration of six months for each client. This package will be offered through the case managers of Udaan to begin with. We will also train the staff of RMHN using our master trainers. We will run the same

Tata Trusts, Behind OPD Building, Regional Mental Hospital, Chhindwara Road, Nelson Square, Nagpur - 440030

Website - www.tatatrusts.org | Email: rmhnagpur@tatatrusts.org | Phone no. 0712 - 2588240





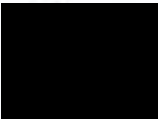
measurements to assess how effective the intervention has been at the end of six months.

The intervention will be provided in batches. This will also help us assess if the intervention has any real effect. If it is effective, this can be replicated in other hospitals of Maharashtra.

I request you to kindly grant permission for the same.

Thanking you

Yours Sincerely,



Tasneem Raja

Lead – Mental Health

Tata Trusts

Encl: The Udaan Design

Permitted
A handwritten signature in blue ink that reads "Permitted" is written over a solid black rectangular redaction box.

Tata Trusts, Behind OPD Building, Regional Mental Hospital, Chhindwara Road, Nelson Square, Nagpur – 440030

Website – www.tatatrusts.org | Email: mhnagpur@tatatrusts.org | Phone no. 0712 - 2588240

12.6.2 India ethics approval

VAF/2018-19/012

VAF
VikasAnvesh Foundation
An Institute of TATA TRUSTS

INSTITUTIONAL ETHICS COMMITTEE (IEC)
VikasAnvesh Foundation (VAF)

Dr. Jaya Sagade	Mr. Atul Deulgaonkar	Dr. Jacquleen Joseph (Chair person)
Dr. Vineeta Deshmukh	Dr. Saumitra Pathare	Mr. Mahesh Kamble
Dr. Laxmikant Yenge	Dr. Abhijeet Jadhav (Member Secretary)	

Date- 06/12/2018

To,
Ms. Tasneem Raja
Principle Investigator, Tata Trusts

DECISION LETTER

Subject: Decision regarding your submission to VAF IEC- "VAF/18-19/IW/003"

- Submission for IEC meeting on- 05th Oct 2018
- Suggestions by IEC for revision were given on- 17th Oct 2018
- The revised proposal was submitted on- 26th Nov 2018
- Decision letter by the IEC is given on- 06th Dec 2018

Dear Madam,

With regard to your submission and re-submission thereafter to the IEC for your study titled '*Psychiatric Hospital Reform in Low and Middle-Income Countries*', the VAF-IEC members deliberated on the revisions submitted by your team and the compliance letter from you, in response to the ethics related concerns raised by the Committee. The Committee appreciated the efforts taken by the team towards this submission.

The IEC committee has decided to give an approval to the study.

The Committee expects a commitment that-

- A. The study will be undertaken only in the mentioned geographical areas and for the mentioned time period
- B. The research design approved by the Committee will be followed throughout the study and for any need of change in study plan due to unforeseen, unavoidable ground situations, a special permission will be taken from the committee
- C. The PI or Co-PI will report immediately any ethical compromise or unexpected effect on human rights due to the conduct of the study
- D. A mid-term progress report will be submitted to the Committee (with a focus on the ethical conduct of the study)

Address: 601, 6th floor, Galore Tech IT Park, Survey No. 22, LMD chowk. Bavdhan Khurd,
Pune, Maharashtra, 411 021.
CIN No. U74999PN2017NPL167979, PAN: AAFCV8651G, NGO Unique ID: MH/2018/0200256



INSTITUTIONAL ETHICS COMMITTEE (IEC)
VikasAnvesh Foundation (VAF)

- E. Study outputs will preferably be shared with the Committee at the earliest. Any other use of data other than research purpose is not expected and should be informed to the committee a priori if at all needed
- F. The study team should note that the IEC as an independent oversight body which can conduct a research monitoring visit at its discretion during the conduct of the research

Best wishes.



Dr. Abhijeet Jadhav

Member Secretary, VAF-IEC

12.6.3 Ethics approval UK (University Of Warwick)



PRIVATE
Professor Swaran Singh
WMS
University of Warwick
Coventry
CV4 7AL

21 March 2019

Dear Professor Singh,

Study Title and BSREC Reference: *Psychiatric Hospital Reform In Low and Middle-Income Countries*
REGO-2019-2332

Thank you for submitting the revisions to the above-named study to the University of Warwick's Biomedical and Scientific Research Ethics Committee for approval.

I am pleased to confirm that ethical approval is granted.

In undertaking your study, you are required to comply with the University of Warwick's Research Data Management Policy, details of which may be found on the Research and Impact Services' webpages, under "Codes of Practice & Policies" > "Research Code of Practice" > "Data & Records" > "Research Data Management Policy", at:
http://www2.warwick.ac.uk/services/ris/research_integrity/code_of_practice_and_policies/research_code_of_practice/datacollection_retention/research_data_mgt_policy

You are also required to comply with the University of Warwick's Information Classification and Handling Procedure, details of which may be found on the University's Governance webpages, under "Governance" > "Information Security" > "Information Classification and Handling Procedure", at:
<http://www2.warwick.ac.uk/services/gov/informationsecurity/handling>.
Investigators should familiarise themselves with the classifications of information defined therein, and the requirements for the storage and transportation of information within the different classifications:

Information Classifications:
<http://www2.warwick.ac.uk/services/gov/informationsecurity/handling/classifications>
Handling Electronic Information:
<http://www2.warwick.ac.uk/services/gov/informationsecurity/handling/electronic/>
Handling Paper or other media
<http://www2.warwick.ac.uk/services/gov/informationsecurity/handling/paper/>.

www.warwick.ac.uk

Please also be aware that BSREC grants ethical approval for studies. The seeking and obtaining of all other necessary approvals is the responsibility of the investigator.

These other approvals may include, but are not limited to:

1. Any necessary agreements, approvals, or permissions required in order to comply with the University of Warwick's Financial Regulations and Procedures.
2. Any necessary approval or permission required in order to comply with the University of Warwick's Quality Management System and Standard Operating Procedures for the governance, acquisition, storage, use, and disposal of human samples for research.
3. All relevant University, Faculty, and Divisional/Departmental approvals, if an employee or student of the University of Warwick.
4. Approval from the applicant's academic supervisor and course/module leader (as appropriate), if a student of the University of Warwick.
5. NHS Trust R&D Management Approval, for research studies undertaken in NHS Trusts.
6. NHS Trust Clinical Audit Approval, for clinical audit studies undertaken in NHS Trusts.
7. Approval from Departmental or Divisional Heads, as required under local procedures, within Health and Social Care organisations hosting the study.
8. Local ethical approval for studies undertaken overseas, or in other HE institutions in the UK.
9. Approval from Heads (or delegates thereof) of UK Medical Schools, for studies involving medical students as participants.
10. Permission from Warwick Medical School to access medical students or medical student data for research or evaluation purposes.
11. NHS Trust Caldicott Guardian Approval, for studies where identifiable data is being transferred outside of the direct clinical care team. Individual NHS Trust procedures vary in their implementation of Caldicott guidance, and local guidance must be sought.
12. Any other approval required by the institution hosting the study, or by the applicant's employer.

There is no requirement to supply documentary evidence of any of the above to BSREC, but applicants should hold such evidence in their Study Master File for University of Warwick auditing and monitoring purposes. You may be required to supply evidence of any necessary approvals to other University functions, e.g. The Finance Office, Research & Impact Services (RIS), or your Department/School.

Please note that before research commences, the data requirements should be resolved directly with the Information and Data Compliance Team and all relevant contracts in place.

May I take this opportunity to wish you success with your study, and to remind you that any Substantial Amendments to your study require approval from BSREC before they may be implemented.

Yours sincerely



Dr David Ellard
Chair
Biomedical and Scientific
Research Ethics Committee

Biomedical and Scientific
Research Ethics Sub-Committee
Research & Services
University of Warwick
Coventry, CV4 8UW.
E: BSREC@Warwick.ac.uk

http://www2.warwick.ac.uk/services/rs/research_integrity/researchethicscommittees/biomed

12.7 Informed consent tools and forms

12.7.1 Participant Statement (Informed consent form)

Participant identification number for this project: _____

Statement of the treating psychiatrist

I have assessed the participant and acknowledge the following-

The participant is in a position to give informed consent

Yes No

The participant has the ability to participate in the study

Yes No

If no, please specify the reason based on your assessment

Date:

Signature of the treating psychiatrist

The information sheet has been provided to me. The contents of the information sheet have been read carefully/explained in detail to me, in a language that I comprehend. I have fully understood the contents. I confirm that I have had the opportunity to ask questions. All the questions have been answered to my satisfaction.

The nature and purpose of the project and its potential risks / benefits and expected duration of the interview, schedules of follow up interview, focus group discussions and other relevant details of the project have been explained to me to my satisfaction.

I understand that my participation is voluntary and that I am free to withdraw at any time without my medical care or legal right being affected. I will not be obliged to give any reasons for the same I understand that the information collected about me from my participation in this project and sections of any of my medical notes may be looked at by responsible individuals from the Udaan program

I give permission for these individuals to have access to my records.

I understand that my records will be kept private.

[] I do not agree to be part of the study

[] I agree to be part of the study

Date:

(Signature)

Place

In case the participant is illiterate, the information has been explained to him/her verbally in the language he/she comprehends.

Date:

(Left hand's thumb impression)

Place:

Interviewer's statement:

I, the undersigned, have explained to the volunteer, in a language he/she understands, the procedures to be followed in the project and the risks and benefits involved.

Date:

Signature of Interviewer

Place:

Date:

Signature of Ward- in-charge

Place:

12.7.2 SITAR- participant information sheet

About the Udaan program

Udaan is an initiative of Tata Trusts working on mental health care. Programs under Udaan are developed and implemented in partnership with the Government of Maharashtra. Reforming the Regional Mental Hospital, Nagpur is one of the programs under Udaan.

What is SITAR?

SITAR stands for Structured Individualised Intervention and Recovery and refers to the individual patient services component under the Udaan program. It is a study to understand if the services being offered under this component make any real difference to the lives of patients.

What is your role in SITAR?

If you agree to be a participant in the study, you will be put in one of the two groups on random basis. You will receive services based on your allocation. The effect of this study on you will be assessed.

What are the components of this intervention?

The intervention will be designed in consultation with you and the staff of the hospital directly responsible for your treatment. The intervention will be designed to address your unmet needs in these areas –

1. Accommodation and Safety – To provide you with a safe and secure place to live
2. Psychoeducation – To provide enough and sufficient information of your illness
3. Symptom management – To provide care and support to be able to manage the symptoms of your illness
4. Physical Health – To ensure your basic health needs are taken care of through regular health check-ups, medical care and exercise
5. Emotional Well-being – To ensure your emotional needs are taken care of and to help you manage negative emotions effectively
6. Self-care and other living skills – To ensure you can take care of yourself and perform the activities of daily living
7. Social Relationships – To ensure that you can create and maintain social relationships

8. Connecting to family – To ensure that you can effectively communicate and connect with your family members
9. Leisure activities – To ensure that you can enjoy leisure activities of your choice effectively
10. Occupational and financial inclusion – To help in providing employment options that will have associated financial remuneration
11. Spiritual Needs – To ensure you are able to practice/fulfil religious or spiritual activities of your choice

What will I have to do if I participate in SITAR?

You will have to answer questions posed to you from time to time. These questions are designed to assess the symptoms of your illness and its impact on your day to day functioning. Such assessments will be done four times in one year. Each assessment session will approximately take three to four hours. This can be done over multiple sessions as well. You can opt to stop the assessment whenever you feel you want to stop.

Apart from this, depending on which group you are in, you will be allocated a case manager who will work with you and the staff in your ward to help meet whatever needs you may have at that point in time.

This case manager will spend a lot of time with you and you can ask the case manager to leave whenever you so desire.

What happens if I get allocated to the control arm of the study?

You will continue to receive all the care you are receiving right now.

Participating in group discussion

You may also be asked to participate in group discussions to talk about your experience of being a service user.

Are there any risks to me?

This is an intervention of psycho social rehabilitation. It could be wearisome at times and the intervention services can be altered as per your choice.

Can I stop being a part of the study?

You can stop being a part of the study at any point in time.

What happens to the data?

All the data that is collected will be securely stored. The data will be entered on the computer and kept safely on password-protected files. No form will have your name written anywhere on it.

Will my information be kept confidential?

Yes, all your information will be confidential. When it is used for analysis, no information that identifies you as an individual will be shared or disclosed. The only people who have access to your information will be the people responsible for your treatment.

What if I do not want to join SITAR?

You can choose not to take part in SITAR. You will still be offered all the services of the hospital.

12.7.3 Participant pictorial information flipchart and handout

Participant information sheet



About the Udaan program

Udaan is an initiative of Tata Trusts working on mental health care.

Programs under Udaan are developed

and implemented in partnership with the Government of Maharashtra.

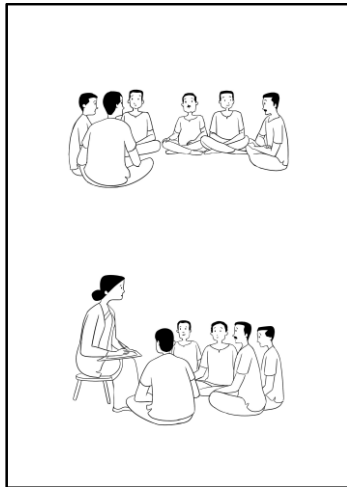
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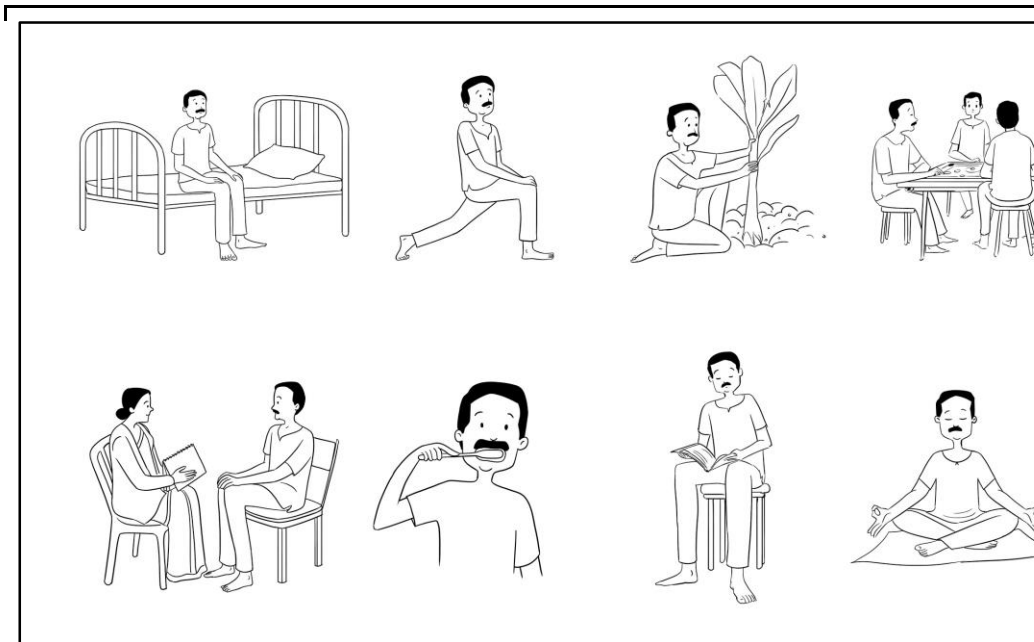
The effect of this study on you will be assessed.

What are the components of this intervention?

The intervention will be designed in consultation with you and the staff of the hospital that is directly responsible for your treatment. The intervention will be designed to address your unmet needs in these areas:

- Accommodation and Safety: To provide you with a safe and secure place to live
- Psycho-education: To provide enough and sufficient information of your illness
- Symptom management: To provide care and support to be able to manage the symptoms of your illness
- Physical Health: To ensure your basic health needs are taken care of through regular health check-ups, medical care and exercise
- Emotional Well-being: To ensure your emotional needs are taken care of and to help you manage negative emotions effectively
- Self-care and other living skills: To ensure you can take care of yourself and perform the activities of daily living

-
- Social Relationships: To ensure that you can create and maintain social relationships
 - Connecting to family: To ensure that you can effectively communicate and connect with your family members
 - Leisure activities: To ensure that you can enjoy leisure activities of your choice effectively
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 - Spiritual Needs: To ensure you are able to practice/fulfil religious or spiritual activities of your choice



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assessments will be done four times in one year. Each assessment session will approximately take three to four hours. This can be done over multiple sessions as well. You can opt to stop the assessment whenever you feel you want to stop.

Apart from this, depending on which group you are in, you will be allocated a case manager who will work with you and the staff in your ward to help meet whatever needs you may have at that point in time.

This case manager will spend a lot of time with you and you can ask the case manager to leave whenever you so desire.



Are there any risks to me?

This is an intervention of psycho-social rehabilitation. It could be wearisome at times and the intervention services can be altered as per your choice.

Can I stop being a part of the study?

You can stop being a part of the study at any point in time.

What if I do not want to join SITAR?



You can choose not to take part in SITAR.
You will still be offered all the services of
the hospital.

**What happens if I get allocated to the
control arm of the study?**

You will continue to receive all the care
you are receiving right now.



Participating in group discussion

You may also be asked to participate in
group discussions to talk about your
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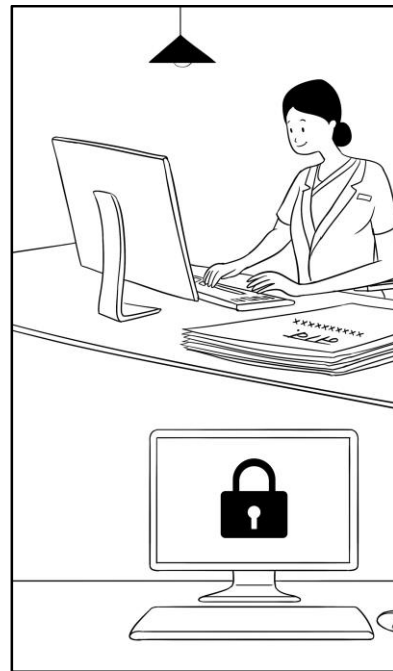
What happens to the data?

All the data that is collected will be securely stored. The data will be entered on the computer and kept safely on password-protected files. No form will have your name written anywhere on it.

Will my information be kept confidential?

Yes, all your information will be confidential. When it is used for analysis, no information

that identifies you as an individual will be shared or disclosed. The only people who have access to your information will be the people responsible for your treatment.



12.8 SITAR adverse events record form

Participant ID _____

Adverse Events

Events	Details
Acute illness (psychosis) episode As determined by transfer of service user to the acute care ward	Date of transfer to acute ward
Episode of isolation or restraint (Note the time duration for which the person was restrained)	
Transferred to IGMC / GMC for medical reasons (Record purpose and date of transfer	
Absconding from the facility Date on which the event occurred	
Any other event that may be considered adverse by the clinician / case-manger/ ward-in-charge	

Serious Adverse Events	Details
Self-harm (Self-harm is to be recorded separately if this is the cause of transfer to the acute ward) Date self harm was reported Details of method of self-harm	
Death Date of death.	

Date on which the event has occurred _____

Date on which it was reported _____

Reported by _____

Action taken _____

Date of action taken _____

Adverse Event deemed serious on _____

Causality

In the opinion of the reporting clinician was the event related to the trial intervention?

Unlikely- There is little evidence to suggest a causal relationship (e.g. because the event did not occur within a reasonable time after administration of the trial treatment). There is another reasonable explanation of the event (e.g. the participants' s clinical condition, other concomitant medications).

Possibly- There is some evidence to suggest a causal relationship (e.g. because the event occurs within a reasonable time after administration of the trial treatment). However, the influence of other factors may have contributed to the event (e.g. the participants' s clinical condition, other concomitant medications).

Probably-There is evidence to suggest a causal relationship and the influence of other factors is unlikely.

Definitely- There is clear evidence to suggest a causal relationship and other possible contributing factors can be ruled out.

Expectedness

Was this event- Expected Unexpected No

Severity of adverse event

Mild- Does not interfere with service users usual functioning

Moderate- Interferes to some extent with the day to day functioning of service user

Severe- Interferes significantly with day to day functioning of service user

Fatal- There is a risk of death to the service user

Outcome of event

Was the event Resolved? Yes

If resolved- what was the action taken?

If unresolved why?

Form filled by _____ Signature _____ Date _____

Reporting clinician _____ Signature _____

Date _____

Adverse events reported to the PI on _____

Serious adverse events reported to the PI on _____

Signature of the PI _____ Date _____

Follow-up details- Date of Follow Up _____

Adverse Events

Events	Follow-up (at 15 day intervals)
Acute illness (psychosis) episode As determined by transfer of service user to the acute care ward	Current status Is the service user still on the acute ward or has the service user been transferred back to chronic stable ward?
Episode of isolation or restraint	Nil The details of this event will be recorded at the time of the event itself.
Transferred to IGMC / GMC for medical reasons	Duration of medical admission Current status- Has the service user been brought back to the chronic stable ward
Absconding from the facility	Date of police FIR Current status
Any other event that may be considered adverse by the clinician / case-manger/ ward-in-charge	

Serious Adverse Events	Details
Self-harm (Self-harm is to be recorded separately if this is the cause of transfer to the acute ward)	Current Status- Is the service user still under clinical observation? If transferred back to chronic stable ward- what is the current risk according to clinician and ward-in-charge
Death	Record date of autopsy and date of police FIR along with concluding remarks of the autopsy report.

Follow up done by _____ Signature _____

12.9 Basic demographic and treatment data of the service user

Service user ID

Gender/ age/ region/ caste/ state

Date of admission / Length of stay

Primary diagnosis

Family known / not known

Education / literacy level

Vocational skills or training if any?

12.10 Outcome measurement instruments for SITAR

12.10.1 WHODAS



WHODAS 2.0

WORLD HEALTH ORGANIZATION
DISABILITY ASSESSMENT SCHEDULE 2.0

36-item version, proxy-administered

This questionnaire asks about difficulties due to health conditions experienced by the person about whom you are responding in your role as friend, relative or carer. Health conditions include diseases or illnesses, other health problems that may be short or long lasting, injuries, mental or emotional problems, and problems with alcohol or drugs.

Think back over the past 30 days and, to the best of your knowledge, answer these questions thinking about how much difficulty your friend, relative or carer had while doing the following activities. (Note: the questionnaire uses the term "relative" to mean "friend", "relative" or "carer".) For each question, please circle only one response.

H4 ^a	I am the _____ (choose one) of this person.	1 =	husband or wife	5 =	other relative
		2 =	parent	6 =	friend
		3 =	son or daughter	7 =	professional carer
		4 =	brother or sister	8 =	other (specify) _____

^a Questions H1–H3 appear at the end of the questionnaire.

Please continue to next page ...



WHODAS 2.0

WORLD HEALTH ORGANIZATION
DISABILITY ASSESSMENT SCHEDULE 2.0

36

Proxy

In the past 30 days, <u>how much difficulty</u> did your relative have in:						
Understanding and communicating						
D1.1	<u>Concentrating</u> on doing something for <u>ten minutes</u> ?	None	Mid	Moderate	Severe	Extreme or cannot do
D1.2	<u>Remembering</u> to do <u>important things</u> ?	None	Mid	Moderate	Severe	Extreme or cannot do
D1.3	<u>Analysing and finding solutions to problems</u> in day-to-day life?	None	Mid	Moderate	Severe	Extreme or cannot do
D1.4	<u>Learning a new task</u> , for example, learning how to get to a new place?	None	Mid	Moderate	Severe	Extreme or cannot do
D1.5	<u>Generally understanding</u> what people say?	None	Mid	Moderate	Severe	Extreme or cannot do
D1.6	<u>Starting and maintaining a conversation</u> ?	None	Mid	Moderate	Severe	Extreme or cannot do
Getting around						
D2.1	<u>Standing for long periods</u> such as <u>30 minutes</u> ?	None	Mid	Moderate	Severe	Extreme or cannot do
D2.2	<u>Standing up</u> from sitting down?	None	Mid	Moderate	Severe	Extreme or cannot do
D2.3	<u>Moving around inside their home</u> ?	None	Mid	Moderate	Severe	Extreme or cannot do
D2.4	<u>Getting out of their home</u> ?	None	Mid	Moderate	Severe	Extreme or cannot do
D2.5	<u>Walking a long distance</u> such as a <u>kilometre</u> [or equivalent]?	None	Mid	Moderate	Severe	Extreme or cannot do

Please continue to next page ...



WHODAS 2.0

WORLD HEALTH ORGANIZATION
DISABILITY ASSESSMENT SCHEDULE 2.0

36
Proxy

Because of their health condition, in the past 30 days, <u>how much difficulty</u> did your relative have in:						
Self-care						
D3.1	Washing his or her <u>whole body</u> ?	None	Mild	Moderate	Severe	Extreme or cannot do
D3.2	Getting <u>dressed</u> ?	None	Mild	Moderate	Severe	Extreme or cannot do
D3.3	Eating?	None	Mild	Moderate	Severe	Extreme or cannot do
D3.4	Staying <u>by himself or herself</u> for a few <u>days</u> ?	None	Mild	Moderate	Severe	Extreme or cannot do
Getting along with people						
D4.1	Dealing with people he or she <u>does not know</u> ?	None	Mild	Moderate	Severe	Extreme or cannot do
D4.2	Maintaining a <u>friendship</u> ?	None	Mild	Moderate	Severe	Extreme or cannot do
D4.3	Getting <u>along</u> with people who are <u>close</u> to him or her?	None	Mild	Moderate	Severe	Extreme or cannot do
D4.4	Making <u>new friends</u> ?	None	Mild	Moderate	Severe	Extreme or cannot do
D4.5	<u>Sexual</u> activities?	None	Mild	Moderate	Severe	Extreme or cannot do
Life activities						
D5.1	Taking care of his or her <u>household responsibilities</u> ?	None	Mild	Moderate	Severe	Extreme or cannot do
D5.2	Doing his or her most important household tasks <u>well</u> ?	None	Mild	Moderate	Severe	Extreme or cannot do
D5.3	Getting all the household work <u>done</u> that is needed?	None	Mild	Moderate	Severe	Extreme or cannot do
D5.4	Getting the household work done as <u>quickly</u> as needed?	None	Mild	Moderate	Severe	Extreme or cannot do

If your relative works (paid, non-paid, self-employed) or goes to school, complete questions D5.5–D5.8, below. Otherwise, skip to D6.1 near the top of the following page.



WHODAS 2.0

WORLD HEALTH ORGANIZATION
DISABILITY ASSESSMENT SCHEDULE 2.0

36

Proxy

In the past 30 days, how much difficulty did your relative have in:						
D5.5	His or her day-to-day <u>work/school</u> ?	None	Mild	Moderate	Severe	Extreme or cannot do
D5.6	Doing his or her most important work/ school tasks <u>well</u> ?	None	Mild	Moderate	Severe	Extreme or cannot do
D5.7	Getting all the work <u>done</u> that is needed?	None	Mild	Moderate	Severe	Extreme or cannot do
D5.8	Getting the work done as <u>quickly</u> as needed?	None	Mild	Moderate	Severe	Extreme or cannot do

Participation in society in the past 30 days						
D6.1	How much of a problem did <u>your relative</u> have in <u>joining in community activities</u> (for example, festivities, religious or other activities) in the same way as anyone else can?	None	Mild	Moderate	Severe	Extreme or cannot do
D6.2	How much of a problem did your relative have because of <u>barriers or hindrances</u> in the world around him or her?	None	Mild	Moderate	Severe	Extreme or cannot do
D6.3	How much of a problem did your relative have <u>living with dignity</u> because of the attitudes and actions of others?	None	Mild	Moderate	Severe	Extreme or cannot do
D6.4	How much <u>time</u> did <u>your relative</u> spend on his or her health condition, or its consequences?	None	Mild	Moderate	Severe	Extreme or cannot do
D6.5	How much has <u>your relative</u> been <u>emotionally affected</u> by his or her health condition?	None	Mild	Moderate	Severe	Extreme or cannot do
D6.6	How much has his or her health been a <u>drain on his or her financial resources</u> or on the financial resources of other relatives?	None	Mild	Moderate	Severe	Extreme or cannot do
D6.7	How much of a problem did <u>you</u> or the <u>rest of his or her family</u> have because of his or her health problems?	None	Mild	Moderate	Severe	Extreme or cannot do
D6.8	How much of a problem did your relative have in doing things <u>by himself or herself</u> for relaxation or pleasure?	None	Mild	Moderate	Severe	Extreme or cannot do

Please continue to next page ...



WHODAS 2.0

WORLD HEALTH ORGANIZATION
DISABILITY ASSESSMENT SCHEDULE 2.0

36

Proxy

H1	Overall, in the past 30 days, <u>how many days</u> were these difficulties present?	<i>Record number of days</i> ____
H2	In the past 30 days, for how many days was your relative <u>totally unable</u> to carry out his or her usual activities or work because of any health condition?	<i>Record number of days</i> ____
H3	In the past 30 days, not counting the days that your relative was totally unable, for how many days did your relative <u>put back</u> or <u>reduce</u> his or her usual activities or work because of any health condition?	<i>Record number of days</i> ____

This completes the questionnaire. Thank you for participating.

12.10.2 Clinical Global Improvement Scale

CGI

Clinical Global Impressions – Severity and Improvement Scales

Clinical Global Impressions-Severity Scale (CGI-S)

Severity of illness

Considering your total clinical experience with this particular population,
how mentally ill is the patient at this time? Severity Score:.....

- 0 Not assessed
- 1 Normal, not at all ill
- 2 Borderline mentally ill
- 3 Mildly ill
- 4 Moderately ill
- 5 Markedly ill
- 6 Severely ill
- 7 Among the most extremely ill of subjects

Note: Evaluation should be made as a comparison to baseline

Clinical Global Impressions-Improvement Scale (CGI-I)

Compared to the subject's condition at baseline,
how much has he/she changed? Improvement Score:.....

- 0 Not assessed
- 1 Very much improved
- 2 Much Improved
- 3 Minimally Improved
- 4 No change
- 5 Minimally worse
- 6 Much worse
- 7 Very much worse

12.10.3 Social and Occupational Functioning Assessment Scale (SOFAS)

(Please rate not applicable (N/A) if necessary, for questions 8 and 9)

General rating scale:

- 1= no impairment (behaviour is appropriate to social background),
- 2= mild impairment (minor deviations or problems occasionally, able to work or function independently),
- 3= moderate impairment (obvious deviations or problems occur),
- 4= severe impairment (marked deviation from normal behaviour, usually requires assistance to function),
- 5= extreme impairment (incapable of functioning, needs constant supervision).

1. Bathing and grooming

Quality and regularity of personal hygiene and bodily care.

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
No impairment	Mild	Moderate	Severe	Extreme

2. Clothing and dressing

Ability to dress appropriately and maintain own clothing

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
No impairment	Mild	Moderate	Severe	Extreme

3. Eating, feeding and diet

Eating habits, food intake and preparation of simple meal.

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
No impairment	Mild	Moderate	Severe	Extreme

4. Neatness and maintenance activities

Ability to maintain own living area and contribute to household maintenance tasks (make the bed, dispose garbage)

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
No impairment	Mild	Moderate	Severe	Extreme

5. Conversational skills

Ability to initiate, maintain and terminate conversation, speech output, non-verbal (eye contact) and paralinguistic skills (pitch and tone of voice).

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
No impairment	Mild	Moderate	Severe	Extreme

6. Social appropriateness/politeness

Ability to interact in a socially appropriate and polite manner.

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
No impairment	Mild	Moderate	Severe	Extreme

7. Social engagement

Ability to form and maintain close, stable relationships outside of the immediate family, to provide and receive social support.

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
No impairment	Mild	Moderate	Severe	Extreme

8. Money management

Ability to calculate correct change, understand the value of money, budget and spend money wisely.

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
No impairment	Mild	Moderate	Severe	Extreme

9. Orientation/mobility

Awareness and knowledge of frequently used routes, ability to move about alone, use own or public transport.

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
No impairment	Mild	Moderate	Severe	Extreme

10. Instrumental social skills

Understanding of social roles, contact appropriate persons (e.g. doctor) directly or through communication facilities (telephone and letter)

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
No impairment	Mild	Moderate	Severe	Extreme

11. Recreation/leisure

Interest and participation in passive (watching TV) and active (playing games) leisure activities.

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
No impairment	Mild	Moderate	Severe	Extreme

12. Work

Ability to spend time in a structured and meaningful way; includes gainful employment, household work or studying.

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
No impairment	Mild	Moderate	Severe	Extreme

13. Respect for property

Understanding of the difference between own and others' property.

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
No impairment	Mild	Moderate	Severe	Extreme

14. Independence/responsibility

Ability to take care of self and others (esp. children or elderly) if left alone, follow general safety measures

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
No impairment	Mild	Moderate	Severe	Extreme

12.10.4 EQ-5D

Figure 1: EQ-5D-5L (UK English sample version)

Under each heading, please tick the **ONE** box that best describes your health TODAY

MOBILITY

- I have no problems in walking about
- I have slight problems in walking about
- I have moderate problems in walking about
- I have severe problems in walking about
- I am unable to walk about

SELF-CARE

- I have no problems washing or dressing myself
- I have slight problems washing or dressing myself
- I have moderate problems washing or dressing myself
- I have severe problems washing or dressing myself
- I am unable to wash or dress myself

USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)

- I have no problems doing my usual activities
- I have slight problems doing my usual activities
- I have moderate problems doing my usual activities
- I have severe problems doing my usual activities
- I am unable to do my usual activities

PAIN / DISCOMFORT

- I have no pain or discomfort
- I have slight pain or discomfort
- I have moderate pain or discomfort
- I have severe pain or discomfort
- I have extreme pain or discomfort

ANXIETY / DEPRESSION

- I am not anxious or depressed
- I am slightly anxious or depressed
- I am moderately anxious or depressed
- I am severely anxious or depressed
- I am extremely anxious or depressed

12.11 Protocol for computing interrater reliability for the SITAR study

The interrater reliability was computed on six Research Assistants (RAs) for baseline and outcome measures. These raters were independent to the intervention program.

For SITAR, interrater reliability was defined as the level of agreement between RAs on the measures relevant to and in the context of the study (Stemler, 2004). Interrater reliability was computed on the primary outcome of disability measured by WHODAS 36 item proxy version.

The PI trained all the RAs on all measures to be used in the study. A pre-post knowledge measure was used to assess knowledge levels for all the RAs. A minimum score of 70% was required for a RA to be used in the study.

consensus ratings for all the RAs were computed based on the assumption that reasonable RAs would be able to come to exact agreements on the stated measure in the given time frame of measurement.

	Pt1	Pt2	Pt3	Pt4	Pt5	Pt6	Pt7	Pt8	Pt9	Pt10	
RA1	D1	D15	D12	D9	D6	D3	D1	D15	D12	D9	RAs are the 6 individual interviewers used for the study Pt- Patients- who do not fit the inclusion criteria of the study D- refers to the day on which the assessment is being done
RA2	D3	D1	D15	D12	D9	D6	D3	D1	D15	D12	
RA3	D6	D3	D1	D15	D12	D9	D6	D3	D1	D15	
RA4	D9	D6	D3	D1	D15	D12	D9	D6	D3	D1	
RA5	D12	D9	D6	D3	D1	D15	D12	D9	D6	D3	
RA6	D15	D12	D9	D6	D3	D!	D15	D12	D9	D6	

Estimated sample size for a pilot study to assess agreement between 6 RAs on a continuous outcome (WHODAS score) among in-patients at RMHN

Population reliability value	0.98
Sample reliability value	0.90
Power (1- beta) %	90
Alpha error (%)	5
1 or 2 sided	2
Number of replicates	6
Required sample size	9

12.11.1 Assumptions:

Reliability (Intra Class Correlation) coefficient in population for total WHODAS score =0.98 (Source: Figure 3.1 Test-retest summary in WHODAS manual, pg 27 (Üstün, 2010)).

Reliability (Intra Class Correlation) coefficient in sample =0.90 (With 10% relative precision)

Number of replicates =6 (as the same patient was assessed by six observers - A, B, C, D, E, F)

Required Sample size = 9

Hence **10 patients** were evaluated before and after test by **6 observers** which will generate

6*10 = 60 measurements at Domain level

10 measurements at patient (Overall) level

WHODAS assesses disability over a 30-day period, hence a 15-day measurement reference ensured assessment within the same time frame.

12.11.2 Reliability and consistency analysis

Reliability analysis was performed at item level, domain level and summary (Overall) level.

Reliability coefficients (i.e. Intra Class Correlation coefficients) for the continuous outcome (WHODAS score) were obtained from one-way ANOVA by test-retest (i.e. pre-test and post-test) method.

The pre-test and post –test changes in reliability coefficients at all levels (domain and overall) were compared by Friedman’s ANOVA for paired samples.

Based on the severity level of disability or degree of difficulty (None=0, Mild=1, Moderate=2, Severe=3, Extreme=4 or cannot do=5), WHODAS score were categorised on a 5-point response scale. Concordance among the RAs (Interrater agreement) was assessed by agreement statistics like Kappa.

Validity analysis was performed including face-validity and construct-validity.

Internal consistencies at the domain and summary levels were assessed by scale reliability coefficient i.e. Cronbach's Alpha. Item-test and Item-rest correlations and the effects of removing an item from the scale will also be analysed.

12.11.3 Reliability assessment

12.11.3.1 Intrarater reliability (All rates combined)

Computed by a measure alpha = Cronbach's alpha for inter-item correlations (covariances)

. alpha q1- q36

q20 q25 q26 q27 q28 constant in analysis sample, dropped from analysis

Test scale = mean(unstandardized items)

Reversed item: q10

Average interitem covariance: .6052404

Number of items in the scale: 31

Scale reliability coefficient: 0.9448

. alpha q1 -q36, item label

q20 q25 q26 q27 q28 constant in analysis sample, dropped from analysis

Combined intra-rater reliability was good (Cronbach's alpha =0.9448).

Combined Item-wise intra-rater reliability ranged between 0.9401(for q24) to 0.9523 (for q10) which indicated good consistency among scale items.

Intra-rater reliability (Individual observer)

Computed by a measure alpha = Cronbach's alpha for inter-item correlations (covariances)

bysort observer: alpha q1- q36

-> observer = 1PI

q8 q9 q14 q15 q20 q25 q26 q27 q28 q34 constant in analysis sample, dropped from analysis

Test scale = mean(unstandardized items)

Average interitem covariance: .8970945

Number of items in the scale: 26

Scale reliability coefficient: 0.9606

-> observer = 2

q15 q20 q25 q26 q27 q28 q34 constant in analysis sample, dropped from analysis

Test scale = mean(unstandardized items)

Average interitem covariance: .5229656

Number of items in the scale: 29

Scale reliability coefficient: 0.9581

-> observer = 3

q20 q25 q26 q27 q28 constant in analysis sample, dropped from analysis

Test scale = mean(unstandardized items)

Reversed item: q10

Average interitem covariance: .5468497

Number of items in the scale: 31

Scale reliability coefficient: 0.9614

-> observer = 4

q14 q15 q20 q25 q26 q27 q28 q34 constant in analysis sample, dropped from analysis

Test scale = mean(unstandardized items)

Average interitem covariance: .7013521

Number of items in the scale: 28

Scale reliability coefficient: 0.9155

-> observer = 5

q15 q20 q25 q26 q27 q28 q34 constant in analysis sample, dropped from analysis

Test scale = mean(unstandardized items)

Average interitem covariance: .623098

Number of items in the scale: 29

Scale reliability coefficient: 0.9798

-> observer = 6

q15 q20 q25 q26 q27 q28 q34 constant in analysis sample, dropped from analysis

Test scale = mean(unstandardized items)

Average interitem covariance: .7664751

Number of items in the scale: 29

Scale reliability coefficient: 0.9554

Individual intra-rater reliability was also found very good (Cronbach's alpha =0.9115 (for observer 2) to 0.9798 (for observer 5).

12.11.3.2 Interrater reliability

Inter-observer reliability was measured by Cohen's kappa (k) – a measure of agreement

Agreement among 6 observers was found good specifically for 2 responses (0 and 4).

Agreement between observers 1, 2 and 3 was more consistent for all the responses as compared to observers 4, 5 and 6. Thus we used raters **1, 2 and 3 for the trial.**

12.11.4 Validity assessment

Validity of results of observers with Gold Standard by item (using Kruskal Wallis one-way ANOVA test for equality of ranks)

Observer 1(PI) = Gold standard

- q1: all 5 observers results validated with observer 1.
- q2: all 5 observers results validated with observer 1.
- q3: all 5 observers results validated with observer 1.
- q4: all 5 observers results validated with observer 1.
- q5: all 5 observers results validated with observer 1.
- q6: all 5 observers results validated with observer 1.
- q7: Except observer 4, all observers results validated with observer 1.
- q8: Except observer 4, all observers results validated with observer 1.
- q9: Except observer 3, all observers results validated with observer 1.
- q10: all 5 observers results validated with observer 1.
- q11: all 5 observers results validated with observer 1.
- q12: all 5 observers results validated with observer 1.
- q13: Except observer 6, all observers results validated with observer 1.
- q14: all 5 observers results validated with observer 1.
- q15: all 5 observers results validated with observer 1.
- q16: all 5 observers results validated with observer 1.
- q17: Except observer 6, all observers results validated with observer 1.
- q18: all 5 observers results validated with observer 1.
- q19: all 5 observers results validated with observer 1.
- q20: all 5 observers results validated with observer 1.
- q21: all 5 observers results validated with observer 1.
- q22: all 5 observers results validated with observer 1.
- q23: all 5 observers results validated with observer 1.
- q24: all 5 observers results validated with observer 1.
- q25: no observations
- q26: no observations
- q27: no observations
- q28: no observations
- q29: all 5 observers results validated with observer 1.
- q30: Except observers 4, 5, 6, all observers results validated with observer 1.
- q31: Except observers 5, 6, all observers results validated with observer 1.

q32: Except observer 6, all observers results validated with observer 1.
q33: Except observers 4, 6, all observers results validated with observer 1.
q34: only observer 3's results available.
q35: Except observers 4, 6, all observers results validated with observer 1.
q36: Except observers 4, all observers results validated with observer 1.

Observers (RAs) 4, 5 and 6 results were not found consistent with observer 1 on many items, hence these RAs were not used for the Trial measurements.

12.11.5 Conclusion

Reliability and validity exercise of the pilot study indicated high intrarater reliability. Interrater reliability for RAs 4 5 and 6 did not validate with observer 1 on several items, these RAs were dropped. We used RAs 1, 2 and 3 for all outcome measurements on SITAR.

12.12 Focus Group Discussion- facilitators guide / discussion guide

1. Introduction- The PI will introduce the session saying that this is a discussion about the experience of the participants as patients receiving in-patient care from the hospital. Participants are free to express their views. The discussion of this session is confidential and no individual's identity will be revealed. The session will be recorded to facilitate documentation.
2. Round of introduction where each participant is invited to say who they are
3. What has been the experience of patients in terms of the care they have received from the hospital as in-patients
 - a. What services do they receive from the hospital- doctors, medication ect.
4. Have the participants interacted with the Udaan (Colloquially called Tata program) directly or in-directly.
 - a. Probe with names of case managers- do the patients know the members of the Udaan team
5. What are some of the activities that happen in their wards?
 - a. What do you do when you wake up, activities after that-
6. What in their view has changed over the last couple of years?
 - a. New services they have received
7. Has there been any change in these activities since they have been at the hospital
8. What in their view is the impact of these changes on their daily lives?
9. Could they give some examples of these changes?
10. In their view have these changes made a difference in the way they are treated by the hospital staff?
11. Are there any other changes they would like to see happen in their wards?
12. Thank participants and saying goodbye

12.13 Case management tools

12.13.1 Individual Needs Assessment Form

Date	
Patient ID	

To be done in collaboration with ward staff and service user- mark those needs that are unmet and that need to be worked on in the intervention plan

Domain	Need	Yes	Comments/ action points
Accommodation, safety & Food	1. Does the person have a comfortable and clean space in the ward		
	2. Does the person have access to enough nutritious food		
	3. Episodes of verbal or physical violence		
	4. Episodes of physical or chemical restraint		
	5. Discrimination from others		
	6. Thoughts of harming self		
A. Information	7. On illness / condition		
	8. Treatment		
B. Symptom Management	9. positive symptoms		
	10. Negative symptoms		
	11. Cognitive symptoms		
	12. Symptoms due to medications		
	13. Medication adherence		
	14. Health check up		

C. Physical Health	15. Regular dental care		
	16. Tobacco use		
	17. Mobility		
	18. Managing other diseases		
	19. Exercise and physical activity		
D. Emotional wellbeing	20. Hope for the future		
	21. Meaningful activities		
	22. Managing negative emotions (depression, anxiety, anger)		
	23. Low self-esteem or feeling of shame		
E. Self-care and other living skills	24. Hygiene		
	25. Grooming		
	26. Cleaning and caring for personal utilities such as plates, spoons etc.		
	27. Cleaning and caring for clothes		
F. Social Relationships	28. Relationship with the case manager		
	29. Relationship with the staff in the hospital		
	30. Relationship with other service users- peer group		
	31. Relationship with volunteers		
	32. Relationship with Udaan team members		
	33. Involvement in group activities		
	34. Family known		

G. Connecting to family	35. Engagement with the family		
H. Leisure activities	36. Hobbies		
	37. Sports and games		
	38. Movies		
	39. Outings		
I. Occupational and financial inclusion	40. Citizenship		
	41. Skill building		
	42. Employment related activities		
	43. Wages or earning		
	44. Bank account		
	45. Opportunity to use earning		
J. Spiritual needs	46. Involvement in religious activities		
	47. Pursuit of yoga / meditation systematically		
K. Any other needs			

Comments of the Case Manager

12.13.2 Symptoms checklist for case managers

Symptoms (Tick as appropriate)	Comments (Provide details for symptoms identified)	Strategy for symptom management (in discussion with hospital staff)
Behavioural Changes		
<input type="checkbox"/> Lack of personal care		
<input type="checkbox"/> Wandering		
<input type="checkbox"/> Anger and aggression		
<input type="checkbox"/> Excessive / very reduced activity		
<input type="checkbox"/> Others- Please specify		
Changes in biological functions		
<input type="checkbox"/> Sleep (reduced or excessive)		
<input type="checkbox"/> Appetite (reduced or excessive)		
<input type="checkbox"/> Menstrual cycle (regular or irregular)		
<input type="checkbox"/> Others (Please specify)		
Changes in mood		
<input type="checkbox"/> Sad and unhappy most of the time		
<input type="checkbox"/> Angry and irritable most of the time		
<input type="checkbox"/> Very happy and cheerful most of the time without obvious reason		
<input type="checkbox"/> Dull and not interested		
<input type="checkbox"/> Anxious and fearful most of the time		
<input type="checkbox"/> Others (Please specify)		
Abnormal thinking		
<input type="checkbox"/> Talking about plans of conspiracy to harm him or her		
<input type="checkbox"/> People talking about him/her behind his/her back		

<input type="checkbox"/> Convinced about his/her superior abilities		
<input type="checkbox"/> Feeling hopeless and worthless		
<input type="checkbox"/> Worried excessively about something going wrong		
<input type="checkbox"/> Others (Please specify)		
Having unusual experiences		
<input type="checkbox"/> Seeing things others cannot		
<input type="checkbox"/> Hearing things others cannot		
<input type="checkbox"/> Smelling/tasting things others cannot		
Suicidal thoughts or plan		
Service user's perception of problem		
<input type="checkbox"/> Does not have any problem		
<input type="checkbox"/> Thinks s/he has a problem but does not know what it is		
<input type="checkbox"/> Thinks that there is a supernatural cause of the illness		
<input type="checkbox"/> Thinks that there is something wrong with the brain or mind		
<input type="checkbox"/> Not sure		
Any other comments		

12.13.3 Self-care assessment checklist for case managers

Self-care and other living skills	Requires no assistance	Some assistance needed	Complete assistance needed
1. Bathing: Bathes self regularly and properly	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Dressing: dresses self, asks for change of clothes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Grooming: Maintains a good personal appearance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Toileting: Is able to use the toilet and clean self	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Continence: Exercises control over urination and defecation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Feeding: Is able to feed self in a hygienic manner	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Takes charge of his/her own clothes/ laundry	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Cleans own plate/ utensil after a meal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

12.13.4 Intervention care plan

Date	
------	--

Service user ID	
-----------------	--

Domains	Identified need	Action completed & current status	Action plan for the month
Accommodation, safety & food	<input type="checkbox"/>		
Information	<input type="checkbox"/>		
Symptom management	<input type="checkbox"/>		
Physical health	<input type="checkbox"/>		
Emotional well being	<input type="checkbox"/>		
Self-care & other living skills	<input type="checkbox"/>		
Social relationships	<input type="checkbox"/>		
Connecting to family	<input type="checkbox"/>		
Leisure activities	<input type="checkbox"/>		
Occupational & financial inclusion	<input type="checkbox"/>		
Spiritual needs	<input type="checkbox"/>		
Any other identified need	<input type="checkbox"/>		

Supervisor's comments _____

12.13.5 Case management record form

Service user ID	Date of session	Session No

Review of the previous session and tasks agreed upon

Tasks	Status

Summary of today's discussion

Key action points

Individual level	Systemic level

Barriers or problems

Barriers / problems	Action

Record of family if traced:

12.14 Training curriculum for case managers

12.14.1 Module one- introduction to mental health and mental

Illness

Session One				
Activity No.	Objectives	Methodology	Materials Required	Estimated Time
1	To break the ice at the beginning of the training workshop To introduce the participants and facilitators to one another	Game	----	30 minutes
2	To understand participants' expectations from the training workshop To introduce the objectives, methodology, schedule, and logistical details of the workshop to participants To help participants to begin working together as a team	Large group discussion Presentation by facilitator Game	Slide presentation titled <i>Welcome to the Workshop!</i> A large balloon	30 minutes
3	To assess participants' understanding of mental illness, case management, and the case manager's role, at the beginning of the training workshop	Writing exercise	Copies of pre-test questionnaire (one copy per participant)	45 minutes
Session Two				
Activity No.	Objectives	Methodology	Materials Required	Estimated Time
1	To explore participants' understanding of mental health and mental illness To provide basic information on the prevalence of mental illness and mental health care in India	Group work and presentation Presentation by facilitator	Sheets of chart paper Slide presentation titled Introduction to Mental Illness	45 minutes
2	To explore the reality of being homeless and mentally ill, and how this impacts the individual, family, and community To examine social attitudes towards people who are homeless and have a mental illness To create empathy towards people living with mental illness, especially those who are homeless	Film screening Group work and presentation Large group discussion	Five copies (on pen drives) of film: <i>Lapata Zindagi</i> Cards for group work	1 hour 30 minutes

	To understand the barriers and enabling factors in seeking treatment, especially for those who are homeless			
Session Three				
Activity No.	Objectives	Methodology	Materials Required	Estimated Time
1	To provide basic information to participants on the structure and functions of the human brain	Film screening Large group discussion	Film: Human Brain: Parts & Functions	30 minutes
2	To strengthen participants' understanding of the human brain and how it works, and how the brain's functioning is closely linked to mental health and mental illness To provide an opportunity for participants to share their understanding of the working of the human brain and its link to mental health and mental illness	Small group work and presentation	Copies of Chapter 1.1 of A Manual for Working with People with Schizophrenia and their Families (one copy per participant)	1 hour 15 minutes
Session Four				
Activity No.	Objectives	Methodology	Materials Required	Estimated Time
1	To provide an opportunity for participants to reflect on their strengths and weaknesses To help them get to know themselves and their interactions with others better	Writing exercise Large group discussion Presentation by facilitator	Sheets of writing paper and pens Safety pins (one per participant)	1 hour 15 minutes
2 (optional activity)	To give participants an opportunity to discover something new about themselves	Games	---	30 minutes

12.14.2 Module 2 - understanding schizophrenia

Session One				
Activity No.	Objectives	Methodology	Materials Required	Estimated Time
1	To recap the main ideas explored in the first module	Large group discussion	----	15 minutes
2	To provide basic information on psychosis and psychotic disorders	Large group discussion Presentation by facilitator	Slide presentation titled Introduction to Psychosis (including video clip)	45 minutes
3	To help participants identify the factors that put people at risk of developing severe mental disorders To provide an understanding of the factors that affect the outcome of severe mental illness	Game	A set of 10 'case cards' A list of statements to be read out Chalk or marker	30 minutes
4	To provide an overview of the course and outcome of severe mental disorders	Presentation by facilitator Large group discussion	Slide presentation titled Course and Outcome of Severe Mental Disorders	30 minutes
Session Two				
Activity No.	Objectives	Methodology	Materials Required	Estimated Time
1	To provide an opportunity for participants to find out and share information on schizophrenia	Small group work and presentation	Copies of chapters 1.2, 1.3, 1.4, and 1.5 of <i>A Manual for Working with People with Schizophrenia and their Families</i> (one copy per participant)	1 hour
2	To provide detailed information on schizophrenia – including information on types, course and outcomes, treatment, and symptoms	Presentation by facilitator Large group discussion	Slide presentation titled Introduction to Schizophrenia (including video clips) Copies of the Symptoms Checklist (one copy per participant)	1 hour 15 minutes
Session Three				
Activity No.	Objectives	Methodology	Materials Required	Estimated Time

1	To help participants understand how to assess the positive, negative, and cognitive symptoms of schizophrenia To provide an opportunity for participants to assess and identify the different symptoms of schizophrenia	Presentation by facilitator Case analysis	Slide presentation titled Assessing Symptoms of Schizophrenia (including video clips) Three copies of a set of three case studies	2 hours
SESSION FOUR				
Activity No.	Objectives	Methodology	Materials Required	Estimated Time
1	To help participants understand the disabilities that result from schizophrenia To help them understand and reflect on the impact of schizophrenia on the individual and her/his family	Large group discussion Presentations by facilitator	Slide presentation titled Disabilities caused by Schizophrenia Slide presentation titled Impact on an Individual Living with Severe Mental Disorders (including video clips) Copies of chapters 1.6 and 1.7 of A Manual for Working with People with Schizophrenia and their Families (one copy per participant)	1 hour
2	To sum up the module by providing an overview of the lives of people living with severe mental disorders and the impact on their families	Film screening	Copy of film: <i>Devrai</i>	2 hours
3	To elicit feedback from participants on the two modules conducted so far	Writing exercise	Copies of the feedback form for module 2 (one copy per participant)	15 minutes

12.14.3 Module three- skill building for case managers

SESSION ONE				
Activity No.	Objectives	Methodology	Materials Required	Estimated Time
1	To help participants recall the main ideas explored over the first two modules of the training workshop To give participants an idea of the themes that will be taken up for discussion in the next few sessions	Quiz	Quiz titled The story so far Stopwatch or timer	30 minutes
2 (optional activity)	To explore participants' understanding of the role of a case manager in the care and treatment of people with schizophrenia	Game Large group discussion	Sheets of drawing or chart paper (one sheet per participant) Pencils (one per participant) Sketch pens and crayons (two or three of each per participant) Music Chalk	45 minutes
3	To provide an opportunity for participants to discuss and arrive at an understanding of the attributes, skills, and values required to be an effective case manager	Small group work and presentation	Three large sheets of chart paper Index cards and drawing pins (around 40—50 of each)	30 minutes
Session Two				
Activity No.	Objectives	Methodology	Materials Required	Estimated Time
1	To help participants understand the all-pervasive nature of communication and the integral role that interpersonal communication plays in day-to-day life To refresh their understanding and practice of some of the basic interpersonal communication skills	Games Large group discussion Blackboard work and explanation by facilitator	Eight chits with instructions for game 1 Two chits with directions for game 4	1 hour 45 minutes
Session Three				
Activity No.	Objectives	Methodology	Materials Required	Estimated Time

1	To create an understanding of the term 'counselling' To help participants understand the key features of the counselling relationship	Large group discussion Presentation by facilitator	Large sheet of chart paper Slide presentation titled <i>Understanding Counselling</i>	20 minutes
2	To help participants understand the salient attributes of an effective counsellor with specific emphasis on empathy	Large group discussion Writing exercise	Large sheet of chart paper Slide presentation titled <i>Understanding Counselling</i>	40 minutes
3	To introduce participants to the basic attributes and skills involved in effective counselling	Small group work and presentation Presentation by facilitator	Copies of note titled <i>Understanding Counselling</i> (one copy per participant) Three pen drives, each with four video clips on counselling Slide presentation titled <i>Effective Counselling: Review of Role Plays</i>	1 hour
4	To provide participants an opportunity to practise the skill of reflecting	Role play Large group discussion	Six narrations for role play (a few copies of each)	1 hour
Session Four				
Activity No.	Objectives	Methodology	Materials Required	Estimated Time
1	To provide an opportunity for participants to practise the skills and values required of a good counsellor To help them observe, learn, and share views on effective approaches and attitudes to counselling	Role play Large group discussion	Set of seven Situation Cards Copies of Observation Sheet (one copy per participant)	1 hour 15 minutes
2	To help participants understand the need to strengthen negotiation skills To provide an opportunity for them to practise these skills	Small group work Large group discussion	A pack of playing cards (each card cut into four pieces) Four envelopes	30 minutes

3	To help participants understand the need to build relationships with people working in or connected to a psychiatric hospital	Game Large group discussion	Set of cards, each with the name of a specific worker/person in a psychiatric hospital (one card per participant) A large ball of wool or twine	30 minutes
4	To conclude the module with a motivational exercise	Game Large group discussion	A large mat	15 minutes

12.14.4 Module four effective case management and individual intervention plans

Session One				
Activity No.	Objectives	Methodology	Materials Required	Estimated Time
1	To recap the main ideas explored in the first three modules of the training programme	Large group work and discussion	Two large sheets of chart paper Coloured pens	15 minutes
2	To introduce participants to the case management approach to the treatment of individuals with severe mental disorders	Game and discussion Presentation by facilitator	Slide presentation titled <i>An Introduction to Case Management</i>	30 minutes
3	To discuss the importance of assessing individual needs before creating an intervention plan To help participants understand how to use the Individual Needs Assessment tool	Presentation by facilitator Large group discussion	Slide presentation titled <i>Needs Assessment in Severe Mental Disorders</i> (including video clips) Copies of the Individual Needs Assessment form (one copy per participant)	1 hour
4	To provide participants an opportunity to use the Individual Needs Assessment tool	Role play Large group discussion	Instruction Sheet for role play (a few copies) Set of four case studies (five or six	1 hour

			copies of each case) Copies of the Symptoms Checklist (one copy per participant)	
Session Two				
Activity No.	Objectives	Methodology	Materials Required	Estimated Time
1	To establish the fact that every individual is unique and interprets the world differently To help participants understand the need to develop a unique intervention plan for each individual as part of case management To familiarize participants with the different components of an intervention plan	Game and discussion Presentation by facilitator Brainstorming	Sheets of drawing paper (one sheet per participant) Slide presentation titled <i>Individual Treatment Plans</i> (including video clip) Copies of the Individual Intervention Plan (one copy per participant) One or two sheets of chart paper Copies of note titled <i>Individual Intervention Plan: A Brief Introduction</i> (one copy per participant)	1 hour
2	To familiarize participants with the first component of the individual intervention plan, namely, accommodation, food, and safety	Small group work and presentation	Set of four case studies along with completed Needs Assessment form (from previous session) Copies of note titled <i>Accommodation, Food, and Safety</i> (one copy per participant)	30 minutes
Session Three				
Activity No.	Objectives	Methodology	Materials Required	Estimated Time
1	To introduce participants to the second component of the individual intervention plan, namely, the need for psycho-education To provide information related to	Presentation by facilitator	Slide presentation titled <i>Individual Intervention Plan – Psycho-education</i> (including video clips) Key-ring of cards on Schizophrenia	1 hour

	psycho-education for schizophrenia		Copies of note titled <i>Psycho-education about the Illness</i> (one copy per participant)	
2	To provide an opportunity for participants to practise the skills related to providing psycho-education on schizophrenia	Role play	Key-ring of cards on Schizophrenia (three or four sets) Copies of the Observation Checklist (one copy per participant) Instruction Sheet for role play (a few copies)	1 hour
Session Four				
Activity No.	Objectives	Methodology	Materials Required	Estimated Time
1	To familiarize participants with the third component of the individual intervention plan, namely, symptom management To provide them an opportunity to discuss symptom management based on assessment of symptoms in individual cases	Large group discussion Small group work and presentation	Copies of note titled <i>Symptom Management</i> (one copy per participant) Set of three case studies Copies of the Symptoms Checklist (three copies)	1 hour
2	To familiarize participants with the fourth and fifth components of the individual intervention plan, namely, physical health and emotional well-being To provide an opportunity for participants to share their understanding of these two components	Presentation by facilitator Small group work and presentation Large group discussion	Slide presentation titled <i>Physical health in schizophrenia</i> Copies of note titled <i>Physical health and Emotional well-being</i> (one copy per participant)	1 hour 15 minutes

12.15 Frequency & % of type of intervention by domain of need and month of intervention

Need domain	Month	Ind		Systemic		Systemic & Ind		Not Applicable		Missing	
		F	%	F	%	F	%	F	%	F	%
Accommodation	Month 1	13	14.4	2	2.2	37	41.1	34	37.8	4	4.4
Information		42	46.7	1	1.1	28	31.1	15	16.7	4	4.4
Symptoms		15	16.7	8	8.9	42	46.7	21	23.3	4	4.4
Physical		20	22.2	3	3.3	51	56.7	12	13.3	4	4.4
Emotional		27	30	1	1.1	37	41.1	21	23.3	4	4.4
Self-care		13	14.4	0	0	59	65.6	14	15.6	4	4.4
Social		36	40	0	0	35	38.9	15	16.7	4	4.4
Family		21	23.3	5	5.6	32	35.6	28	31.1	4	4.4
Leisure		27	30	0	0	47	52.2	12	13.3	4	4.4
Occupational		11	12.2	11	12.2	30	33.3	34	37.8	4	4.4
Spiritual		9	10	2	2.2	33	36.7	42	46.7	4	4.4
Accommodation	Month 2	13	14.4	2	2.2	31	34.4	38	42.2	6	6.7
Information		51	56.7	2	2.2	20	22.2	11	12.2	6	6.7
Symptoms		18	20	10	11.1	35	38.9	21	23.3	6	6.7
Physical		19	21.1	4	4.4	51	56.7	10	11.1	6	6.7
Emotional		30	33.3	0	0	33	36.7	21	23.3	6	6.7
Self-care		23	25.6	0	0	43	47.7	18	20	6	6.7
Social		35	38.9	1	1.1	26	28.9	22	24.4	6	6.7
Family		26	28.9	3	3.3	23	25.6	32	35.5	6	6.7
Leisure		34	37.8	3	3.3	36	40	11	12.2	6	6.7
Occupational		11	12.2	7	7.8	32	35.5	34	37.8	6	6.7

Need domain	Month	Ind		Systemic		Systemic & Ind		Not Applicable		Missing	
		F	%	F	%	F	%	F	%	F	%
Spiritual		13	14.4	4	4.4	28	31.1	39	43.3	6	6.7
Accommodation	Month 3	10	11.1	3	3.3	25	27.8	45	50	7	7.8
Information		47	52.2	0	0	21	23.3	15	16.7	7	7.8
Symptoms		13	14.4	5	5.6	34	37.8	31	34.4	7	7.8
Physical		20	22.2	7	7.8	42	46.6	14	15.6	7	7.8
Emotional		35	38.9	2	2.2	28	31.1	18	20	7	7.8
Selfcare		19	21.1	2	2.2	46	51.1	16	17.8	7	7.8
Social		31	34.4	3	3.3	26	28.9	23	25.6	7	7.8
Family		24	26.7	3	3.3	21	23.3	35	38.9	7	7.8
Leisure		33	36.7	3	3.3	34	37.8	13	14.4	7	7.8
Occupational		13	14.4	5	5.6	28	31.1	37	41.1	7	7.8
Spiritual		15	16.7	2	2.2	28	31.1	38	42.2	7	7.8
Accommodation		Month 4	12	13.3	0	0	19	21.1	50	55.6	9
Information	45		50	0	0	14	15.6	22	24.4	9	10
Symptoms	20		22.2	6	6.7	23	25.6	32	35.5	9	10
Physical	23		25.6	10	11.1	34	37.7	14	15.6	9	10
Emotional	33		36.7	2	2.2	21	23.3	25	27.8	9	10
Selfcare	27		30	2	2.2	40	44.4	12	13.3	9	10
Social	40		44.4	0	0	16	17.8	25	27.8	9	10
Family	23		25.6	2	2.2	18	20	38	42.2	9	10
Leisure	46		51.1	1	1.1	21	23.3	13	14.4	9	10
Occupational	16		17.8	5	5.6	26	28.9	34	37.8	9	10
Spiritual	18		20	2	2.2	24	26.7	37	41.1	9	10

Need domain	Month	Ind		Systemic		Systemic & Ind		Not Applicable		Missing	
		F	%	F	%	F	%	F	%	F	%
Accommodation	Month 5	7	7.8	2	2.2	18	20	54	60	9	10
Information		41	45.6	0	0	19	21.1	21	23.3	9	10
Symptoms		21	23.3	5	5.6	26	28.9	29	32.2	9	10
Physical		17	18.9	3	3.3	44	48.9	17	18.9	9	10
Emotional		41	45.6	0	0	23	25.6	17	18.9	9	10
Selfcare		20	22.2	1	1.1	45	50	15	16.7	9	10
Social		33	36.7	0	0	23	25.6	25	27.8	9	10
Family		27	30	5	5.6	14	15.6	35	38.9	9	10
Leisure		46	51.1	1	1.1	21	23.3	13	14.4	9	10
Occupational		14	15.6	15	16.7	32	35.6	20	22.2	9	10
Spiritual		19	21.1	3	3.3	30	33.3	29	32.2	9	10
Accommodation	Month 6	5	5.6	0	0	10	11.1	66	73.3	9	10
Information		40	44.4	0	0	25	27.8	16	17.8	9	10
Symptoms		22	24.4	7	7.8	19	21.1	33	36.7	9	10
Physical		23	25.6	3	3.3	41	45.6	14	15.6	9	10
Emotional		42	46.7	1	1.1	19	21.1	19	21.1	9	10
Selfcare		16	17.8	1	1.1	44	48.9	20	22.2	9	10
Social		26	28.9	0	0	17	18.9	38	42.2	9	10
Family		33	36.7	4	4.4	17	18.9	27	30	9	10
Leisure		38	42.2	0	0	21	23.3	22	24.4	9	10
Occupational		13	14.4	17	18.9	31	34.4	20	22.2	9	10
Spiritual		11	12.2	4	4.4	27	30	39	43.3	9	10

12.16 Analysis of the patients not included on the SITAR trial






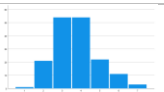
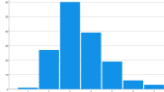

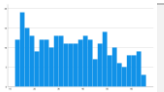


12.16.1 Baseline sample characteristics of patients not included in the SITAR study


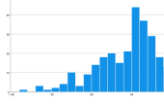
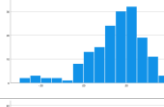



	Non- SITAR hospital population		
	Total patients assessed at baseline (n = 287)	Patients who did not complete 4 assessments (n = 134) Discharge cohort	Patients who completed 4 assessments (n = 153) Hospital cohort
Age mean (SD)	46.59 (15.73)	40.13 (12.74)	52.24 (15.97)
Age- median (IQR)	44 (35 - 57)	40 (31 – 48)	53 (41 – 64)
Gender			
Female	140 (48.8%)	52 (38.8%)	88 (57.5%)
Male	147 (51.2%)	81 (61.2%)	65 (42.5%)
Religion			
Hindu	175 (61%)	110 (82.1%)	65 (42.5%)
Muslim	13 (4.5%)	8 (6%)	5 (3.3%)
Buddhist	6 (2.1%)	3 (2.2)	3 (2%)
Unknown	93 (32.4%)	13 (9.7%)	80 (52.3%)
Marital Status			
Married	26 (9.1%)	25 (18.7%)	1 (0.7%)
Unmarried	97 (33.8%)	63 (47%)	34 (22.2%)
Separated	-	-	-
Not known	164 (57.1)	46 (34.3%)	118 (77.1%)
Education			
Illiterate	32 (11.1%)	12 (9%)	20 (13.1%)
Partial schooling	60 (21%)	36 (27%)	24 (15.6%)
Completed school	44 (15.3%)	23 (17%)	4 (2.6%)
Graduation	12 (4.2%)	10 (7.5%)	-
Post-graduation	5 (1.7%)	3 (2.2%)	2 (1.3%)
Not known	134 (46.7%)	33 (24.6%)	101 (66%)
Domicile			
From Maharashtra	204 (71.1%)	117 (87.3%)	87 (56.9%)
Outside Maharashtra	19 (6.6%)	5 (3.7%)	14 (9.2%)
Not known	64 (22.3%)	12(9%)	52 (34%)
Duration of stay in months Mean (SD)	157.78 (171.84)	41.43 (88.74)	248.43 (168.92)
Duration of stay in months median IQR	49 (18.56- 267.41)	18.83 (17.63 – 24.36)	252 (101.2 – 339.3)
Diagnosis			
Epilepsy	15 (5.2%)	3 (2.2%)	12 (7.8%)
Intellectual disability with comorbidity	60 (20.9%)	10 (7.5%)	50 (32.7%)
Psychosis with comorbidity	6 (2.1%)	4 (3%)	2 (1.3%)
Psychosis	206 (71.8%)	117 (87.3%)	89 (58.2%)

12.16.2 Status of patients in the Non-SITAR cohort discharged from hospital













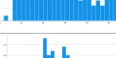




	F	%
Death	10	7.5%
Discharged through visitors committee	31	23.1
Discharged to family	93	69.4

12.16.3 Outcome measures for the Non-SITAR sample (n = 287)

Measure	Period	N	Mean (SD)	Median (IQR)	Distribution
Total WHODAS Score	Baseline	287	45.67 (25.30)	42.99 (23.52 – 66.15)	
	6 months	166	51.01 (19.92)	52.39 (38.99 – 64.34)	
	9 months	155	48.34 (20.60)	47.54 (34.47 – 65.52)	
	12 months	153	48.18 (20.79)	47.71 (33.27 – 61.80)	
CGI	Baseline	287	4.17 (0.80)	4 (4 – 5)	
	6 months	166	3.72 (1.17)	4 (3 – 4)	
	9 months	155	3.50 (1.16)	3 (3 – 4)	
	12 months	153	3.52 (1.22)	3 (3 – 4)	
SOFAS	Baseline	287	35.15 (14.89)	35 (22 – 47)	
	6 months	166	38.45 (10.91)	39 (31 – 46)	
	9 months	155	38.14 (12.76)	36 (29 – 47)	

Measure	Period	N	Mean (SD)	Median (IQR)	Distribution
	12 months	153	37.55 (12.99)	34 (28 – 46)	
EQ5D (Utility score)	Baseline	287	0.47 (0.38)	0.55 (0.22 – 0.74)	
	6 months	166	0.36 (0.32)	0.40 (0.18 – 0.57)	
	9 months	155	0.43 (0.32)	0.42 (0.26 – 0.63)	
	12 months	153	0.43 (0.33)	0.47 (0.23 – 0.67)	
QALY		153	0.09 (0.08)	0.10 (0.04 – 0.15)	

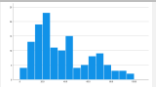



12.16.4 Subset of patients from the non-SITAR sample who completed all 4 assessments – Hospital cohort

	Period	Mean (SD)	Median (IQR)	Distribution
WHODAS total	baseline	52.84 (24.49)	54.51 (34.71 – 70.83)	
	6-months	50.79 (19.50)	52.33 (38.99 – 63.59)	
	9 months	48.24 (20.62)	47.54 (33.91 – 65.40)	
	12 months	48.18 (20.79)	47.71 (33.27 – 61.8)	
CGI	baseline	4.18 (0.78)	4 (4 – 5)	
	6-months	3.65 (1.15)	4 (3 -4)	
	9 months	3.5 (1.17)	3 (3-4)	
	12 months	3.52 (1.22)	3 (3-4)	
SOFAS	baseline	39.14 (14.65)	40 (29 – 50)	
	6-months	38.44 (10.70)	39 (31 – 45)	
	9 months	38.12 (12.82)	36 (29 - 47)	
	12 months	37.55 (12.99)	34 (28 – 46)	
EQ5D Utility scores	baseline	0.38 (0.4)	0.43 (0.11 – 0.68)	
	6-months	0.38 (0.31)	0.41 (0.19 – 0.58)	
	9 months	0.43 (0.32)	0.42 (0.27 – 0.64)	
	12 months	0.43 (0.33)	0.47 (0.23 – 0.67)	
QALY		0.09 (0.08)	0.10 (0.04 – 0.15)	

12.16.5 Changes in WHODAS, CGI, SOFAS & EQ5D scores from baseline to 6, 9 and 12 months in the hospital cohort

		Mean	SD	Min	Max	Percentile			P value
WHODAS	Baseline to 6 months difference	2.05	17.79	-51.87	50.82	-9.06	4.74	11.11	0.098
	Baseline to 9 months difference	4.60	17.25	-39.33	49.09	-8.73	4.72	15.85	0.002
	Baseline to 12 months difference	4.66	17.85	-45.73	41.90	-9.03	5.55	15.88	0.002
CGI	Baseline to 6 months difference	0.52	0.84	-3	-2	0	1	1	P < 0.001
	Baseline to 9 months difference	0.67	0.89	-2	3	0	1	1	P < 0.001
	Baseline to 12 months difference	0.65	0.94	-2	3	0	1	1	P < 0.001
SOFAS	Baseline to 6 months difference	0.70	10.97	-32	24	-8	2	8	0.202
	Baseline to 9 months difference	1.02	10.93	-30	25	-6	2	7	0.176
	Baseline to 12 months difference	1.58	10.82	-22	28	-7	1	10	0.113
EQ5D utility scores	Baseline to 6 months difference	0.01	0.32	-0.91	0.97	-0.21	0	0.19	0.966
	Baseline to 9 months difference	-0.49	0.31	-0.87	0.67	-0.27	-0.02	0.16	0.088
	Baseline to 12 months difference	-0.55	0.31	-0.98	0.67	-0.24	-0.03	0.13	0.052

12.16.6 Baseline outcome scores for the discharged cohort

	Period	Mean (SD)	Median (IQR)	Distribution
WHODAS total	baseline	37.48 (23.76)	28.95 (19.7 – 54.88)	
CGI	baseline	4.16 (0.83)	4 (4 – 5)	
SOFAS	baseline	30.58 (13.86)	26.50 (19 – 40)	
EQ5D Utility scores	baseline	0.57 (0.32)	0.64 (0.48 – 0.78)	

12.17 Economic evaluation of Udaan and sitar

12.17.1 Costing framework for Udaan and SITAR

	Resources or inputs	Source	Kind of input on larger structural and process reform	Comments	Additional costs for NB-ICM
Staff Time	PI s time	Tata Trusts	Design of the Udaan programme Setting up the implementation process Day to day running of the programme	<p>The programme design and planning began from Oct 2015. 80% costs taken from Oct 2015 to March 2016.</p> <p>The overall reform costs start from April 1, 2016. It took a good part of two years to build the reform base before we had the various components ready to start the individual intervention. 90% time in 2016 and entire 2017 40% time in 2018 and in 2019 the time was allocated to case management.</p>	<p>Design of intervention</p> <p>Training of case managers</p> <p>Monthly supervision of case managers</p> <p>Training of research assistants in assessments</p> <p>Adverse events reports and records</p> <p>Data collection and management</p>
	HQ team Archana Sudhakaran	Tata Trusts	Support the implementation of the Udaan reform programme	<p>All administrative aspects of the programme with respect to TT including recruitment, work plan supervision.</p> <p>Management of technical collaborations such as SCARF for clinical SOPs and dance and movement for patient engagement. 30% of time from Sept 2017 onwards</p>	<p>Baseline assessment</p> <p>Outcome measurement</p> <p>1st follow up measurement</p> <p>2nd follow up measurement</p>

Health Advisor Dr A. Bang	Tata Trusts	Support the implementation of the Udaan reform programme	10% of time Oct 2015 onwards	
Nitin Kanade Health IT HQ	Tata Trusts	Led the development of automation	10% time	
Dr Jena Management consultant	Tata Trusts	Supported the conceptualization of SOP framework Development of indicators	Exact number of days spent on site plotted according to per day costs.	
Ward reform staff	Udaan Budget	One person responsible for implementing reform per ward	Worksheet calculating staff time and salary.	No additional costs
Case manager time	Udaan budget	Case managers support to general reform includes: Ward management and maintenance as per protocol Running overall reform processes such as movie club, meal buffets etc.	Case managers have other additional tasks in the reform process. This will be captured in the different input areas further.	Case management for individual patients

	Accounts' managers	Udaan budget	<p>Expenditure management and financial reporting</p> <p>Building the internal banking system for patient stipend linked to employment</p> <p>Managing accounts linked to employment activities that have been set up</p> <p>Managing patient passbooks and stipends</p> <p>Procurement of material required for case management as well as for reform wards</p> <p>Maintenance of stock registers etc.</p>	<p>Setting up the banking system is a one-time activity. The rest are recurring.</p> <p>100% time from Aug 2018 onwards</p> <p>From Jan 2017 it is 50%. Case management related time plotted under case management.</p>	<p>Management of individual patient passbooks</p> <p>Procurement and management of consumables related to case management</p> <p>10% time</p>
	Program manager	Udaan budget	<p>Managing the government liaisons and permissions at all levels of government which includes hospital, Nagpur level as well as of State of Maharashtra</p> <p>Coordinating with collaborators for skill training of patients</p> <p>Setting up the business models for employment including vendor negotiations</p> <p>Managing external collaborations for receiving goods and services -- the in-kind</p>	<p>Most of these activities are recurring in nature. Time contribution at 100% from Dec 2016 to Dec 2017. It is 50% from Jan 2018 onwards. Post shared with DMHP.</p>	<p>No additional costs</p>

			<p>contribution from companies like Indian Hotels, person time from TCS, etc.</p> <p>Program management including monthly work plans etc.</p>		
	Technical expert	Udaan budget	<p>Leading the reform agenda with the core reform group</p> <p>Attending the Visitors committee meeting and ensuring Udaan reform processes move forward</p> <p>Overseeing translation of all developed protocols and training manuals/ modules</p> <p>Content development of software</p> <p>Oversight on cascade training being done by master trainers</p>	Recurrent activity. 80% of time March 2017 onwards	<p>Coordinating with external services for health to ensure the physical needs of service users are looked after. These have included needs like ophthalmic exam and procurement of spectacles etc.</p> <p>Helping with the reading of clinical files where case managers find it difficult to decipher or understand</p>

Structural reform manager	Udaan budget	Running the entire process of refurbishment of an old building for use in the reform process. This involves identifying the building, getting the architectural reports on strength etc., collaborating with all government bodies on estimates, putting up files, getting approvals and ensuring fund flow from the government. Coordinating with the PWD and ensuring that the construction and repair work is executed with high quality standards.	Recurring activities – 80% of time.	Case management time captured under case manager
Employment coordinator	Udaan budget	Development of the various pathways of employment. This involves end to end tasks involved for a particular set-up. These include farming, tailoring unit, Housekeeping, broom making, food truck. Bakery and laundry are being set up	70% time since Aug 2016.	Case management time captured under case manager
Reform ward staff	Udaan budget	No additional costs	No additional costs.	Reform ward staff

	data manger	Udaan budget	Managing the hospital dataset as well as the process of development and implementation of Udaan	The cost is variable 100% till Dec 2017. From Jan 2018 it is 50% since the post is shared with DMHP.	
	Day care coordinator	Udaan budget	100 % time Management of the day care program	To be initiated. As per actual salary per month from point of initiation.	Case management may actually be completed by the time this initiative starts. However, people discharged (cases) will be offered this program
	Food truck cook	Udaan budget	Food truck cook	100% time from point of initiation.	
	Hospital staff	Government			This is a base cost on which all other costs rest. Therefore, cost of reform is over and above base costs of hospital care and NB ICM costs are additional costs to the cost of reform
Structural Reform	Clearing overgrowth	TAL CSR	Cleaning up of land and overgrowth on buildings.	Plotted in number of JCB days of rent. This will be plotted as per standard marker rates for hire of a JCB.	No additional costs
	Grass cutting machine (included with JCB days)	TAL CSR	Cleaning of hospital spaces and making them habitable	Plotted by number of days used based on market value of rent.	No additional costs
	Acute ward	Government	This includes the cost of refurbishment of ward no 8	As per costs plotted on the government order.	No additional costs
	Family wards	Government	Cost of refurbishment as per order issued by the government. This is for six family units.	This is the cost of refurbishment of existing buildings. These buildings will serve the hospital for decades post intervention.	No additional costs

Recovery wards (half way home wards)	Government	Two male wards and one female ward. Cost of refurbishment of existing building as per order issued by government	Soft costs of setting up the ward have been drawn both from government as well as Udaan expenditure and are included separately below.	No additional costs
Bakery unit	Government	Refurbishment of space for the bakery	Plotted as per the value on government order.	No additional costs
Library spaces	Government	Refurbishment of cells	As per amount spent by Government. Soft cost of library development is plotted else where.	No additional costs
Meditation room	Government	Refurbishment of cells	As per amount spent by Government. Soft cost of meditation room? development is plotted else where	No additional costs
Men's salon	Government	Refurbishment of cells	As per amount spent by Government. Soft cost of men's salon development is plotted elsewhere.	No additional costs
Female beauty parlour	Government	Refurbishment of cells	As per amount spent by Government. Soft cost of female beauty parlour development is plotted elsewhere.	No additional costs
Hand was platforms	Government	Fresh construction	Cost as per sanctioned amount on government order.	No additional costs
Benches	Government	Fresh construction	Cost as per sanctioned amount on government order.	No additional costs
Day care centre	Government	Refurbishment of building	Refurbishment costs as per government sanctions. Operational costs included elsewhere.	No additional costs
Record room	Government	Refurbishment of building	Refurbishment costs as per government sanctions. Operational costs included elsewhere.	No additional costs

	OPD structural changes	Government Individual donations Udaan budget	Decluttering of information material Redesign of communication material Change in process flow and clear labelling Painting of the OPD Restructuring of Pharmacy Automation	Automation is covered under a separate head. For the rest a separate back-end sheet was plotted since input costs have come from different sources.	No additional costs
	Automation	Udaan budget Government costs	OPD & IPD software OPD & IPD hardware AMC and server costs Server room hosting costs	Costs plotted as a separate sheet since it comprises of multiple inputs from different sources.	No additional costs
Process Reform	Baseline measures	Udaan Budget	QR baseline OPD dissemination Clinical audits	Cost of collaboration and dissemination.	No additional costs
	Clinical SOPs	Udaan Budget	SCARF Costs	Costs of clinical audit and SOP development days. Costs of training as per days spent on site to be included in capacity building.	No additional costs
		Udaan Budget	Writing of SOPs Cost of Kamala Easwaran	Cost to be incurred as per contract	No additional costs
	Day care centre	Udaan Budget Government Other CSR funds	Constitutes soft costs of set-up Monthly operationalization costs	Costs yet to be initiated, plotted as a separate worksheet.	Anticipated costs of transportation to day care

Recovery wards (half way home wards)	Udaan budget Government CSR partnerships	Only for the NBICM group up to duration of study		Lockers, bedsheets, clothes, slippers, ward cleaning supplies, One- time costs such as mirrors, patient utility supplies, Patient entertainment material
Men's salon	Udaan Budget Government CSR partnerships	Soft costs of set including furnishing etc. Cost of utilities	Plotted as a separate worksheet.	No additional costs
Beauty parlour	Udaan Budget Government CSR partnerships	Soft costs of set including furnishing etc. Cost of utilities	Plotted on a backend sheet.	No additional costs
Library	Local library / CSR donors Udaan budget	Soft costs of setting up Recurring expenditure	Plotted on a backend sheet.	No additional costs
Meditation hall	Udaan Budget CSR donors	Soft costs of setting up Recurring expenditure	Plotted on a backend sheet.	No additional costs
Movie club	Udaan Budget CSR Donors	Cost of related equipment		No additional costs
Meal services	Udaan Budget CSR costs Government	Set up costs	Plotted in details of costs of tables, seating, utensils, etc.	No additional costs

	Patient engagement material	Udaan Budget Government CSR contribution	Costs of engagement material such as envelope making, games etc.	Plotted on a backend sheet.	No additional costs
	Dance and movement therapy	Udaan budget	Cost of materials procured.	Cost of training reflected elsewhere.	No additional costs
	Drama therapy	Samnum Udaan budget	Cost of development	Costs of Samnum included.	No additional costs
	Recreation and entertainment	Udaan budget CSR contribution	Cost of recreation material, green gym, televisions etc.	Plotted on a backend sheet.	No additional costs
	Staff participation	Udaan Budget	Cost of core committee and ward champions meetings. Cost of master trainers covered under capacity building	Plotted on a backend sheet.	No additional costs
Capacity building	Human rights and mental health	Udaan budget CSR contribution	Cost of master trainer training	Costs include training collaboration costs and complete cost of conducting the training, including venue, training material, transport, etc.	No additional costs
	SMD and its management	Udaan budget Government	Cost of master trainer training	Costs include training collaboration costs and complete cost of conducting the training, including venue, training material, transport, etc.	No additional costs

	Suicide risk assessment and prevention	Udaan Budget	Cost of master trainer training	Costs include training collaboration costs and complete cost of conducting the training, including venue, training material, transport, etc.	No additional costs
	Dance and movement therapy	Udaan Budget Government	Cost of master trainer training	Costs include training collaboration costs and complete cost of conducting the training, including venue, training material, transport, etc.	No additional costs
	Clinical protocols and SOPs	Udaan Budget Government	Cost of master trainer training	Costs include training collaboration costs and complete cost of conducting the training, including venue, training material, transport, etc.	No additional costs
	NB ICM	Udaan Budget CSR contribution		Costs include training collaboration costs and cost of developing module, cost of external trainer and complete cost of conducting the training including, venue, training material, transport, etc.	Cost of master trainer training
Individual service package	Accommodation	CSR Contribution	Bed sheets	Costed as per numbers used at par with market price.	Bed sheets
	Psychoeducation	Udaan budget			Cards on a key ring
	Self-care and personal hygiene	Udaan budget CSR contribution			Costs of all personal care
	Employment coordinator	Udaan budget	Soft input costs for all the five employment pathways developed		

Overheads	Travel	Udaan Budget Koshish budget	Travel for other aspects of reform		Home visit costs
	Office rent	Government	Cost of office rent	Plotted at market value	
	Office running expenditure	Udaan Budget Government	Monthly expenditure	Plotted as backend sheet.	

12.17.2 Adjusted costs of Udaan and SITAR by component

		Staffing	Operations	Refurbishment	Training	Research	Overheads	Total	%
Costs amortised for four years with an annual discount rate of 3%	Structural reform	20,000.00	6,666.67	10,90,950.31	-	-	-	11,17,616.98	42
	Process Reform	76,562.50	2,22,051.40	-	-	-	-	298,613.90	11
	Capacity building	-	-	-	1,07,846.93	-	-	107,846.93	4
	Udaan overall	7,18,333.33	8,085.00	-	-	-	199,245.02	925,663.35	34
	Udaan total	814,895.83	236,803.07	1,090,950.31	107,846.93	-	199,245.02	2,449,741.16	
	USD	12,681.23	3,685.08	16,977.13	1,678.29	-	3,100.61	38,122.33	
	SITAR	17,500.00	46,026.69	-	21,517.79	160,038.81	-	245,083.29	9
	USD	272.33	716.26	-	334.86	2,490.49	-	3,813.93	
	Udaan + SITAR	832,395.83	282,829.76	1,090,950.31	129,364.72	160,038.81	199,245.02	2,694,824.45	
		31%	10%	40%	5%	6%	7%		
	USD	12,953.56	4,401.33	16,977.13	2,013.15	2,490.49	3,100.61	41,936.27	
Costs amortised for 10 years with an	Structural reform	20,000.00	6,666.67	4,11,063.07	-	-	-	437,729.74	23
	Process Reform	76,562.50	1,72,812.92	-	-	-	-	249,375.42	13
	Capacity building	-	-	-	1,07,846.93	-	-	107,846.93	5
	Udaan overall	718,333.33	8,085.00	-	-	-	167,648.46	894,066.79	46
	Udaan total	814,895.83	187,564.59	411,063.07	107,846.93	-	167,648.46	1,689,018.88	

		Staffing	Operations	Refurbishment	Training	Research	Overheads	Total	%
	USD	12,681.23	2,918.84	6,396.87	1,678.29	-	2,608.91	26,284.14	
	SITAR	17,500.00	46,026.69	-	21,517.79	1,60,038.81	-	2,45,083.29	13
	USD	272.33	716.26	-	334.86	2,490.49	-	3,813.93	
	Udaan + SITAR	832,395.83	233,591.28	411,063.07	129,364.72	160,038.81	167,648.46	1,934,102.17	
	%	43	12	21	6	9	9		
	USD	12,953.56	3,635.10	6,396.87	2,013.15	2,490.49	2,608.91	30,098.07	
Costs amortised for four years with an annual discount rate of 6%	Structural reform	20,000.00	6,666.67	1,154,868.27	-	-	-	1,181,534.94	47
	Process Reform	76,562.50	2,26,682.65	-	-	-	-	303,245.15	12
	Capacity building	-	-	-	71,943.53	-	-	71,943.53	3
	Udaan overall	718,333.33	8,085.00	-	-	-	122,958.95	849,377.28	34
	Udaan total	814,895.83	241,434.32	1,154,868.27	71,943.53	-	122,958.95	2,406,100.90	
	USD	12,681.23	3,757.15	17,971.81	1,119.57	-	1,913.46	37,443.21	
	SITAR	17,500.00	46,026.69	-	21,517.79	20,247.14	-	105,291.62	4
	USD	272.33	716.26	-	334.86	315.08	-	1,638.53	
	Udaan + SITAR	832,395.83	287,461.01	1,154,868.27	93,461.32	20,247.14	122,958.95	2,511,392.52	
	%	33	11	46	4	1	5		
USD	12,953.56	4,473.41	17,971.81	1,454.42	315.08	1,913.46	39,081.74		

		Staffing	Operations	Refurbishment	Training	Research	Overheads	Total	%
Costs amortised for ten years with an annual discount rate of 6%	Structural reform	20,000.00	6,666.67	411,063.07				437,729.74	26
	Process Reform	76,562.50	172,837.85					249,400.35	15
	Capacity building				71,943.53			71,943.53	4
	Udaan overall	718,333.33	8,085.00				88,391.91	814,810.24	49
	Udaan total	814,895.83	187,589.52	411,063.07	71,943.53	-	88,391.91	1,573,883.86	
	USD	12,681.23	2,919.23	6,396.87	1,119.57	-	1,375.54	24,492.43	
	SITAR	17,500.00	46,026.69		21,517.79	20,247.14		105,291.62	6%
	USD	272.33	716.26	-	334.86	315.08	-	1,638.53	
	Udaan + SITAR	832,395.83	233,616.21	411,063.07	93,461.32	20,247.14	88,391.91	1,679,175.48	
	%	50	14	24	6	1	5		
	USD	12,953.56	3,635.48	6,396.87	1,454.42	315.08	1,375.54	26,130.96	

12.17.3 Count of In-patients at the end of each quarter for four years of Udaan

Financial Year (1st April to 31st March)	Date	IPD Count
2016-17	30-06-2016	665
	30-09-2016	640
	31-12-2016	610
	31-03-2017	580
Total		2495
Average		623.75
2017-18	30-06-2017	614
	30-09-2017	595
	31-12-2017	634
	31-03-2018	633
Total		2476
Average		619
2018-19	30-06-2018	578
	30-09-2018	556
	31-12-2018	487
	31-03-2019	518
Total		2139
Average		534.75
2019-20	30-06-2019	540
	30-09-2019	518
	31-12-2019	491
	31-03-2020	445
Total		1994
Average		498.5

12.17.4

ICUR for Udaan costs amortised for four years with an annual discount rate of 3%

	Year 1	Year 2	Year 3	Year 4	
Cost per patient month of Udaan	487.32	487.32	487.32	487.32	
Period in months	12	12	12	12	
Annual costs	5847.84	5847.84	5847.84	5847.84	
QALY gain	0.02	0.09	0.09	0.09	
Discount factor	0.97	0.96	0.93	0.90	
Discounted incremental Costs of Udaan for four years at 3%	5,759.45	5,586.67	5,419.07	5,256.50	22,021.69
Discounted incremental QALY of Udaan for four years	0.02	0.09	0.08	0.08	0.27
Total monthly costs of Udaan at 3% discount & four-year amortisation	24,49,741.16				
No of patients	5027				
Per patient monthly costs	487.32				
ICUR	₹81,568.35				

12.17.5 ICUR for Udaan costs amortised for 10 years with an annual discount rate of 3%

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10	
Cost per patient month of Udaan	336	336	336	336	336	336	336	336	336	336	
Period in months	12	12	12	12	12	12	12	12	12	12	
Annual costs	4,032.00	4,032.00	4,032.00	4,032.00	4,032.00	4,032.00	4,032.00	4,032.00	4,032.00	4,032.00	
QALY gain	0.02	0.09	0.09	0.09	0.09	0.09	0.09	0.09	0.09	0.09	
Discount factor	0.97	0.96	0.93	0.90	0.87	0.85	0.82	0.80	0.77	0.75	
Discounted incremental Costs of Udaan for ten years at 3%	3,971.06	3,851.93	3,736.37	3,624.28	3,515.55	3,410.08	3,307.78	3,208.55	3,112.29	3,018.92	34,756.81
Discounted incremental QALY of Udaan for ten years	0.02	0.09	0.09	0.09	0.09	0.09	0.09	0.09	0.09	0.09	0.83
Total monthly costs of Udaan at 3% discount & 10-year amortisation	16,89,018.88										
No. of patients	5,027										
Per patient monthly costs	335.99										
ICUR	₹41,875.67										

12.17.6 ICUR for Udaan costs amortised for four years with an annual discount rate of 6%

	Year 1	Year 2	Year 3	Year 4	
Cost per patient month of Udaan	478.64	478.64	478.64	478.64	
Period in months	12	12	12	12	
Annual costs	5,743.63	5,743.63	5,743.63	5,743.63	
QALY gain	0.02	0.09	0.09	0.09	
Discount factor	0.97	0.91	0.86	0.81	
Discounted incremental Costs of Udaan for four years at 6%	5,568.65	5,234.53	4,920.46	4,625.23	20,348.88
Discounted incremental QALY of Udaan for four years	0.02	0.08	0.08	0.07	0.25
Total monthly costs of Udaan at 6% discount & four-year amortisation	24,06,100.90				
No. of patients	5,027				
Per patient monthly costs	478.64				
ICUR	₹81,395.52				

12.17.7 : ICUR for Udaan costs amortised for ten years with an annual discount rate of 6%

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10	
Cost per patient month of Udaan	313.09	313.09	313.09	313.09	313.09	313.09	313.09	313.09	313.09	313.09	
Period in months	12	12	12	12	12	12	12	12	12	12	
Annual costs	3,757.03	3,757.03	3,757.03	3,757.03	3,757.03	3,757.03	3,757.03	3,757.03	3,757.03	3,757.03	
QALY gain	0.02	0.09	0.09	0.09	0.09	0.09	0.09	0.09	0.09	0.09	
Discount factor	0.97	0.91	0.86	0.81	0.76	0.71	0.67	0.63	0.59	0.56	
Discounted incremental Costs of Udaan for ten years at 6%	3,642.58	3,424.02	3,218.58	3,025.47	2,843.94	2,673.30	2,512.91	2,362.13	2,220.40	2,087.18	28,010.51
Discounted incremental QALY of Udaan for ten years	0.02	0.08	0.08	0.07	0.07	0.06	0.06	0.06	0.05	0.05	0.60
Total monthly costs of Udaan at 6% discount & 10-year amortisation	15,73,883.86										
No. of patients	5,027										
Per patient monthly costs	313.09										
ICUR	₹46,684.18										

