Abbreviated Title: ***Feasibility of the MhINT Recovery program***

IRB #: *BREC/00007597/2024*

Title: *Feasibility trial of a health systems strengthening intervention (MhINT Recovery) to reduce hospital re-admission following acute psychiatric hospitalization among people living with severe mental illness in uMgungundlovu, KwaZulu-Natal*

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STATEMENT OF COMPLIANCE

The trial will be carried out in accordance with International Council for Harmonisation Good Clinical Practice (ICH GCP) and the following:

- United States (US) Code of Federal Regulations (CFR) applicable to clinical studies (45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56, 21 CFR Part 312, and/or 21 CFR Part 812)

National Institutes of Health (NIH)-funded investigators and clinical trial site staff who are responsible for the conduct, management, or oversight of NIH-funded clinical trials have completed Human Subjects Protection and ICH GCP Training.

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the Institutional Review Board (IRB) for review and approval. Approval of both the protocol and the consent form must be obtained before any participant is enrolled. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. In addition, all changes to the consent form will be IRB-approved; an IRB determination will be made regarding whether a new consent needs to be obtained from participants who provided consent, using a previously approved consent form.

1 PROTOCOL SUMMARY

1.1 SYNOPSIS

Title:	Feasibility trial of a health systems strengthening intervention (MhINT Recovery) to reduce hospital re-admission following acute psychiatric hospitalization among people living with severe mental illness in uMgungundlovu, KwaZulu-Natal.
Study Description:	A multilevel health system strengthening intervention, the Mental Health Integration program for Psychosis care (MhINT Recovery), was co-developed between partners from the University of KwaZulu-Natal, the South African Medical Research Council, and the Department of Health. The purpose of this intervention is to develop mechanisms along the cascade of care that can provide psychosocial support to people living with severe mental illness following discharge from acute psychiatric hospitalization in order to reduce re-admission rates. The intervention will be tested for feasibility using a cluster randomized control trial in the uMgungundlovu District, KwaZulu-Natal.

Objectives:	The overall aim of this research is to determine the feasibility of real-world implementation of a co-produced health system strengthening intervention in reducing hospital re-admission rates related outcomes among people living with severe mental illness following acute psychiatric hospitalization. The specific study objectives are as follows: Primary outcomes: To test the limited-efficacy of the intervention on the following: i. Re-admission of people living with severe mental illness following acute psychiatric hospitalisation (primary outcome) ii. Recovery of people living with severe mental illness (secondary outcome) iii. Internalised stigma of people living with severe mental illness (secondary outcome) iv. Treatment adherence of people living with severe mental illness (secondary outcome) Secondary outcomes: To assess the feasibility of the intervention in terms of its i. Acceptability to stakeholders; ii. Demand in the health system; iii. Implementation processes; iv. Practicality; v. Adaptation following testing; vi. Integration into the health system; and vii. Expansion potential of the intervention.
Endpoints:	Primary Endpoint: 4 months Secondary Endpoints: 4 months

Study Population:	86 people living with severe mental illness, as determined by the ICD-10 codes in their clinical records (43 participants in the intervention and 43 participants in the control groups); the primary caregivers of participants (86); nursing staff at PHC clinics and community health centres; nursing staff and mental health professionals in district, regional and specialist hospitals.
Phase or Stage:	Pilot feasibility trial.
Description Sites/Facilities	Hospitals: 1 Specialist psychiatric hospital, 1 regional hospital, 1 district hospital
Enrolling Participants:	PHC facilities: 3 Community Health Centres, 48 Primary Healthcare Clinics Describe the study intervention (a.k.a, experimental manipulation; hereafter referred to as “study intervention”). Include intervention dose (length and frequency) and how it will be administered. Include method of delivery (e.g., group vs. individual, web-based, etc.).
Description of Study Intervention:	The intervention consists of training and mentorship of healthcare workers on tertiary, secondary, and primary levels of care, as well as training and mentorship of caregivers of people living with severe mental illness. People living with severe mental illness, who have been hospitalized following an acute psychotic event, will be recruited following stabilization in the medical and psychiatric wards of hospitals. Both intervention and control groups will be exposed to a hospital-based psychosocial rehabilitation program administered by hospital nursing and allied staff (depending on hospital resources). Once discharged, enhanced linkage to a PHC facility will occur, after which PHC nursing staff will monitor outpatient care following refresher training in psychiatric management. A trained, dedicated community health worker (CHW) will use vignette-based psychosocial support and psychoeducation materials to provide home

	support to caregivers and care recipients. The caregiver will further be empowered through training, mentorship, and a self-directed manual for psychosocial support and care of someone living with a severe mental illness.
Study Duration:	16 months
Participant Duration:	4 months

1.2 SCHEMA

Flow Diagram

Enrollment
<Day 1 – Day 60>

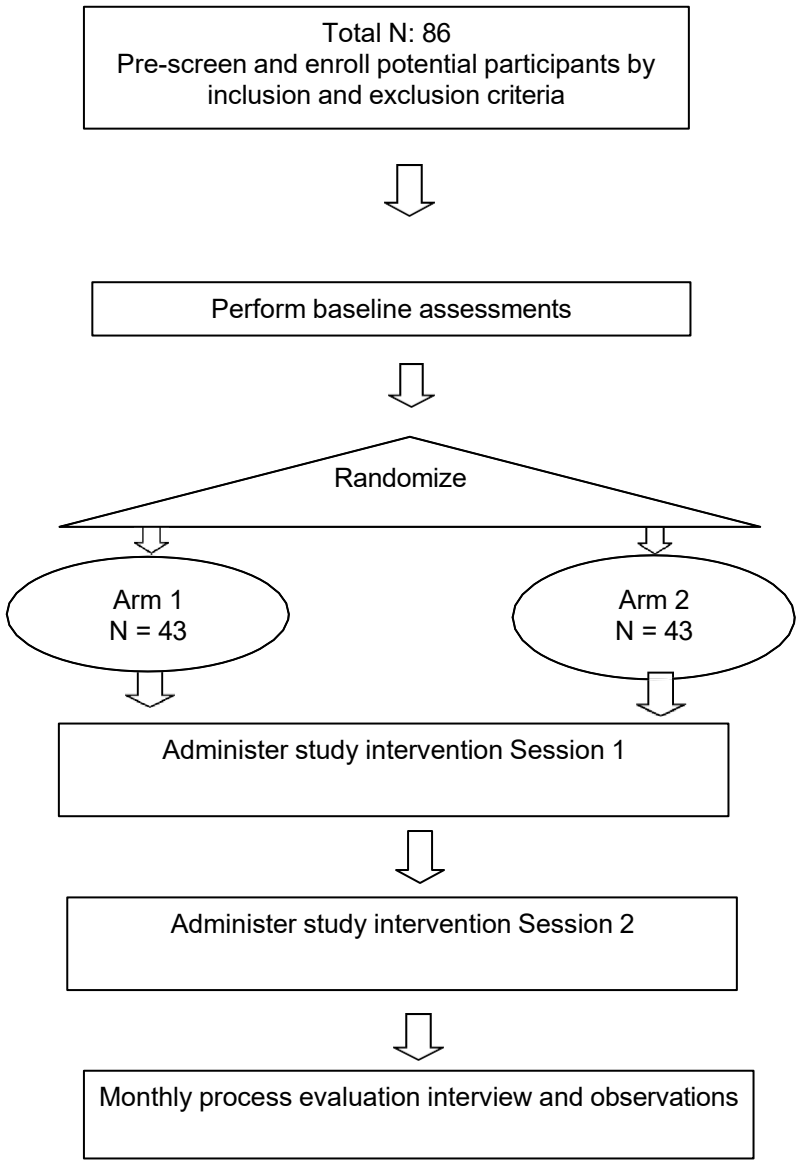
Baseline
assessment
<Day 1 – Day 60 >

Intervention PHC

<Discharge + 7
days>

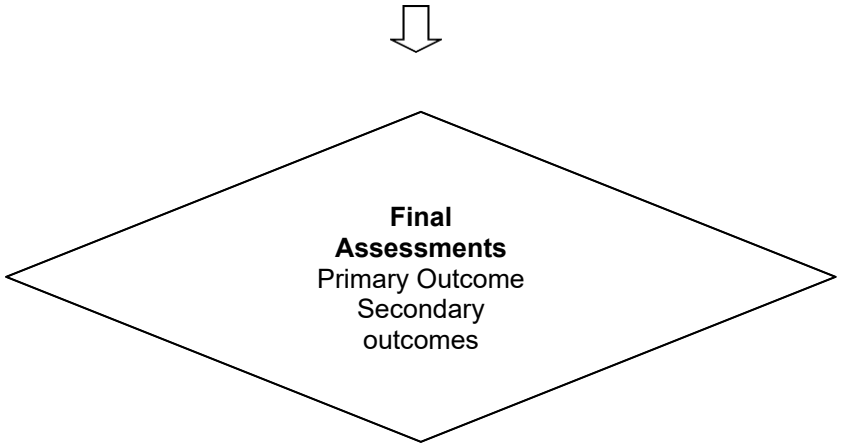
Intervention Household
<Monthly>

Process assessments <Monthly>



Final assessments

<Enrolment +4 months>



2 INTRODUCTION

2.1 BACKGROUND

People living with serious mental illness (SMI) – "a mental, behavioral, or emotional disorder resulting in serious functional impairment, which substantially interferes with or limits one or more major life activities" [1] – have, globally, been repeatedly shown to have higher rates of excess mortality and reduced life expectancy (estimated at 10-20 years less) than the general population [2-4]. Individuals with SMI are more likely to die from cardiovascular disease [5 6]; hospitalized or die from pneumonia, influenza and sepsis [7]; be diagnosed with infectious diseases such as COVID-19 [8 9], tuberculosis [10], and blood-borne viral infections such as hepatitis B and C [11]; and die from unnatural causes such as suicide and violent homicide [12]. While reasons for these disparities remain empirically ambiguous, inequities in healthcare access and delivery – often due to persistent program verticalization, pervasive stigma associated with mental illness, the consequences and complexities involved in the treatment of mental illness – have been pointed out to be major contributing causes [13]. While the bulk of evidence of these inequities emerged from high-income countries (HICs), limited evidence from low-and-middle income countries (LMICs) has substantiated these trends, with an Ethiopian study suggesting that people with SMI died approximately three decades earlier than the general population, mainly due to infectious diseases, suicide, accidents and homicide [14]. In both HIC and LMIC settings, homelessness among individuals with SMI are also pervasive, which carries with it a range of aggravating factors [15]. In LMIC settings, the burden faced by people with SMIs is no doubt compounded by systems that are under-resourced, hospicentric and crisis-oriented; services with low population coverage; and the principal responsibility for care being shared between families and informal, non-profit caregivers, with traditional and spiritual health practitioners involved and varying degrees [16]. These are typical features of South Africa's mental health system where critical gaps remain in community-based care for people with SMI despite commendable policy reforms [17-19].

As demonstrated by the deinstitutionalization experiences of the 1980s and 1990s, the inadequate contexts of care beyond inpatient facilities often result in the generation of a subpopulation of individuals with SMI that are frequently readmitted to hospital settings following discharge into community settings [20]. Selected studies from South Africa

suggest one-year readmission rates of 46% [21] and 66% [22], while a national survey suggested an average rate of 24.5% after three months discharged, translating into an annual figure of USD112.6 million, accounting for 18% of the country's total mental healthcare expenditure [23]. This "revolving door" phenomenon has been an obstinate challenge to mental health systems, due a range of multilevel, complex factors. Research has suggested that substance use; a history of and high frequency of past acute hospitalizations; type of residence; quality of life after being discharged; violence and suicidality; familial conflict; family stigma towards mental illness; unmet needs during the post-discharge period; social isolation; a sense of community belonging; lapses in post-discharge consultations; poor support networks; challenging social environments; and medication non-adherence could all contribute to frequent acute psychiatric rehospitalization [20 24-29]. Significantly, in South Africa, pressure to free up psychiatric beds in hospitals for acute care has resulted in "crisis discharge", whereby service users are discharged earlier than intended significantly increasing the risk of early re-admission [30].

Several critical bottlenecks have been identified that impede recovery post-discharge generally viewed in terms of common service user pathways which have been described in several descriptive studies [30-39]. Individuals who suffer from an acute psychiatric event in the community, either at home or in a public space, can be transported to a public hospital emergency ward. The mode of transport can depend on the severity and nature of the event, as well as on the availability of public resources [19 40]. Family and friends may bring in less severe cases, while individuals with particularly severe and violent psychosis may require policy and/or ambulance assistance. Once the individual arrives at the emergency department, an attending physician and nursing staff will proceed to stabilize and call for a psychiatric consult (if available). Depending on these assessments, the individual will be admitted for a period of 72 hours to be stabilized and observed before further actions are taken. Here, a particular bottleneck emerges, namely, a chronic lack of beds in public hospitals, no doubt aggravated by COVID-19, means that many people with severe mental disorders wait in emergency or general medical wards for beds to be vacated before they can be admitted as psychiatric service users. Further, a lack of mental health professionals means that in many areas, individuals admitted for psychiatric reasons often wait for extended periods before they can be assessed, treated, and discharged. A lack of available social workers also means

that little to no contact is made with caregivers prior to discharge and a void exists between hospital settings and contexts at home, where poor treatment adherence, substance abuse, lack of psychosocial support and socioeconomic determinants increases the possibility of relapse following discharge. The discharge procedure itself involves referring the service user to a clinic near their place of residence (often unaccompanied, with no feedback information) from where they will be able to access medication and six-monthly assessment for script renewals. While there are non-governmental organizations (NGOs) that provide limited support in community settings, these services are extremely limited and contingent on donor funding. There is particularly weak coordination between government departments and NGOs resulting in a highly fragmented, inefficient service package for people with severe mental disorders. In terms of residential settings, some service users may be accommodated in community care centers run by NGOs, though these are mostly in urban locations, poorly regulated and poorly funded. Most service users in South Africa contexts receive their basic care from family and friends, who often depend on a monthly government disability grant to help cover household expenses with little to no support provided to either service users or their caregivers. Low levels of mental health literacy remain a crucial barrier to treatment adherence in addressing complex needs and recognizing early signs of relapse. These issues are illustrated in Figure 1 below:

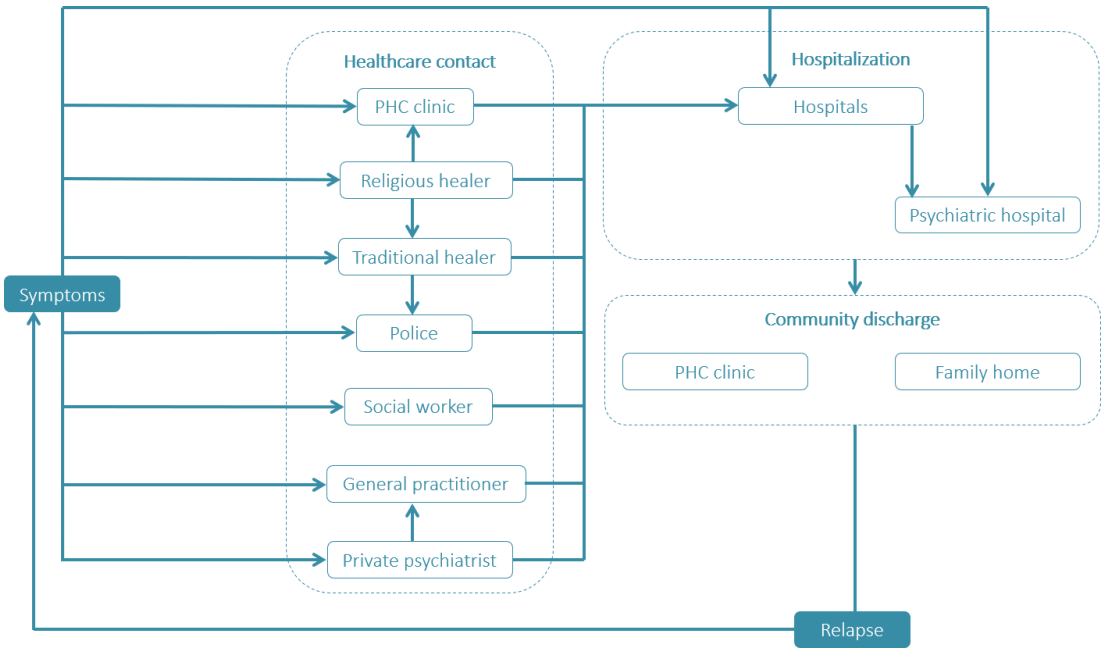


Figure 1: Pathway for people with SMIs in South Africa to illustrate rehospitalization cycle [30-39]

The numerous factors that may predict psychiatric rehospitalization following discharge can be grouped according to individual vulnerability factors, aftercare-related factors, community care and service responsiveness, and contextual factors and social support [41]. Several intervention strategies have been applied to address these factors and improve readmission rates, specifically, interventions that focus on 1) the pre-discharge period, 2) the post-discharge period, and interventions that attempt to bridge these periods [42]. In South Africa, transitional interventions of this nature are limited, with examples mostly from the Western Cape province. Here, the New Beginnings program has shown promise as a model to promote post-acute discharge outcomes [43]. Attached to Stikland Hospital, New Beginnings is an intermediary, step-down facility focusing on psychosocial rehabilitation and can care for 40 patients in step-down or step-up settings. Stikland Hospital is tied to several community-based treatment and care programs, which includes an Assertive Community Treatment (ACT) team that has shown significant reductions in psychiatric readmission rates [44]. Despite these promising developments, questions remain regarding the feasibility of broader scale-up of programs that rely heavily on close participation of mental health specialists. Given South Africa's lack and unequal distribution of mental health specialists [45], the establishment of non-specialized community mental health teams (within the Balanced Care Model)[46] based on task-sharing principles, has a potentially good fit with the country's resources and health system structure [17 47-49]. In this vein, co-developed, health system strengthening along the cascade of care – from hospital to household level – is required for optimal reduction of re-admission rates. To date, there has been no significant evidence produced for a program that promotes wellbeing, create care capacity and prevents hospital readmission, integrated into the health system across secondary, primary and community levels. Following a co-creation approach, a comprehensive health system strengthening intervention has been developed between the research team, and stakeholders from the Department of Health, caregivers and people living with severe mental illness. Before embarking on large-scale efficacy testing, it is important to first determine the feasibility (which includes limited effectiveness) of this co-created intervention.

3 OBJECTIVES AND ENDPOINTS

The overall aim of this research is to determine the feasibility of real-world implementation of a co-produced health system strengthening intervention in reducing hospital re-admission rates related outcomes among people living with severe mental illness following acute psychiatric hospitalization. Following Bowen et al.'s feasibility framework [50], the study will assess feasibility through measurements of Limited Efficiency, Acceptability, Demand, Implementation, Practicality, Adaptation, Integration, and Expansion. The specific study objectives are as follows:

1. To test the limited-efficacy of the intervention on the following:

   v. Re-admission of people living with severe mental illness following acute psychiatric hospitalization (primary outcome)

   vi. Recovery of people living with severe mental illness (secondary outcome)

   vii. Internalized stigma of people living with severe mental illness (secondary outcome)

   viii. Treatment adherence of people living with severe mental illness (secondary outcome)

2. To assess the feasibility of the intervention in terms of its

   viii. Acceptability to stakeholders;

   ix. Demand in the health system;

   x. Implementation processes;

   xi. Practicality;

   xii. Adaptation following testing;

   xiii. Integration into the health system; and

   xiv. Expansion potential of the intervention.

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
Primary		
Change in rate of hospital psychiatric re-admission among people living with severe mental illness, as assessed by medical record, at 4 months.	The proportion of intervention arm participants who have not relapsed and re-hospitalised for an acute psychiatric event within a period of 4 months since enrolment, compared to control arm participants, as measured by trial monitoring data.	Main outcome
Secondary		
Change in recovery score among people living with severe mental illness, as assessed by the total score on the Recovery Assessment Scale – Domains and Stages (RAS-DS), at 4 months	The proportion of intervention arm participants who have shown changes in recovery scores, as measured by the Recovery Assessment Scale – Domains and Stages (RAS-DS), following an acute psychiatric event within a period of 4 months since enrolment, compared to control arm participants.	Mediator of main outcome
Change in internalized stigma score among people living with severe mental illness, as assessed by the total score on the Brief version of the Internalized Stigma of Mental Illness (ISMI) scale, at 4 months	The proportion of intervention arm participants who have shown changes in internalized stigma as measured by the Brief version of the Internalized Stigma of Mental Illness (ISMI) scale, following an acute psychiatric event within a period of 4 months since enrolment, compared to control arm participants.	Mediator of main outcome

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
Change in treatment adherence score among people living with severe mental illness, as assessed by the total score on a tailored scale, at 4 months	The proportion of intervention arm participants who have shown changes in treatment adherence scores as measures by a tailored measure, following an acute psychiatric event within a period of 4 months since enrolment, compared to control arm participants.	Mediator of main outcome
Description of stakeholder views regarding the acceptability of the MhINT Recovery intervention after 4 months of implementation	A qualitative measure of the degree to which the MhINT Recovery intervention is deemed acceptable to people receiving the intervention, their caregivers, healthcare workers, managers, and policymakers.	Moderator of main outcome
Description of perceptions of stakeholders regarding the demand of the MhINT Recovery intervention after 4 months of implementation	A qualitative measure of the degree to which the MhINT Recovery intervention meets the demands of people receiving the intervention, their caregivers, healthcare workers, managers, and policymakers.	Moderator of main outcome
Description of perceptions of stakeholders regarding the barriers and facilitators of the implementation of the MhINT Recovery intervention, in terms of the Consolidated Framework for Implementation Research (CFIR) domains, after 4 months of implementation	A qualitative measure describing barriers and facilitators in implementation of the MhINT Recovery intervention, in terms of the Consolidated Framework for Implementation Research (CFIR) domains (Inner, Outer, Implementation, Innovation, Individual and Implementation), after 4 months of implementation.	Moderator of main outcome
Description of perceptions of stakeholders regarding the practicality of the MhINT Recovery intervention, after 4 months of implementation	A qualitative measure of the degree to which the MhINT Recovery intervention is deemed to be practical by people receiving the intervention, their caregivers, healthcare workers, managers, and policymakers.	Moderator of main outcome
Description of perceptions of stakeholders regarding the degree to which the MhINT Recovery intervention can be adapted for specific subgroups after 4 months of implementation	A qualitative measure of the degree to which the MhINT Recovery intervention can be adapted to the needs of different subgroups of people receiving the intervention.	Moderator of main outcome

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
Description of perceptions of stakeholders regarding the degree to which the MhINT Recovery intervention can be integrated into the local health system after 4 months of implementation	A qualitative measure of the degree to which the MhINT Recovery intervention is perceived to be integrated with the local health system.	Moderator of main outcome
Description of perceptions of stakeholders regarding the potential of scaling the MhINT Recovery intervention in future, after 4 months of implementation	A qualitative measure of the perceived potential of the MhINT Recovery intervention to be scaled from trial to routine and sustained service changes for people living with severe mental illness.	Moderator of main outcome

4 STUDY DESIGN

4.1 OVERALL DESIGN

This feasibility study is a multisite randomized control trial with a parallel mixed methods process evaluation. Simple randomization will be undertaken by trained research assistants with a 1:1 ratio of allocation to intervention (n=43) and control (n=43) groups. The following hypothesis applies:

Re-admission among discharged people living with severe mental illness following acute psychiatric hospitalization is statistically significantly lower among participants being exposed to an integrated psychosocial support intervention for nine months compared to those in a control group.

4.2 JUSTIFICATION FOR INTERVENTION

The MhINT Recovery intervention is a multilevel health system intervention, that has been co-designed through a human-centered design approach with people living with severe mental illness, their caretakers, healthcare workers on community, primary, secondary and tertiary levels, managers, and subject experts. The intervention has been designed to expose people living with severe mental illness who have been hospitalized due to an acute psychiatric event to psychosocial support at critical times of transition, from hospital to PHC clinic level, as well in their home environment with their caregivers and family. MhINT Recovery has been designed with sustainability and scalability in mind, meaning that the focus is largely on using existing service

platforms and resources. On hospital level, the psychosocial rehabilitation will be delivered by hospital staff, including nurses, allied workers, and medical officers. On PHC clinic level, nurses and medical officers will deliver enhanced outpatient services. On community level, CHWs will deliver a vignette-based psychoeducation, support and monitoring program, while caregivers will be empowered through a self-directed household champion program. All intervention implementers will receive face-to-face training by a specialist training team in coordination with the DoH Training Unit, with additional mentorship and continuous quality improvement (CQI) being provided by a field manager. This strategy has been workshopped with the DoH, and has been previously successfully been implemented in previous collaborations between UKZN and DoH team members. This will result in minimized disruption of daily clinical routines, while providing psychosocial support structures at critical levels from discharge downward to household level.

4.3 End-Of-Study Definition

A participant is considered to have completed the study if he or she has completed the baseline assessment, one post-discharge clinic appointment, monthly clinic and CHW outreach visits, process evaluation assessments, and 4-month follow-up assessments.

5 STUDY POPULATION

5.1 Inclusion Criteria

The inclusion criteria for participation in the study will be as follows:

Service user inclusion criteria:

- Adults (aged 18 years and above);
- Being admitted to the psychiatric ward of a hospital for observation and treatment due to an acute psychiatric event, based on ICD diagnosis on patient charts according to the following criteria:
    - F20-29 including schizophrenia, delusional disorders, schizotypal disorders, acute polymorph psychotic disorders, schizoaffective disorders

- F30-39 Mood [affective] disorders with psychoses
- F30.2 Mania with psychotic symptoms
- F31.2 Bipolar affective disorder, current episode manic with psychotic symptoms
- F31.5 Bipolar affective disorder, current episode severe depression with psychotic symptoms
- F32.3 Severe depressive episode with psychotic symptoms
- F33.3 Recurrent depressive disorder, current episode severe with psychotic symptoms

- Determined by the attending psychiatrist to be discharged into community settings following appropriate recovery from the psychiatric event;
- Willing and able to participate in the intervention program
- Resides with a caregiver (which could be a family member or member of the household).
- Resides within the geographic boundaries of uMgungundlovu

Caregiver inclusion criteria:

- Adults (aged 18 years and above)
- Willing and able to participate in the intervention program
- Resides with a caregiver (which could be a family member or member of the household).
- Resides within the geographic boundaries of uMgungundlovu

5.2 EXCLUSION CRITERIA

Service user exclusion criteria:

- Under 18 years of age
- Are indicated by their chart history to have the following conditions:

- Active suicidal ideation
- Substance abuse or dependence as primary diagnosed psychiatric condition
- Personality disorders
- Serious cognitive or other sensorial impairment likely to preclude informed consent and reliable assessment

- Does not reside with a caregiver
- Does not reside within the geographic boundaries of uMgungundlovu

5.3 Strategies for Recruitment and Retention

People living with severe mental illness and their caregivers

The study aims to reduce re-admission and associated outcomes by improving transitional care through health system strengthening. Therefore, the care pathway of service users played a role in conceptualizing the recruitment strategy. Recruitment will occur at hospital level. Fieldworkers will be stationed in Harry Gwala and Northdale Hospitals, where an agreement with hospital management would alert fieldworkers when a potential participant has been admitted for an acute psychiatric episode. Once informed consent of a service user has been confirmed, the clinical team and service user will assist the fieldworker to contact the primary caregiver of the service user in order to obtain their consent as well. The fieldworker will request an appointment with the caregiver, and will then take them through the information sheet, allow for questions, and request informed, written consent for participation. Following successful informed consent from both the service user and caregiver, the two parties will receive a number in sequence with a pre-randomized worksheet. On an Excel worksheet, cells will be numbered from 1 to 86, and will be randomized into two groups, intervention and control. The fieldworker will not know prior to assignment which group a participant will be allocated to, as the fieldwork manager will check the number assigned to a participant pair in the randomization sheet, and will then communicate to the fieldworker which group the pair has been assigned to, who in turn will communicate the assignment result to the service user and caregiver. Once a service user and their caregiver have been

assigned to the intervention group, the intervention will be initiated prior to discharge.

Health care providers

Healthcare workers will be invited to participate in a cross-sectional survey, semi-structured interviews, focus group discussions and participatory workshops. Healthcare workers will be identified in consultation with facility management. Healthcare workers will be invited to participate in a cross-sectional survey, where, on the hospital level, doctors, nurses, social workers, and psychologists routinely working with people living with severe mental illness will be invited to participate. On the PHC clinic level, nursing staff (including professional and enrolled nurses), Outreach Team Leaders, and CHWs in the WBPHCOT working in the specific PHC clinics where the participants have been referred to, as well as a similar number of corresponding clinics in the control group, will be invited to participate. Eligible health care professionals will be approached by the research staff, have the study introduced to them and receive the information sheet. They will be given an opportunity to ask questions and to decide whether they choose to take part in the research. They will be assured that taking part in the study is voluntary and that they can choose to not to take part or to withdraw from the study at any time without affecting their work in anyway. If they choose to participate in the study, they will be asked to sign voluntarily a consent form. They will be informed that deciding not to participate will not affect their performance reviews or prejudice them in any way. Following informed and written consent, they will receive a copy of the consent form and a fieldworker will administer a questionnaire electronically using a digital capturing device.

For the qualitative activities, HCWs will be purposively selected from different cadres and wards in the hospitals. Semi-structured interviews will be conducted with hospital staff and PHC nursing staff, while focus group discussions will be conducted with CHWs. Participatory workshops will also be conducted, where invitations will be extended to intervention facilities for HCW representatives to attend. Eligible health care professionals will be approached by the research staff, have the study introduced to them and receive the information sheet. They will be given an opportunity to ask questions and to decide whether they choose to take part in the research. They will be assured that taking part in the study is voluntary and that they can choose to not to take part or to withdraw from the study at any time without affecting their work in anyway. If they choose to participate in the study, they will be asked to sign voluntarily a consent

form. They will be informed that deciding not to participate will not affect their performance reviews or prejudice them in any way. Following informed consent, all activities will be audio recorded and transcribed verbatim, translated and back-translated to ensure accuracy.

5.3.1 Costs

Due to the intervention being embedded in routine health system operations, it is not anticipated that participation in the study will lead to any personal financial costs beyond what is spent for routine health service visits that would have already been happening. Service users in the intervention arm will receive enhanced primary mental health services during their monthly clinic visits for their medication, and will additionally be visited at home, along with their care givers. All activities introduced as part of the intervention arm for healthcare workers, are within their existing scopes of practice and responsibilities, thereby minimizing additional workloads.

5.3.2 Compensation

Service users and caregivers will each receive R150-00 in grocery store vouchers for each data collection event, including for baseline and post-intervention assessments, process evaluation interviews and observations, and participatory workshops. This will be provided to compensate the participants' time, inconvenience and expenses. Healthcare workers will not receive compensation for participation, in line with DoH regulations about receiving payment for research. Workshops will be conducted at spaces that are central and relatively reachable by participants, travel will be compensated with grocery store vouchers and catering will be provided.

6 STUDY INTERVENTION

6.1 INTERVENTION CONTENT

The intervention is the product of a human-centered design process, involving a range of health system actors and focusing on the pathway of service users from hospital to household level following discharge. Specifically, the intervention has been designed to target key areas of improvement. A person suffering from a psychotic episode is taken to hospital (the bulk at Northdale and Harry Gwala Hospitals), usually by family or community members, and sometimes by SAPS. Once admitted, the clinical team

(doctors and nurses) will assess the admitted service user, and start a process of stabilization. During this period, some service users might have contact with a rehabilitation team (made up of social workers, nurses, psychologists). There usually also is contact with the family to inform them of the process. Following a period of observation and stabilization, the service user will be discharged to a clinic in their community, usually into the care of a caregiver. The service user is to present a referral form from the hospital to the clinic in order to initiate outpatient treatment. There is little to no evidence of follow-up visits from CHWs, who do not have the tools or training to undertake home visits. There are also no standardized SOPs for discharge, referral, care coordination, outreach, or pharmacy support. Service users receive care in the community by and large in terms of monthly treatment visits to the clinic.

The intervention of this project has been developed following an extensive period of formative work and co-creation with the DoH. The intervention aims to enhance service user support along the care cascade as follows:

Hospital level (District, Regional, Specialist):

- Following hospital admission, the hospital clinical team will follow an SOP to initiate early family readiness, by contacting the clinic to which the service user will be referred for outpatient care, who in turn will send a trained CHW to the hospital to visit the service user with the rehabilitation team. The CHW will, through the rehabilitation team, also make contact with the caregiver and conduct a family readiness session.
- During stabilization, hospital multidisciplinary teams (MDT) and nursing staff will initiate a co-developed psychosocial rehabilitation (PSR) program, which will be individualized in duration and dose in terms of the intensity of need and length of stay (as determined by the attending psychiatrist).
- Prior to discharge, discharge nursing staff will follow an SOP and checklist that will alert the clinic that the service user is about to be discharged, and will ensure that appropriate medication is packed and ready.

PHC facility level:

- After discharging the service user into the care of a caregiver, the service user will be requested to take their referral form to the clinic within six days, after which a CHW will be sent to their home to make sure that they are doing well. After receiving

the referral form, the clinic will call the discharge team at the hospital to confirm that the service user has been logged in the clinic system, and this will be documented in a project register.

Household level:

- Following discharge, the service user will be visited at their home by a trained, project-dedicated CHW, who will provide psychoeducation to both the service user and the caregiver, integrated into an existing CHW tool (Community Mental Health Education and Detection Tool – CMED). Psychosocial support and education will be provided during monthly visits thereafter, and will further include treatment monitoring and adherence, and screening for potential early signs of distress that could lead to a relapse. If any potential signs of distress emerge, the service user and caregiver will be referred to the nurse in the Chronic Stream of the local PHC clinic, who will also be provided with a standardized and integrated symptom monitoring checklist. Should medicine stock-outs occur, the issue will be fast-tracked to the district pharmacist through the District Specialist Team.
- Additionally, the primary caregiver will receive training and mentorship in a self-directed psychosocial management manual, as part the DoH Household Champion program. This will ensure a supplementary level of support of monitoring of service users, as well as providing a degree of support to caregivers.
- All referrals, both downwards and upwards, are integrated in the new KwaZulu-Natal provincial referral policy, which will be enacted through facility SOPs.

Implementation strategies are as follows:

Hospital level:

- A one-day workshop at each hospital, facilitated by an adult education team, supported by the DoH Training Unit, aimed at medical officers, MDTs, nursing staff who have been nominated by hospital management to participate. Training will include an overview and illustrated examples of the PSR, with manuals distributed to all participants and wards.
- A project-dedicated CQI specialist will provide on-going mentorship and support during the first three months of recruitment.

PHC level:

- A two-day workshop in the district, at a central venue, to which nurses and operational managers of clinics will be invited, facilitated by an adult education team, supported by the DoH Training Unit. Training will include an overview and illustrated examples of the enhanced APC guidelines, with manuals distributed to all participants and clinics.
- A project-dedicated CQI specialist will provide on-going mentorship and support during the first three months of recruitment.

Community level:

- Three CHWs will be recruited for the project to carry out the intervention. Recruits would need a strong background in mental health and community health settings, and will undergo three-day face-to-face training using roleplay and case studies, sensitivity training for work involving people living with psychosis, and including how to orientate caregivers towards becoming Household Champions.
- Caregivers will be trained during a one-day contact session at their homes, and be provided with an overview of the program and a detailed demonstration of the self-directed manual. CHWs will continue to support caregivers in day-to-day management, and will be available via mobile phone for any support issues.
- CHWs will be mentored and supported by a CQI specialist to ensure fidelity and optimize implementation.

Additional implementation mechanisms will include posters about service user pathways in all participating healthcare facilities, and an overall orientation workshop to all stakeholders that will map out activities across levels. Quarterly feedback will be provided to facility, subdistrict and district management, as well as to the provincial PHC Transformation Committee (an intersectoral governance and policy-making body in KwaZulu-Natal).

6.2 Study Intervention Adherence

Service user adherence and fidelity to the intervention will be monitored and determined by the following:

- Attending PSR sessions in hospital, the number and duration of which determined during the first contact and PSR planning session (project register completed by HCWs).
- Visiting the down referred clinic within 7 days (PHC visitation records)
- Attending monthly PHC clinic visits for mental health status examinations and medication, during the 4-month intervention period (PHC visitation records)
- Attending monthly CHW outreach visits at home (project register)

Caregiver adherence and fidelity to the intervention will be monitored and determined by the following:

- Caregivers using the self-directed manual (observations and fidelity checklists)

HCW adherence and fidelity to the intervention will be monitored and determined by the following:

- Relevant and nominated HCWs on all levels attend all training and engage during mentorship and CQI sessions (project registers)
- Hospital staff implement the PSR program (observations, project registers, fidelity checklists)
- PHC nursing staff employ enhanced APC guidelines (observations, fidelity checklists)
- CHWs reach out to caregivers for family readiness during hospitalization, provide outreach to all intervention households every month over a 4-month period, orientate caregivers in the Household Champions program (project registers, observations, fidelity checklists)

7 STUDY INTERVENTION DISCONTINUATION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

7.1 DISCONTINUATION OF STUDY INTERVENTION

Service user participants will have bimonthly access with health services as part of the intervention, namely visiting their assigned clinic for routine medication and care, as well as CHW visits to their household. Both PHC clinic and household level interventions include a level-appropriate mental health status examination, which will be recorded on project registers. Should the mental health of a participant decline during these

monitoring points, the fieldwork supervisor and PIs will be contacted for further steps. Two of the PIs are senior psychologists, and will, in consultation with the DoH District Specialist Team for mental health, refer the participant for additional assessment by a psychiatrist at Town Hill Hospital. Based on the assessment of the psychiatrist, and in consultation with the District Specialist Team, the participant and their caregivers, the participant can either continue with additional support and monitoring, or discontinue their participation. In the latter case, the participant will be referred to an appropriate health service provider based on the psychiatric assessment.

When a participant discontinues from the intervention but not from the study, remaining study procedures will be completed as indicated by the study protocol. If a clinically significant finding is identified (including, but not limited to changes from baseline) after enrolment, the investigators will determine if any change in participant management is needed. Any new clinically relevant finding will be reported as an adverse event (AE).

The data to be collected at the time of study intervention discontinuation will include the following:

- The reason(s) for discontinuing the participant from the intervention, and methods for determining the need to discontinue
- If the participant is due to complete assessments within 2 weeks of being discontinued from the study intervention, those assessments will be administered at the time of discontinuation; if the next scheduled assessments are more than 2 weeks from the discontinuation date, the discontinued participant will wait for the next scheduled assessment. Thereafter, the participant will be included in all future scheduled assessments, even though not participating in the intervention.

7.2 Participant Discontinuation/Withdrawal from the Study

Participants are free to withdraw from participation in the study at any time upon request. A participant may be discontinued from the study for the following reasons:

- Significant study intervention non-compliance, unless varying compliance is an aspect of the study objectives
- Lost-to-follow up; unable to contact subject
- Any event or medical condition or situation occurs such that continued collection of

follow-up study data would not be in the best interest of the participant or might require an additional treatment that would confound the interpretation of the study

- The participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation
- Screen Failure
- Subject has completed the study follow-up period

The reason for participant discontinuation or withdrawal from the study will be recorded on a Study Case Report Form (CRF). Subjects who sign the informed consent form, and are randomized and receive the study intervention, and subsequently withdraw, or are discontinued from the study, will not be replaced.

7.3 LOST TO FOLLOW-UP

A participant will be considered lost to follow-up if he or she fails to return for three consecutive scheduled visits and is unable to be contacted by the study site staff.

The following actions must be taken if a participant fails to return to the clinic for a required study visit:

- The site will attempt to contact the participant and reschedule the missed visit and counsel the participant on the importance of maintaining the assigned visit schedule and ascertain if the participant wishes to and/or should continue in the study.
- Before a participant is deemed lost to follow-up, the investigator or designee will make every effort to regain contact with the participant (where possible, 3 telephone calls). These contact attempts should be documented in the participant's medical record or study file.
- Should the participant continue to be unreachable, he or she will be considered to have withdrawn from the study with a primary reason of lost to follow-up.

8 STUDY ASSESSMENTS AND PROCEDURES

8.1 SCREENING PROCEDURES

Recruitment of service users will happen in hospital settings, after being admitted and in consultation with attending healthcare workers. Following the stabilization period, and in

consultation with the clinical team in the medical and psychiatric wards, the eligible, stabilized service user be identified by a member of the clinical team based on the clinical history and current diagnostic status. If they are eligible according to their clinical profile, the service user will be asked by a member of the clinical team if they would be willing to meet with a fieldworker regarding a research project. If the service user is willing, a trained fieldworker with a BPsych degree and experience in mental health research will visit the service user and will be introduced to the research project. They will be provided an information sheet, which will be summarized by the fieldworker verbally as well. The questions (1) “What is the purpose of the study?” (2) “What are the risks?” and (3) “What are the benefits?” will help to determine consent capacity, in line with South African psychiatric requirements that “a mental disorder should not prevent a patient from understanding what s/he consents to; a mental disorder should not prevent a patient from choosing decisively for/against the intervention; a mental disorder should not prevent a patient from communicating his/her consent (presuming that at least reasonable steps have been taken to understand the patient's communication if present at all), and a mental disorder should not prevent a patient from accepting the need for intervention”. If consent capability has been determined, the service user will be taken step-by-step through the informed consent form, and will be provided with a copy. If there is doubt around eligibility and capacity to provide consent, the fieldworker will engage with the fieldwork manager and PIs, who will consult the clinical team regarding further steps.

8.2 STUDY EVALUATIONS & PROCEDURES

Service users				
Baseline, 4-month follow-up fieldworker-administered questionnaire				
Measure	Items	Scoring	Used in South Africa	Source
Demographic background: Age, sex, language, housing, employment	5	Categorical Open answer	N/A	N/A

Internalised Stigma of Mental Illness (ISMI) scale (brief version)	10	4-point Likert-type scale: Strongly disagree, Disagree, Agree, Strongly agree	Yes	Matshabane OP, Appelbaum PS, Faure MC, et al. Lessons learned from the translation of the Internalised Stigma of Mental Illness (ISMI) scale into isiXhosa for use with South African Xhosa people with schizophrenia. Transcultural Psychiatry. 2023;0(0). doi:10.1177/13634615231168461
Alcohol, Smoking and Substance Involvement Screening Test (ASSIST) (Question 2)	10	5-point Likert-type scale: Never, Once or twice, Monthly, Weekly, Daily or almost daily	Yes	Adlard RJ, Roos T, Temmingh H. Alcohol, Smoking and Substance Involvement Screening Test validity in bipolar and psychotic disorders. S Afr J Psychiatr. 2023 Dec 21;29:2109. doi: 10.4102/sajpsychiatry.v29i0.2109.
Recovery Assessment Scale - Domains and Stages (RAS-DS)		4-point Likert-type scale: Untrue, A bit untrue, A bit true, Completely true	Yes	Hancock N, Scanlan JN, Honey A, Bundy AC, O'Shea K. Recovery Assessment Scale - Domains and Stages (RAS-DS): Its feasibility and outcome measurement capacity. Aust N Z J Psychiatry. 2015 Jul;49(7):624-33. doi: 10.1177/0004867414564084. Epub 2014 Dec 19. PMID: 25526940; PMCID: PMC4941096.
Medication adherence (tailored question)	3	Yes/No	No	N/A
Health service use (tailored question)	1	Yes/No	No	N/A
Hospitalisation history (tailored question)	2	Yes/No	No	N/A
Monthly semi-structured interviews				
Experiences of care				N/A
Acceptability of intervention				N/A
Practicality of intervention				N/A
Family and household interactions				N/A
Caregivers				
Baseline, 4-month, 9-month follow-up fieldworker-administered questionnaire				
Demographic background: Age, sex, language, housing, employment	5	Categorical Open answer	No	N/A
Health profile of household	7	Yes/No	No	N/A
Stigma by Association	9	5-point Likert scale ranging from “Never” to “Always”, scoring 1–5.	No	Goldberg JO, McKeag SA, Rose AL, Lumsden-Ruegg H, Flett GL. Too Close for Comfort: Stigma by Association in Family Members Who Live with Relatives with Mental Illness. Int J Environ Res Public Health. 2023 Mar 16;20(6):5209. doi: 10.3390/ijerph20065209.
Multidimensional Scale of Perceived Social Support	12	5-point Likert-type scale ranging from strongly disagree (1) to strongly agree (5)	Yes	Bruwer B, Emsley R, Kidd M, Lochner C, Seedat S. Psychometric properties of the Multidimensional Scale of Perceived Social Support in youth. Compr Psychiatry. 2008 Mar-Apr;49(2):195-201. doi: 10.1016/j.comppsych.2007.09.002.

Medication adherence (tailored question)	3	Yes/No	No	N/A
Care competent household measure (adapted from HIV care competency scale)	5	6-point Likert scale ranging from 'completely disagree' to 'completely agree'	Yes	Campbell LS, Masquillier C, Knight L, Delport A, Sematlane N, Dube LT, Wouters E. Stay-at-Home: The Impact of the COVID-19 Lockdown on Household Functioning and ART Adherence for People Living with HIV in Three Sub-districts of Cape Town, South Africa. AIDS Behav. 2022 Jun;26(6):1905-1922. doi: 10.1007/s10461-021-03541-0.
Household functioning	16	Agree/Disagree	Yes	Campbell LS, Masquillier C, Knight L, Delport A, Sematlane N, Dube LT, Wouters E. Stay-at-Home: The Impact of the COVID-19 Lockdown on Household Functioning and ART Adherence for People Living with HIV in Three Sub-districts of Cape Town, South Africa. AIDS Behav. 2022 Jun;26(6):1905-1922. doi: 10.1007/s10461-021-03541-0.
Monthly semi-structured interviews				
Acceptability of intervention				N/A
Practicality of intervention				N/A
Family and household interactions				N/A
Additional process measures				
Fidelity checklists (completed during each interaction with participant) and focus group discussions (every three months): Hospital staff implementing PSR PHC clinic staff implementing enhanced APC CHWs implementing CMED Observations: Interactions between CHWs and household members during visits (every three months) Weekly debriefing sessions between CHWs				

Measures		Service users	Caregivers	Hospital staff	PHC staff	CHWs	Managers
Baseline survey		X	X				
4-month follow-up survey		X	X				
Process measures	Monthly interviews	X	X				
	Monthly observations	X	X				
	Monthly FGDs					X	

	Weekly Feedback sessions					X	
	Fidelity checklists			X	X	X	
	Feedback workshops	X	X	X	X	X	X

8.3 ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

8.3.1 Definition of Adverse Event

Adverse event means any untoward medical occurrence associated with the use of an intervention in humans, whether or not considered intervention-related.

8.3.2 Definition of Serious Adverse Events (SAE)

An adverse event (AE) or suspected adverse reaction is considered "serious" if, in the view of either the investigator or sponsor, it results in any of the following outcomes: death, a life-threatening adverse event, inpatient hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the participant and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include a rapidly deteriorating mental state, suicidal ideation, and severe substance abuse leading to incapacity and medical or psychological harm.

8.3.3 Classification of an Adverse Event

8.3.3.1 Severity of Event

For adverse events (AEs) not included in the protocol defined grading system, the following guidelines will be used to describe severity.

- Mild – Events require minimal or no treatment and do not interfere with the participant's daily activities.
- Moderate – Events result in a low level of inconvenience or concern with the therapeutic measures. Moderate events may cause some interference with functioning.
- Severe – Events interrupt a participant's usual daily activity and may require systemic

drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating. Of note, the term “severe” does not necessarily equate to “serious”.]

8.3.3.2 Relationship to Study Intervention/Experimental Manipulation

All adverse events (AEs) will have their relationship to study procedures, including the intervention, assessed by an appropriately trained clinician based on temporal relationship and his/her clinical judgment. The degree of certainty about causality will be graded using the categories below.

Related – The AE is known to occur with the study procedures, there is a reasonable possibility that the study procedures caused the AE, or there is a temporal relationship between the study procedures and the event. Reasonable possibility means that there is evidence to suggest a causal relationship between the study procedures and the AE.

Not Related – There is not a reasonable possibility that the study procedures caused the event, there is no temporal relationship between the study procedures and event onset, or an alternate etiology has been established.

OR

Definitely Related – There is clear evidence to suggest a causal relationship, and other possible contributing factors can be ruled out. The clinical event occurs in a plausible time relationship to study procedures administration and cannot be explained by concurrent disease or other drugs or chemicals. The response to withdrawal of the study procedures should be clinically plausible. The event must be phenomenologically definitive.

Probably Related – There is evidence to suggest a causal relationship, and the influence of other factors is unlikely. The clinical event occurs within a reasonable time after administration of the study procedures, is unlikely to be attributed to concurrent disease or other drugs or chemicals, and follows a clinically reasonable response on withdrawal.

Potentially Related – There is some evidence to suggest a causal relationship (e.g., the event occurred within a reasonable time after administration of study procedures). However, other factors may have contributed to the event (e.g., the participant’s clinical condition, other concomitant events). Although an AE may rate only as “possibly related” soon after discovery, it can be flagged as requiring more information and later be

upgraded to “probably related” or “definitely related”, as appropriate.

Unlikely to be related – A clinical event whose temporal relationship to study procedures administration makes a causal relationship improbable (e.g., the event did not occur within a reasonable time after administration of the study procedures) and in which other drugs or chemicals or underlying disease provides plausible explanations (e.g., the participant’s clinical condition, other concomitant treatments).

Not Related – The AE is completely independent of study procedures administration, and/or evidence exists that the event is definitely related to another etiology. There must be an alternative, definitive etiology documented by the clinician.

8.3.3.3 Expectedness

A clinician with appropriate expertise in psychiatry will be responsible for determining whether an adverse event (AE) is expected or unexpected. An AE will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the study procedures.

8.3.4 Time Period and Frequency for Event Assessment and Follow-Up

The occurrence of an adverse event (AE) or serious adverse event (SAE) may come to the attention of study personnel during study visits and interviews of a study participant presenting for medical care, or upon review by the field supervisor.

Any medical or psychiatric condition that is present at the time that the participant is screened will be considered as baseline and not reported as an AE. However, if the study participant’s condition deteriorates at any time during the study, it will be recorded as an AE.

Changes in the severity of an AE will be documented to allow an assessment of the duration of the event at each level of severity to be performed. Documentation of onset and duration of each episode will be maintained for AEs characterized as intermittent.

The field manager will record events with start dates occurring any time after informed consent is obtained until 7 (for non-serious AEs) or 30 days (for SAEs) after the last day of study participation. At each study visit, the investigator will inquire about the occurrence of AE/SAEs since the last visit. Events will be followed for outcome information until resolution or stabilization.

8.3.5 Adverse Event Reporting

All AEs, not otherwise precluded per the protocol, will be captured on the appropriate case report form (CRF). Information to be collected includes event description, time of onset, clinician's assessment of severity, relationship to study procedures (assessed only by those with the training and authority to make a diagnosis), and time of resolution/stabilization of the event. All AEs occurring while on study will be documented appropriately regardless of relationship, and will be reported to the Data Safety Management Board and to the Biomedical Research Ethics Committee within 30 days of occurrence.

9 STATISTICAL CONSIDERATIONS

9.1 STATISTICAL HYPOTHESIS

- Primary Endpoint:
- We hypothesize that, compared to service users who receive care as usual (i.e. outpatient psychopharmaceutical support at PHC clinics), service users who receive the MhINT Recovery intervention for post-hospitalization support will have a reduced rate of acute psychiatric re-hospitalization after participating in intervention for 4 months. Alternatively, our null hypothesis is that there will be no difference in the effects of MhINT Recovery in reducing hospital re-admission after 4 months.
- Secondary Endpoint(s):

  i. We hypothesize that, compared to service users who receive care as usual (i.e. outpatient psychopharmaceutical support at PHC clinics), service users who receive the MhINT Recovery intervention for post-hospitalization support will have higher scores in recovery after participating in intervention for 4 months. Alternatively, our null hypothesis is that there will be no difference in the effects of MhINT Recovery in increasing recovery.

  ii. We hypothesize that, compared to service users who receive care as usual (i.e. outpatient psychopharmaceutical support at PHC clinics), service users who receive the MhINT Recovery intervention for post-hospitalization support will have lower scores in internalized stigma after participating in intervention for 4 months. Alternatively, our null hypothesis is that there will be no difference in the effects of MhINT Recovery in reducing internalized stigma.

iii. We hypothesize that, compared to service users who receive care as usual (i.e. outpatient psychopharmaceutical support at PHC clinics), service users who receive the MhINT Recovery intervention for post-hospitalization support will have higher scores in treatment adherence after participating in intervention for 4 months. Alternatively, our null hypothesis is that there will be no difference in the effects of MhINT Recovery in increasing treatment adherence.

9.2 Sample Size Determination

A sample of 86 individual service users are sampled – 43 per arm, obtained by sampling with a 95% power to determine a decrease in hospital re-admission (our primary outcome most difficult to impact) from an estimated 66% (12 months re-admission rate, district hospital in KwaZulu-Natal, Tomita & Moodley, 2016) to 41% (effect size = 25%) post-intervention over a period of 12 months. The proportion in the intervention arm is assumed to be 0.41 under the null hypothesis and 0.66 under the alternative hypothesis. This sample size has been calculated for a 2-sided Z-Test (Unpooled) and 0.1% significance level. The estimated effect size is conservative since this is a new intervention that has not been rigorously assessed in South Africa. We hope to decrease the re-admission levels by 30%, however we have powered the study on a lower effect size (25%) to avoid a type 2 error. One primary caregiver for each service user is additionally added.

9.3 Statistical Analyses

9.3.1 General Approach

A descriptive and outcome analysis of quantitative measures will be undertaken using IBM SPSS The re-hospitalization relapse variable will be derived from routine project monitoring data, allowing for the inclusion of data for all participants including those who did not complete endpoint interviews. A sensitivity analysis will be conducted to exclude individuals who had died or withdrawn. To estimate the potential effect of the intervention group at 4-months, quantitative outcomes will be compared between treatment arms, adjusting for baseline scores and clinic, using linear mixed models for continuous variables and generalized linear mixed models for binary variables based on an intention-to-treat analysis. We will analyze the data using an available case analysis, that is all individuals providing data for any outcome at any timepoint will be included.

10 REGULATORY, ETHICAL, AND STUDY OVERSIGHT CONSIDERATIONS

Full ethics approval has been obtained from the University of KwaZulu-Natal Biomedical Research Ethics Committee (BREC) and the University of Antwerp Institutional Research Ethics Body (attached). Informed consent, participant safety and all research ethics procedures will be followed in line with guidance from these bodies. Further, regulatory approval has been obtained from the National Department of Health Research Database. Additionally, the trial has been registered with South African National Clinical Trials Register (SANCTR). The protocol will also be published in a peer-reviewed journal.

Ethical Principles

The study will adhere to the following fundamental ethical guidelines for research involving vulnerable populations:

To Prevent Injury to Research Participants

This covers any potential psychological and/or physical harm brought on by the research. It also refers to safeguarding the rights and interests of participants. There is little chance of bodily injury. The research team is knowledgeable and experienced in determining when procedures, observations, interviews, and focus groups can be conducted without causing undue inconvenience to participants. Sensitive information communication will be taught to research staff. Each site will have clear referral procedures for social work or counselor support when needed. As described, service users and their families will have twice-monthly interactions with healthcare services, where monitoring of their mental state will occur. In cases where a deteriorating mental state is suspected, the investigators will be alerted, who will enter into discussions with the field team in order to designate a visit from a healthcare worker to the participant in question for assessment. If an adverse even occurs, the steps outlined above will be followed.

To Ensure the Safety of Research

Participation in the study is entirely voluntary. "Voluntary participation" means that before any research data is collected, informed consent to participate in the study must be obtained. "Informed consent" refers to a participant's agreement to participate in a study after being made aware of and comprehending the following: the purpose, methods, and procedures of the study; the research topic; the use of the data; the participant's right to

withdraw from the study at any time; and the possibility that participants who have withdrawn from the study may re-enter the study at any point. People will have time to consider whether or not to participate, and the process of gaining informed consent will not be rushed.

Before gaining informed consent, the researcher will make sure people understand the research by asking them to repeat what they have been told. Written documentation of informed consent will be kept private and kept in a file in a locked cabinet at the Centre for Research in Health Systems. Each participant will receive a copy of the consent form.

Mitigation of potential harms

Information indicating that participants are immediately at risk of negative outcomes may be obtained during the course of the study. Regardless of the trial arm a participant is in, we will refer them for recall or additional clinical evaluation if this happens. This strategy is based on previous studies and strikes a balance between protecting patient participants and acknowledging that inadequate management of severe mental illness is a prevalent issue that is the focus of the trial and intervention.

To Respect Cultural Traditions, Norms and Customs

Being of South African descent, the majority of the research team is cognisant of the diversity of backgrounds and cultures. As sensitivity to various cultures, customs, and norms will be respected, this won't hinder the research. Whichever language each participant feels most comfortable with— isiZulu or English — will be used for the interviews. A large proportion of the population of KwaZulu-Natal adhere to traditional cultural beliefs about mental illness, which will be respected by the research team and within the intervention implementation process. Efforts will be made to include traditional health practitioners and faith-based practitioners within individuals' care network.

To Enhance Equality

Every effort will be made to reduce the power imbalances that exist between participants and researchers. The research team will employ methodologies that are appropriate for working with vulnerable populations. For instance, the research team will use language that participants can understand rather than jargon. The research team will give enough time to explain the study and establish trust with participants during informed consent,

during intervention implementation, and during data collection interactions.

To Prevent Unrealistic Expectations

Regarding the study and the intended use of the data collected, the research team will be transparent and truthful. The research team will let the participants know what to anticipate and that, although health workers will not be compensated for their involvement in the study, service user participants and caregivers will.

To be fair

In order to avoid interfering with participants' personal time and obligations, the focus groups, workshops, and interviews will be arranged at their convenience.

To Honor Autonomy and Privacy

Should a participant choose not to participate in any aspect of the study, their request will be honored. The participants will be made fully aware that their choice to participate or not will not have any consequences. In order to maintain confidentiality, names, addresses, contact information, and other personal data will all be kept private and confidential for the purposes of hiring or gathering data, in compliance with the General Data Protection Regulation (2016) and the South African Protection of Personal Information Act No. 4 of 2013. Every participant in the study will be given a research number, and all information will be encrypted and kept private without revealing the identity or address of the subjects. No staff identifying information or names of medical facilities will be used. Paper-based information will be stored in a locked filing cabinet in the research team office, while electronic data will be stored on a password-protected computer in the Centre for Research in Health Systems' OneDrive secure database. Only the research team will have access to the data. Confidentiality agreements will be signed by transcribers. No third parties will receive participant names or information, and the results report will not name any specific participants. Only in the event that we believed there was a serious risk of harm to a research participant—typically only after consulting with the individual in question—would we divulge personal information to a third party. Participants may agree if they would like their names to appear in the printed materials. Data will be stored for five years following the final data collection, after which in will be destroyed in line with UKZN regulations.

11 BUDGET

UKZN - BUDGET ITEMS

1) Personnel Cost		YEAR 1				YEAR 2				YEAR 3				TOTAL	
Key Personnel	**Project role**	**Months**	**% Effor**	**ZAR**	**USD**	**onth**	**% Effo**	**ZAR**	**USD**	**Months**	**% Effort**	**ZAR**	**USD**	**ZAR**	**USD**
Andre Van Rensburg	Principal Investigator	12,0	30%	R 314 008,20	$20 933,88	12	30%	R 314 008,20	$20 933,88	12	30%	R 314 008,20	$20 933,88	R 942 024,60	$62 801,64
Inge Petersen	Co-Investigator	12,0	10%	R 129 094,50	$8 606,30	12	10%	R 129 094,50	$8 606,30	12	10%	R 129 094,50	$8 606,30	R 387 283,50	$25 818,90
Arvin Bhana	Co-Investigator	12,0	10%	R 129 094,50	$8 606,30	12	10%	R 129 094,50	$8 606,30	12	10%	R 129 094,50	$8 606,30	R 387 283,50	$25 818,90
Tasneem Kathree	Co-Investigator	12,0	30%	R 305 779,50	$20 385,30	12	30%	R 305 779,50	$20 385,30	12	30%	R 305 779,50	$20 385,30	R 917 338,50	$61 155,90
Ezra Susser			8%	R 286 176,91	$20 441,21		5%	R 191 641,95	$12 776,13		5%	R 191 641,95	$12 776,13	R 669 460,81	$45 993,47
Bonga Chiliza	Researcher	12,0	5%	R 142 635,00	$9 509,00	12	5%	R 142 635,00	$9 509,00	12	5%	R 142 635,00	$9 509,00	R 427 905,00	$28 527,00
Edwin Wouters	Researcher	12,0	5%	R 125 000,00	$8 333,33	12	5%	R 125 000,00	$8 333,33	12	5%	R 125 000,00	$8 333,33	R 375 000,00	$25 000,00
Carrie Brooke-Sumner	Researcher	12,0	10%	R 104 669,40	$6 977,96	12	10%	R 104 669,40	$6 977,96	12	10%	R 104 669,40	$6 977,96	R 314 008,20	$20 933,88
Londiwe Mthethwa	Data manager	12,0	0%	R -		12	30%	R 80 250,00	$5 350,00	12	30%	R 80 250,00	$5 350,00	R 160 500,00	$10 700,00
TBC	Psychologist	12	0%	R -		12	100%	R 286 650,00	$19 110,00	12	100%	R 286 650,00	$19 110,00	R 573 300,00	$38 220,00
FW X 5 for 3 months	Fieldworker	0	0%	R -		3	100%	R 126 000,00	$8 400,00	3	100%	R 126 000,00	$8 400,00	R 252 000,00	$16 800,00
UKZN Administration core team	Administrator	12	10%	R 97 035,00	$6 469,00	12	10%	R 97 035,00	$6 469,00	12	10%	R 97 035,00	$6 469,00	R 291 105,00	$19 407,00
TBC	Social Auxiliary Workers	12	100%					R 310 000,00	$20 666,67					R 310 000,00	$20 666,67
Gill Faris		12	30%	272 160,00	$18 144,00									R 272 160,00	$18 144,00
Total: Other Personnel				**R 1 905 653,01**	**$128 406,28**			**R 2 341 858,05**	**$156 123,87**			**R 2 031 858,05**	**$135 457,20**	**R 6 279 369,11**	**$419 987,35**
Total: Personnel Compensation				***R 1 905 653,01***	***$128 406,28***			***R 2 341 858,05***	***$156 123,87***			***R 2 031 858,05***	***$135 457,20***	***R 6 279 369,11***	***$419 987,35***

Direct Cost	Unit Cost	No	YEAR 1		Uni t Co	No	YEAR 2		Unit Cost	No	YEAR 3		TOTAL	
2) Travel, Subsitence & Conference														
Local road travel core team													R -	$0,00
Local accommodation													R -	$0,00
Local travel (PMB)			R 14 822,40	$988,16			R 14 822,40	$988,16			R 14 822,40	$988,16	R 44 467,20	$2 964,48
Domestic/regional travel (2 team members every quarter for 2 days)													R -	$0,00
quarter for 2 days)													R -	$0,00
Local Accommodation (2 ppl for 1 night, DBB) Cape Town													R -	$0,00
Local S&T (2 ppl for 1 night per quarter)													R -	$0,00
Travel Ezra				$0,00										
Total: Travel, Subsitence & Conference			**R 14 822,40**	**$988,16**			**R 14 822,40**	**$988,16**			**R 14 822,40**	**$988,16**	**R 44 467,20**	**$2 964,48**
3) Equipment														
Computer, laptops							R -	$0,00			R -	$0,00	R -	$0,00
Audio recorders							R -	$0,00			R -	$0,00	R -	$0,00
Devices for data collection							R -	$0,00			R -	$0,00	R -	$0,00
Mobile phones							R -	$0,00			R -	$0,00	R -	$0,00
Total: Equipment			**R -**				**R -**	**$0,00**			**R -**	**$0,00**	**R -**	**$0,00**
4) Consumables														
Ezra			R -	$0,00			R -	$0,00			R -	$0,00	R -	$0,00
Total: Consumables			**R -**	**$0,00**			**R -**	**$0,00**			**R -**	**$0,00**	**R -**	**$0,00**

5) CEI														
Community engagement workshops		R	39 000,00	$2 600,00		R	39 000,00	$2 600,00		R	39 000,00	$2 600,00	R	117 000,00	$7 800,00
Community consultant		R	-			R	-	$0,00					R	-	$0,00
Advisory committee		R	5 700,00	$380,00		R	5 985,00	$399,00		R	6 289,00	$419,27	R	17 974,00	$1 198,27
Transformation committee		R	5 700,00	$380,00		R	5 985,00	$399,00		R	6 289,00	$419,27	R	17 974,00	$1 198,27
Peer support workshops - Two per year		R	12 000,00	$800,00		R	12 000,00	$800,00		R	12 000,00	$800,00	R	36 000,00	$2 400,00
Peer support worker attendance fee		R	15 998,00	$1 066,53		R	16 797,50	$1 119,83		R	17 637,00	$1 175,80	R	50 432,50	$3 362,17
Workshop training		R	-			R	-						R	-	$0,00
Total: CEI		**R**	**78 398,00**	**$5 226,53**		**R**	**79 767,50**	**$5 317,83**		**R**	**81 215,00**	**$5 414,33**	**R**	**239 380,50**	**$15 958,70**
6) Dissemination														
Open access publication costs		R	-	$0,00									R	-	$0,00
Policy engagement with provincial and national gov															
Prov close out		R	-	$0,00		R	-	$0,00		R	-	$0,00	R	-	$0,00
Server cost						R	22 050,00	$1 470,00		R	22 050,00	$1 470,00	R	44 100,00	$2 940,00
Total: Dissemination		**R**	**-**	**$0,00**		**R**	**22 050,00**	**$1 470,00**		**R**	**22 050,00**	**$1 470,00**	**R**	**44 100,00**	**$2 940,00**
7) Risk management & assurance														
Audit fee															
Total: Risk management & assurance		**R**	**-**	**$0,00**		**R**	**-**	**$0,00**		**R**	**-**	**$0,00**	**R**	**-**	**$0,00**
8) External Intervention cost														
Train the trainers -trial intervention		R	-	$0,00		R	-	$0,00					R	-	$0,00
Social Auxilliary training workshops						R	28 500,00	$1 900,00					R	28 500,00	$1 900,00
Laboratory test cost		R	-										R	-	$0,00
Primary health care transformation committees															
Quality improvement mentor travel cost		R	-	$0,00									R	-	$0,00
Total: External Intervention cost		**R**	**-**	**$0,00**		**R**	**28 500,00**	**$1 900,00**		**R**	**-**	**$0,00**	**R**	**28 500,00**	**$1 900,00**
9) Other Direct Cost														
Communication expenses		R	14 352,00	$956,80		R	35 880,00	$2 392,00		R	35 880,00	$2 392,00	R	86 112,00	$5 740,80
Total: Other Direct Cost		**R**	**14 352,00**	**$956,80**		**R**	**35 880,00**	**$2 392,00**		**R**	**35 880,00**	**$2 392,00**	**R**	**86 112,00**	**$5 740,80**
10) Subawards														
Columbia - Indirect														
Total: subaward costs		**R**	**-**	**$0,00**		**R**	**-**	**$0,00**		**R**	**-**	**$0,00**	**R**	**-**	**$0,00**
Total: Other Direct Cost		***R***	***107 572,40***	***$7 171,49***		***R181 019,90***		***$12 067,99***		***R153 967,40***		***$10 264,49***	***R***	***442 559,70***	***$29 503,98***
TOTAL DIRECT COSTS		***R***	***2 013 225,41***	***$135 577,77***		***R2 522 877,95***		***$168 191,86***		***R2 185 825,45***		***$145 721,70***	***R***	***6 721 928,81***	***$449 491,33***
10) Indirect Cost														
Indirect including Columbia		R	358 833,03	$23 922,20		R	325 430,24	$21 695,35		R	298 451,04	$19 896,74	R	982 714,30	$65 514,29
Total: Indirect Cost		R	358 833,03	$23 922,20	#	R	325 430,24	$21 695,35		R	298 451,04	$19 896,74	R	982 714,30	$65 514,29
BUDGET TOTAL		R	2 372 058,44	$159 499,98		R	2 848 308,19	$189 887,21		R	2 484 276,49	$165 618,43	R	7 704 643,12	$515 005,62

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UNIVERSITY OF KWAZULU-NATAL
INYUVESI YAKWAZULU-NATALI

20 June 2025

Prof Inge Petersen (3106)
Dr Andries Petrus Janse Van Rensburg
(63777) Dr Arvin Bhana (23304)
School of Nursing & Public Health
Howard College

Dear PI's

Protocol reference number: BREC/00007597/2024
Project title: Feasibility of a health systems strengthening intervention to reduce hospital re-admission following acute psychiatric hospitalization among people living with severe mental illness in uMgungundlovu, KwaZulu-Natal
Non-Degree

FULL COMMITTEE APPROVAL LETTER

The Biomedical Research Ethics Committee (BREC) has considered the abovementioned application at a meeting held on 08 October 2024.

I wish to advise you that your response to BREC correspondence dated 16 September 2024, 25 October 2024 and 09 April 2025 were noted and approved by the Biomedical Research Ethics Committee at a meeting held on 10 June 2025.

Note: Please submit SANCTR approval to BREC once received.

This approval is valid for one year from **20 June 2025.** To ensure uninterrupted approval of this study beyond the approval expiry date, an application for recertification must be submitted to BREC on RIG before the expiry date.

Please ensure that any outstanding site permissions are obtained and forwarded to BREC for approval before commencing research at a new site.

Any amendments to this study, unless urgently required to ensure safety of participants, must be approved by BREC prior to implementation.

Your acceptance of this approval denotes your compliance with South African National Research Ethics Guidelines (2024), South African National Good Clinical Practice Guidelines (2020) (if applicable) and with UKZN BREC ethics requirements as contained in the UKZN BREC Terms of Reference and Standard Operating Procedures, all available at http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx. Pg. 1/…

Biomedical Research Ethics Committee Chair: Professor S Singh

UKZN Research Ethics Office Westville Campus, Govan Mbeki Building

Postal Address: Private Bag X54001, Durban 4000

Email: BREC@ukzn.ac.za

Website: http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx

BREC is registered with the South African National Health Research Ethics Council (REC-290408-009). BREC has US Office for Human Research Protections (OHRP) Federal-wide Assurance (FWA 678).

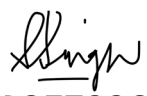
The following Committee members were present at the meeting that took place on 08 October 2024:

Prof S Singh	Dentistry (Chair)
Prof R Bhimma	Paediatrics & Child Health (Deputy Chair)
Prof D Wassenaar	Clinical Psychology and Research Ethics (Deputy Chair)
Prof T Hardcastle	Surgery (Deputy Chair)
Prof N Abbai	Microbiology and Molecular Biology
Dr O B Baloyi	Maternal and Child Health
Ptr S D Chili	Community/Lay Member (External)
Prof M Gordon	Laboratory Medicine and Medical Sciences
Dr A Harrichandparsad	Public Health
Prof K Hlongwana	Public Health
Dr Z Khumalo	KZN Health, General Medicine (External)
Dr M Khan	HIV Clinician

Dr R Lessells	Infectious Diseases Specialist
Prof D Moodley	Women's Health
Dr T Naicker	Laboratory Medicine and Medical Sciences
Dr K Naidoo	Public Health
Dr JR Ncayiyana	Nursing and Public Health
Prof S Paruk	Psychiatry
Dr P Pillay	Clinical Anatomy
Dr D Singh	Critical Care
Prof A Strode	Health Law and Research Ethics
Dr J Toohey	Law

We wish you well with this study. We would appreciate receiving copies of all publications arising out of this study.

This approval will be noted at the next BREC meeting to be held on 08 July 2025.
Yours sincerely,



PROFESSOR S SINGH

Chair: Biomedical Research Ethics Committee

Professor Wouters,Edwin
Buffel,Veerle
Masquillier,Caroline
van Olmen,Josefien
Departement Sociologie
Faculteit Sociale
Wetenschappen University of
Antwerp

Professor Charlotte De Backer
Chair Ethics Committee for
the Social Sciences and Humanities
City campus
Sint Jacobstraat 2
2000 Antwerpen

REFERENCE
SHW_2023_115_1

Date

04 April 2023

RE: Decision Ethics Committee for the Social Sciences and Humanities, file SHW_2023_115_1

FINAL POSITIVE CLEARANCE

Dear professor,

The independent Ethics Committee for the Social Sciences and Humanities (EASHW), installed by the Executive Board of the UAntwerp (03.07.2012) formulates a 'final positive clearance' with regard to your project **"Het gezin in de geestelijke gezondheidszorg: een experimentele studie naar de rol**

van het gezin in de zorg voor mensen met een ernstige mentale aandoening in

Zuid-Afrika." (FWO Senior project & VLIR-UOS Team project (aan de UA) + NIMH finanaciering (aan University of KwaZulu-Natal), PeopleSoft ID Antigoon: 47877).

In its decision making process, the EASHW is guided by the Royal Decree implementing the Act of 30 July 2018 on the protection of privacy in relation to the processing of personal data; the Royal Decree of May 7, 2004 regarding experiments on the human person; the General Data Protection Regulation; the EU-"Guidance Note for Researchers and Evaluators of Social Sciences and Humanities Research"; the deontological code for the researcher (Annex ZAP-statues UAntwerp), and the vademecum of the Belgian Privacy Commission on scientific research and privacy.

Kind regards,

Professor Charlotte De Backer

Chair Ethics Committee for
the Social Sciences and
Humanities

Information sheet General- Health Care Workers

TITLE OF THE RESEARCH PROJECT

Feasibility of a health systems strengthening intervention to reduce hospital re-admission following acute psychiatric hospitalization among people living with severe mental illness in uMgungundlovu, KwaZulu-Natal

Information Sheet

BREC reference number: KZNDoH reference number: Good Day

My name is XXX. I am working on a study led by Prof Andre Van Rensburg (jansevanrensburga@ukzn.ac.za) and a research team based at the University of KwaZulu-Natal.

People living with mental illness face many challenges. In South Africa, people living with these conditions struggle to cope when living in the community, with their family or caregivers. We are unsure about the kind of help and support people living with mental illness need in the community, and would like to spend some time with you to include your inputs into coming up with services that can better support them and their family.

What is this study all about?

In this study, we have gathered information from a range of people, including people who live with mental illness, their families, the healthcare workers, organisations and government. We used that information to work with these partners to come up with a service plan that can better support people living with mental illness, especially after they leave the hospital to go stay with their families.

Why have I been invited to take part study?

We believe that voices like yours should be at the heart of decisions that impact the care of people living with severe mental illness and their caregivers. As someone involved in service provision for person living with mental illness, we would liketo invite you to join an exciting research opportunity so that we can learn from you and better understand what barriers to care exist in the health and social system, so that you can play a crucial role in refining the interventions to strengthen care for people with severe mental illness

Who is doing the study?

This study is a collaboration between the University of KwaZulu-Natal, the University of Antwerp, Columbia University, the University of Cape Town and the Department of Health.

What will happen to me in this study?

If you agree, we would like to interview you regarding the care that is provided to people with severe mental illness in your facility. With your permission, we would like to take notes and record discussions with you, in order to be able to listen to it again later and write it down. Your name and any personal details will be removed from the recordings, and you will not be named when we write up our notes.

Can anything bad happen to me?

We can see no reason why you should suffer any harm from taking part in this study, and your decision to take part or not will not affect the relationship with anybody in the mental health system.

Can anything good happen to me?

Taking part in the study may be of benefit to people living with severe mental illness and their caregivers, in that the intervention you contribute to will strengthen the quality of care that people living with mental illness receive in the community. The services that we have developed will be focused on their needs, and we hope that it will meet their needs and expectations and enhance their well-being.

Financial Risk and benefit: If you participate in this study, you will not incur any financial costs. We appreciate the time that healthcare workers take to participate in the research. Healthcare workers will not be reimbursed. We will ensure that you are interviewed in an easily accessible venue in the department that you work in during work hours.

Will anyone know I am in the study?

All records identifying you will be kept private and only accessed by the researchers. Audio-recordings will be stored using password protected files that can only be accessed by the research team. Any quotes that are used will remain anonymous and will not be linked to you. A participant number will be used to name the electronic files containing your data. Your forms, and records associated with this study will be labelled with this number.

What if I do not want to do this?

Participation in this study is entirely voluntary, as such you are free to stop at any point without the need to give a reason. This will not have any effect on your involvement in any other part of the study or your access to care.

Who can I talk to about the study?

If you have any questions or require more information about this study, please contact the investigators:

Dr Andre Janse van Rensburg

University of KwaZulu-Natal

Tel: 0312601569

Email: jansevanrensburga@ukzn.ac.za

Dr Tasneem Kathree

University of KwaZulu-Natal

0312601569

Kathree@ukzn.ac.za

If you have questions about your rights and are not able to resolve your concerns with the study staff, or if you have general questions about what it means to be in a research study, contact:

BIOMEDICAL RESEARCH ETHICS ADMINISTRATION

Research Office, Westville Campus Govan Mbeki Building

University of KwaZulu-Natal Private Bag X 54001, Durban, 4000 KwaZulu-Natal, SOUTH AFRICA

Tel: 27 31 2602486 - Fax: 27 31 2604609

Email: BREC@ukzn.ac.za

Consent form for service users

UNIVERSITY OF KWAZULU-NATAL
INYUVESI YAKWAZULU-NATALI

TITLE OF THE RESEARCH PROJECT

Feasibility of a health systems strengthening intervention to reduce hospital re-admission following acute psychiatric hospitalization among people living with severe mental illness in uMgungundlovu, KwaZulu-Natal

Ifomu elivumelekile labasebenzisi bensizakalo You will be given a copy of this consent form
Uzonikezwa ikhophi yaleli fomu lemvume

BREC reference number: BREC/00005546/2023 KZNDoH reference number: KZ_202307_14

Good Day

My name is XXX. I am working on a study led by Prof Andre Van Rensburg (Vanrensburga@ukzn.ac.za) and a research team based at the University of KwaZulu-Natal. Thank you for considering taking part in this study.
Siyabonga ukuthi uvume ukuba ingxenye yalolucwaningo.

If you have any questions arising from the information sheet, please ask before you decide whether to take part.
Uma kunemibuzo evuswa ukufunda ulwazi osowulitholile, sicela uyibuze ngaphambi kokuba uvume ukubamba iqhaza kulolucwaningo

People living with mental illness face many challenges. In South Africa, people living with these conditions struggle to cope when living in the community, with their family or caregivers. We are unsure about the kind of help and support people living with mental illness need in the community, and would like to spend some time with you to include your inputs into coming up with services that can better support them and their family.

What is this study all about?

In this study, we have gathered information from a range of people, including people who

live with mental illness, their families, the healthcare workers, organisations and government. We used that information to work with these partners to come up with a service plan that can better support people living with mental illness, especially after they leave the hospital to go stay with their families.

Why have I been invited to take part study?

We believe that voices like yours should be at the heart of decisions that impact the care of people living with severe mental illness and their caregivers. As someone involved in service provision for person living with mental illness, we would like to invite you to join an exciting research opportunity so that we can learn from you and better understand what barriers to care exist in the health and social system, so that you can play a crucial role in refining the interventions to strengthen care for people with severe mental illness. Researchers may visit you a few different times over the course of the study. They will make appointments with you and your family so that they can interview you at a convenient time and place.

Who is doing the study?

This study is a collaboration between the University of KwaZulu-Natal, the University of Antwerp, Columbia University, the University of Cape Town and the Department of Health.

Do I have to participate in this study?

It is your choice whether you want to participate in this study or not. If you decide not to participate, you will not be prejudiced in any way, and your decision will not affect the treatment you receive at your clinic. If you decide to take part, you are still free to withdraw from the study at any time and without giving a reason. Should you decide not to take part, or if you withdraw from the study, this will in no way affect the care you receive at the clinic. Should you agree to participate, we will ask you to sign the attached consent form.

Ngabe kufanele ngibambe iqhaza kulolu cwaningo?

Kungukukhetha kwakho ukuthi ufuna ukubamba iqhaza kulolu cwaningo noma cha. Uma uthatha isinqumo sokungahlanganyeli, ngeke ubandlululwe nganoma iyiphi indlela, futhi isinqumo sakho ngeke sithinte ukwelashwa okutholayo emtholampilo wakho. Uma uthatha isinqumo sokubamba iqhaza, usekhululekile ukuhoxa ocwaningweni nganoma yisiphi isikhathi futhi ngaphandle kokunikeza isizathu. Uma ngabe uthatha isinqumo sokungahlanganyeli, noma uma uhoxa ocwaningweni, lokhu ngeke kuthinte ukunakekelwa okutholayo emtholampilo. Uma kufanele uvume ukubamba iqhaza, sizokucela ukuthi usayine ifomu lokuvuma elinamathiselwe.

Will the information I provide remain confidential?

The regulations from the Research Ethics Committee at Universities of Cape Town and

KwaZulu Natal will apply to all information gathered through interviews. These will be stored in a password-locked computer files and locked cabinets within University of Cape Town and KwaZulu-Natal. We will also comply with laws around personal data including POPIA (Protection of Personal Information Act) in South Africa and General Data Protection Regulation (GDPR) in the United Kingdom.

We will: 1) hold interviews in an area with as much privacy as is possible, 2) use experienced and well-trained fieldworkers to conduct interviews who have signed confidentiality agreements to conduct interviews,

3) store the interview information in a secure online platform, and 4) remove your personal details from the information and use a participant number to name files containing your data. Your forms, and records associated with this study will be labelled with this number. Only information without your personal details will be shared with researchers from the study's Universities for analysis. All study documents will be stored safely and accessible only to members of the research team.

All records identifying you will be kept private and only accessed by the researchers. A participant number will be used to name the electronic files containing your data. Your forms, and records associated with this study will be labelled with this number.

What are the possible drawbacks or discomforts of participating in this study?

We can see no reason why you should suffer any harm from taking part in this study, and your decision to take part or not will not affect the relationship with anybody in the mental health system.

If you agree to participate in this study, a fieldworker will spend time with you and your family, and you will be asked a number of questions about your mental health problem/s in interviews. If you experience any discomfort or distress during the course of this process, related to your condition or you are thought to need treatment, you will be referred to the primary health care psychologist serving the sub-district to help you with your condition/concerns.

Yiziphi izingqinamba noma ukungaphatheki kahle kokubamba iqhaza kulolu cwaningo?

Uma uvuma ukubamba iqhaza kulolu cwaningo, osebenza emkhakheni uzochitha isikhathi nawe nomndeni wakho, futhi uzobuzwa imibuzo eminingana ngenkinga yakho yezempilo yengqondo/s ezingxoxweni. Uma uhlangabezana nanoma yikuphi ukungaphatheki kahle noma usizi phakathi nale nqubo, okuhlobene nesimo

sakho noma kucatshangwa ukuthi udinga ukwelashwa, uzodluliselwa kudokotela wokuqala wezokunakekelwa kwempilo okhonza isifunda esingezansi ukukusiza ngesimo / ngamaconcerns akho.

What are the possible benefits of participating in this study?

If you participate in this study, you will not incur any financial costs. We appreciate the time taken to participate in the study and you will receive a supermarket voucher valued at R150-00 (one hundred and fifty Rands) as a gesture of thanks to acknowledge the time and contributions that you have given towards the study. We hope that the study results will help us to improve the service provision for people living with mental illness in the community.

Yiziphi izinzuzo ezingaba khona zokubamba iqhaza kulolu cwaningo?

Uzothola ivawusha yesuphamakethe ebiza ku-R150-00 isikhathi sakho. Siyethemba ukuthi imiphumela yocwaningo izosisiza ukuthi sithuthukise ukuhlinzekwa kwezidingo zabantu abaphila nokugula kwengqondo emphakathini.

Data Handling and confidentiality

Your identity will not be disclosed to anybody except the Ethics committee and/or regulatory authorities during the course and after completion of the study if required.

Ingabe ulwazi engilunikezayo luzohlala luyimfihlo?

Imithethonqubo evela kwi komidi lezimilo zocwaningo i-Research Ethics Committee eNyuvesi yaseKapa kanye naKwaZulu Natali ingena kulo lonke ulwazi oluqoqwe ngezingxoxo. Lokhu kuzogcinwa kumafayela e-computer akhiyelwe ngama-password namakhabethe akhiyiwe eNyuvesi yaseKapa naKwaZulu-Natal. Sizophinde futhi sithobele imithetho emayelana nolwazi oluqoqiwe ngomuntu siqu ehlanganisa i-POPIA (Umthetho Wokuvikela Ulwazi Ngomuntu Siqu) eNingizimu Afrika kanye Nomthetho Ojwayelekile Wokuvikelwa lolwazi oluqoqiwe (GDPR) e-United Kingdom.

Sizokwenza: 1) ukubamba izingxoxo endaweni esesithe ukugcina izimfihlo, 2) sisebenzise abasebenzi abanolwazi nabaqeqeshwe kahle ukuze benze izingxoxo futhi basayine izivumelwano zokugcina imfihlo, 3) sigcine imininingwane yengxoxo endaweni evikelekile kwizinkundla zomoya we-internet, kanye no-4) sizosusa imininingwane ngawe siqu kulwazi oluqoqiwe bese sisebenzisa inombolo yombambi qhaza ukubhala amafayela aqukethe ulwazi oluqoqiwe ngawe.

Amafomu akho, namarekhodi ahlobene nalolu cwaningo azolebulwa (labelled) ngale nombolo. Ulwazi olungenayo imininingwane ngawe siqu kuphela oluzokwabelwa abacwaningi abavela emaNyuvesi ocwaningo ukuze luhlaziywe. Yonke imibhalo yocwaningo izogcinwa ngokuphepha futhi amalungu ethimba locwaningo azofinyelela kuyo kuphela.

Wonke amarekhodi analowazi oluyizinkomba ngawe azogcinwa eyimfihlo futhi kuzofinyelela abacwaningi kuphela kuwo. Inombolo yombambi qhaza izosetshenziswa ukubhala amafayela akwi-computer aqukethe ulwazi oluqoqiwe lwakho.

Amafomu akho, namarekhodi ahlobene nalolu cwaningo azolebulwa ngale nombolo.

Ukuphathwa kolwazi oluqoqiwe (data) nokugcinwa luyimfihlo?

Angeke budalulwe ubuwena (imininingwane yakho) kunoma ubani ngaphandle kwekomidi Lezimiso Zokuziphatha (Ethics committee) kanye/noma iziphathimandla ezilawulayo ucwaningo phakathi nocwaningo noma nalapho seluphothuliwe uma kudingeka.

How will we report this research?

We intend to publish the findings so that others can also learn from the study. We will report our results and other aspects of the study in scholarly journals, conferences and to the Department of Health via policy briefs and other reporting structures. No identifying information will be used. In line with current requirements from peer-reviewed journals, all research data will be made publicly available once it has been anonymised within a specific period after the research has ended. The researchers will make the data from this research project available publicly upon the request from other researchers.

This study has been ethically reviewed and approved by the UKZN Biomedical research Ethics Committee (approval number BREC reference number: BREC/).

Sizolubika kanjani lolu cwaningo?

Sihlose ukushicilela okutholakele ukuze abanye bakwazi nokufunda ocwaningweni. Sizobika imiphumela yethu nezinye izici zocwaningo kumaphephabhuku ezifundo, izingqungquthela kanye noMnyango Wezempilo ngezithangami zenqubomgomo nezinye izinhlaka zokubika. Akukho minininingwane ekhomba izosetshenziswa. Ngokuhambisana nezidingo zamanje ezivela

kumaphephabhuku abukezwe ontanga, yonke imininingwane yocwaningo izotholakala emphakathini uma sekungaziwa esikhathini esithile ngemuva kokuphela kocwaningo. Abaphenyi bazokwenza imininingwane evela kule phrojekthi yocwaningo itholakale esidlangalaleni ngesicelo esivela kwabanye abacwaningi.
Lolu cwaningo lubuye lwabuyekezwa ngokuziphatha futhi lwavunywa yi-UKZN Biomedical Research Ethics Committee (inombolo yokugunyazwa kwenombolo ye-BREC: BREC / 00005546/2023).

In the event of any problems or concerns/questions you may contact the Principle Investigator, André Janse van Rensburg on 031 260 1709 or the UKZN Biomedical Research Ethics Committee, contact details as follows:
Uma kwenzeka kunezinkinga noma ukukhathazeka / imibuzo ungaxhumana noMphenyi we-Principle, u-André Janse van Rensburg ngomhlaka 031 260 1709 noma iKomidi Lezokuziphatha lase-UKZN Biomedical, imininingwane yokuxhumana ngale ndlela elandelayo:

For questions related to the study ***Ngemibuzo ehlobene nocwaningo***	**For Your rights as a research participant** ***Ngamalungelo akho njengomhlanganyeli wokucwaninga***
The Principal Investigator **Dr André Janse van Rensburg** **Centre for Rural Health** **4th Floor George Campbell Building** **Howard College** **Private Bag X 54001** **Durban** **4000** **KwaZulu-Natal, SOUTH AFRICA** **Tel: 27 31 260 1709** **Email: jansevanrensburga@ukzn.ac.za**	**BIOMEDICAL RESEARCH ETHICS COMMITTEE (BREC)** **Research Office, Westville Campus** **Govan Mbeki Building** **Private Bag X 54001** **Durban** **4000** **KwaZulu-Natal, SOUTH AFRICA** **Tel: 27 31 2604769 - Fax: 27 31 2604609**

	Email: BREC@ukzn.ac.za

You will be given a copy of the information sheet and consent form.

Uzonikezwa ikhophi yalolulwazi nafomu ekhombisa ukuthi uyavuma ukusebenzisana nathi kulolucwaningo

	Statement	**Please tick**
	I confirm that I have read and understood the information sheet for the above study. ***Ngiyavuma futhi ngiqinisekisa ukuthi ngilifundile futhi ngaliqonda kahle ulwazi olubhaliwe ngalolucwaningo***	
	I have had the opportunity to consider the information and ask questions which have been answered to my satisfaction. ***Ngibenalo ithuba lokufunda futhi ngiqonde kahle ulwazi engilunikiwe futhi ngabuza nemibuzo yaphendulwa ngokwanelisekayo***	
	I consent voluntarily to have my activities observed and being interviewed, and understand that if I decide at any time to no longer take part, I can notify the researchers and withdraw without having to give a reason. ***Ngivuma ngokuzithandela ukuthi imisebenzi yami ibhekwe futhi kuxoxwe nayo, futhi ngiyaqonda ukuthi uma nginquma nganoma isiphi isikhathi ukuthi ngingabe ngisabamba iqhaza, ngingakwazi ukwazisa abacwaningi futhi ngihoxe ngaphandle***	

	kokuthi nginikeze isizathu.	
	I consent to my observations and interview being audio recorded. ***Ngiyavuma ukuthi engikubonile kanye nenhlolokhono irekhodwe.***	
	I consent to the processing of my personal information for the purposes explained to me in the Information Sheet. I understand that such information will be handled in accordance with the terms of the POPIA Act (2013) ***Ngiyavuma ukuba imininingwane yami ingacutshungulwa futhi isetshenziswe ngonjongo echazwe kulwazi engilunikeziwe. Ngiyaqonda ukuthi leminingwane izophathwa futhi isetshenziswe ngokuhambisana nemithetho kaHulumeni ikakhulukazi i-POPIA Act (2013)***	
	I understand that confidentiality and anonymity will be maintained, and it will not be possible to identify me in any research outputs. ***Ngiyaqonda ukuthi konke kuzophathwa njengemfihlo futhi kungaziwa ukuthi kushiwo ngubani***	
	I understand that recordings and the written versions of the recordings will only be accessed by the members of the research team and a professional transcriber who would have signed a confidentiality agreement. I give permission for the research team and a professional transcriber to have access to the recording of my consultation. **Ngiyaqonda futhi ukuthi konke okuqoshiwe nokubhaliwe kuzobonwa futhi kusetshenziswe amalungu alolucwaningo nabaqeqeshelwe ukubhala. Ngiyalinikeza ithimba labacwaningi nababhali imvume yokuthola okuqoshwe ngesikhathi sixoxa**	

Participant's statement:

Isitatimende sobambe iqhaza:

I,……

Mina----------

(Name of participant in block letters)

(Igama lobamba iqhaza ngamagama amakhulu)

have read the information sheet and consent form, or they have been read to me. I understand what the study involves and have been given the opportunity to discuss it and ask questions. I voluntarily agree to take part in this research study.

Ngiyilifundile noma ngifundelwe iphepha lolwazi mayelana nocwaningo. Ngiyaqonda ukuthi lolucwaningo lumayelana nani futhi ludingani. Ngilitholile ithuba lokuxoxa ngalo ngibuze nemibuzo. Ngizivumela ngokwami ngingaphoqiwe ukuba yingxenye yalolucwaningo.

……..…… ……

Signature of Participant Date

Investigator's statement:
Isitatimende somcwaningi

I…….
Mina----------

(Name of investigator or designate in block letters) (Igama lomcwaningi ngamagama amakhulu)

confirm that I have carefully explained the nature and purpose of the study to the participant namedabove. Ngiyaqinisekisa ukuthi ngichaze kahle imvelo nenjongo yalolucwaningo kulona ovume ukubamba iqhaza

…… ……

Signature of investigator Date

If I have any further questions or concerns or queries related to the study, I understand that I may contact the researcher at 031 260 1709 or jansevanrensburga@ukzn.ac.za.

If I have any questions or concerns about my rights as a study participant, or if I am concerned about an aspect of the study or the researchers then I may contact the Biomedical Research Ethics Committee (details above).

Consent form for Healthcare workers

TITLE OF THE RESEARCH PROJECT: Feasibility of a health systems strengthening intervention to reduce hospital re-admission following acute psychiatric hospitalization among people living with severe mental illness in uMgungundlovu, KwaZulu-Natal

You will be given a copy of this consent form

BREC reference number: **KZNDoH reference number:**

Thank you for considering taking part in this study. ***Siyabonga ukuthi uvume ukuba ingxenye yalolucwaningo***.

If you have any questions arising from the information sheet, please ask before you decide whether to take part.

Uma kunemibuzo evuswa ukufunda ulwazi osowulitholile, sicela uyibuze ngaphambi kokuba uvume ukubamba iqhaza kulolucwaningo

What are the possible benefits of participating in this study?

We hope that the study results will help us to improve the service provision for people living with mental illness in the community.

What are the possible drawbacks or discomforts of participating in this study?

If you agree to participate in this study, a fieldworker will spend time with you and your family, and you will be asked a number of questions about your mental health problem/s in interviews. If you experience any discomfort or distress during the course of this process, related to your condition or you are thought to need treatment, you will be referred to the primary health care psychologist serving the sub-district to help you with your condition/concerns.

Do I have to participate in this study?

It is your choice whether you want to participate in this study or not. If you decide not to participate, you will not be prejudiced in any way, and your decision will not affect the

treatment you receive at your clinic. If you decide to take part, you are still free to withdraw from the study at any time and without giving a reason. Should you decide not to take part, or if you withdraw from the study, this will in no way affect the care you receive at the clinic. Should you agree to participate, we will ask you to sign the attached consent form.

How will we report this research?

We intend to publish the findings so that others can also learn from the study. We will report our results and other aspects of the study in scholarly journals, conferences and to the Department of Health via policy briefs and other reporting structures. No identifying information will be used. In line with current requirements from peer-reviewed journals, all research data will be made publicly available once it has been anonymised within a specific period after the research has ended. The researchers will make the data from this research project available publicly upon the request from other researchers.

This study has been ethically reviewed and approved by the UKZN Biomedical research Ethics Committee (approval number___).

In the event of any problems or concerns/questions you may contact the Principle Investigator, André Janse van Rensburg on 031 260 1709 or the UKZN Biomedical Research Ethics Committee, contact details as follows:

For questions related to the study	**For Your rights as a research participant**
The Principal Investigator **Dr André Janse van Rensburg** **Centre for Rural Health** **4th Floor George Campbell Building Howard College** **Private Bag X 54001 Durban 4000** **KwaZulu-Natal, SOUTH AFRICA Tel: 27 31 260 1709** **Email: jansevanrensburga@ukzn.ac.za**	**BIOMEDICAL RESEARCH ETHICS COMMITTEE (BREC)** **Research Office, Westville Campus** **Govan Mbeki Building** **Private Bag X 54001** **Durban** **4000** **KwaZulu-Natal, SOUTH AFRICA Tel: 27 31 2604769 - Fax: 27 31 2604609** **Email: BREC@ukzn.ac.za**

You will be given a copy of the information sheet and consent form.
Uzonikezwa ikhophi yalolulwazi nafomu ekhombisa ukuthi uyavuma ukusebenzisana nathi kulolucwaningo

Statement	**Please tick**
I confirm that I have read and understood the information sheet for the above study. ***Ngiyavuma futhi ngiqinisekisa ukuthi ngilifundile futhi ngaliqonda kahle ulwazi olubhaliwe ngalolucwaningo***	

	I have had the opportunity to consider the information and ask questions which have been answered to my satisfaction. ***Ngibenalo ithuba lokufunda futhi ngiqonde kahle ulwazi engilunikiwe futhi*** ***ngabuza nemibuzo yaphendulwa ngokwanelisekayo***	
	I consent voluntarily to participate in an interview and understand that if I decide at any time to no longer take part, I can notify the researchers and withdraw without having to give a reason. ***Ngivuma ngokuzithandela ukubamba iqhaza kunhlolokhono futhi ngiyaqonda ukuthi uma nginquma noma nini ukungabambi iqhaza, ngingazisa abacwaningi futhi ngihoxe ngaphandle kokunikeza isizathu.***	
	I consent to my interview being audio recorded. ***Ngiyavuma ukuthi inhlolokhono yami iqoshwe umsindo.***	
	I consent to the processing of my personal information for the purposes explained to me in the Information Sheet. I understand that such information will be handled in accordance with the terms of the POPIA Act (2013) ***Ngiyavuma ukuba imininingwane yami ingacutshungulwa futhi isetshenziswe*** ***ngonjongo echazwe kulwazi engilunikeziwe. Ngiyaqonda ukuthi leminingwane izophathwa futhi isetshenziswe ngokuhambisana nemithetho kaHulumeni***	

	ikakhulukazi i-POPIA Act (2013)	
	I understand that confidentiality and anonymity will be maintained, and it will not be possible to identify me in any research outputs. ***Ngiyaqonda ukuthi konke kuzophathwa njengemfihlo futhi kungaziwa ukuthi kushiwo ngubani***	
	I understand that recordings and the written versions of the recordings will only be accessed by the members of the research team and a professional transcriber who would have signed a confidentiality agreement. I give permission for the research team and a professional transcriber to have access to the recording of my consultation. Ngiyaqonda futhi ukuthi konke okuqoshiwe nokubhaliwe kuzobonwa futhi kusetshenziswe amalungu alolucwaningo nabaqeqeshelwe ukubhala. Ngiyalinikeza ithimba labacwaningi nababhali imvume yokuthola okuqoshwe ngesikhathi sixoxa	
	I understand that some of the information I share that will be published in academic journals or presented at public and academic events in the future, however all data will be kept anonymous to maintain confidentiality. Ngyaqonda ukuthi ulwazi esabelene ngalo lungasiza ekungeneleleni ezimweni ezithize nase kwenzeni izinhlelo ezinye zocwaningo oluzobhalwa emabhukwini olwazi futhi lwethulwe kwimiphakathi noma emicimbini ehlukene kepha kuqikelelwe ukuthi luyimfihlo futhi akuveli ukuthi luvelaphi	

Participant's statement:

Isitatimende sobambe iqhaza:

I,……

Mina

(Name of participant in block letters)

(Igama lobamba iqhaza ngamagama amakhulu)

have read the information sheet and consent form, or they have been read to me. I understand what the study involves and have been given the opportunity to discuss it and ask questions. I voluntarily agree to take part in this research study.
Ngiyilifundile noma ngifundelwe iphepha lolwazi mayelana nocwaningo. Ngiyaqonda ukuthi lolucwaningo lumayelana nani futhi ludingani. Ngilitholile ithuba lokuxoxa ngalo ngibuze nemibuzo. Ngizivumela ngokwami ngingaphoqiwe ukuba yingxenye yalolucwaningo.

……..…… ……

Signature of Participant Date

Investigator's statement:

Isitatimende somcwaningi

I…….

Mina

(Name of investigator or designate in block letters) (Igama lomcwaningi ngamagama amakhulu)

confirm that I have carefully explained the nature and purpose of the study to the participant named above.

Ngiyaqinisekisa ukuthi ngichaze kahle imvelo nenjongo yalolucwaningo kulona ovume ukubamba iqhaza

…… ……

Signature of investigator Date

If I have any further questions or concerns or queries related to the study, I understand that I may contact the researcher at 031 260 1709 or jansevanrensburga@ukzn.ac.za.

If I have any questions or concerns about my rights as a study participant, or if I am concerned about an aspect of the study or the researchers then I may contact the Biomedical Research Ethics Committee (details above).

Information sheet for Care Givers- Control

TITLE OF THE RESEARCH PROJECT: Feasibility of a health systems strengthening intervention to reduce hospital re-admission following acute psychiatric hospitalization among people living with severe mental illness in uMgungundlovu, KwaZulu-Natal

Information Sheet

BREC reference number: **KZNDoH reference number:**

Good Day

My name is XXX. I am working on a study led by Prof Andre Van Rensburg (Vanrensburga@ukzn.ac.za) and a research team based at the University of KwaZulu-Natal.

People living with mental illness face many challenges. In South Africa, people living with these conditions struggle to cope when living in the community, with their family or caregivers. We are unsure about the kind of help and support people living with mental illness need in the community, and would like to spend some time with you to include your inputs into coming up with services that can better support you and your family.

What is this study all about?

In this study, we have gathered information from a range of people, including people who live with mental illness, their families, the healthcare workers, organisations and government and have used that information to work with these partners to come up with a service plan that can better support people living with mental illness, especially after they leave the hospital to go stay with their families.

Why have I been invited to take part study?

We believe that voices like yours should be at the heart of decisions that impact your life and the lives of people you care about. As a caregiver of a person living with mental illness, we would like to invite you to join an exciting research opportunity so that we can learn from you and better understand what life supporting someone living with mental illness is really like and so that you can play a crucial role in the interventions needed to strengthen their care and participate in decisions that affect the research design and its outputs.

Who is doing the study?

This study is a collaboration between the University of KwaZulu-Natal, other universities, and the Department of Health.

What will happen to me in this study?

If you agree, we would like to spend some time with [INSERT SERVICE USER NAME] and his/her caregivers after he/she has left the hospital. We would also like to interview you regarding your challenges and support in the community during the care of [INSERT SERVICE USER NAME]. With your permission, we would like to take notes and record discussions with you, in order to be able to listen to it again later and write it down. Your name and any personal details will be removed from the recordings, and you will not be named when we write up our notes.

What are the possible benefits of participating in this study?

Taking part in the study may be of benefit to you, in that the intervention you contribute to strengthening the quality of care that people living with mental illness receive in the community. The services that we will develop will be focused on their needs, and we hope that it will meet their needs and expectations and enhance their well-being. We appreciate the time you have taken to participate and as a token to appreciation you will receive a supermarket voucher valued at R150-00 for your time. We hope that the study results will help us to improve the service provision for people living with mental illness in the community.

What are the possible drawbacks or discomforts of participating in this study?

We can see no reason why you should suffer any harm from taking part in this study, and your decision to take part or not will not affect the relationship with anybody that provides you with services.

If you agree to participate in this study, a fieldworker will spend time with you and your family, and you will be asked a number of questions about the mental health problem/s of your family member/person that you care for in interviews. If you experience any discomfort or distress during the course of this process, related to your condition or you are thought to need treatment, you will be referred to the primary health care psychologist serving the sub-district to help you with your condition/concerns.

Will anyone know I am in the study?

All records identifying you will be kept private and only accessed by the researchers. Audio-recordings will be stored using password protected files that can only be accessed by the research team. Any quotes that are used will remain anonymous and will not be linked to you. A participant number will be used to name the electronic files containing your data. Your forms, and records associated with this study will be labelled with this number.

What if I do not want to do this?

Participation in this study is entirely voluntary, as such you are free to stop at any point without the need to give a reason. This will not have any effect on your involvement in any otherpart of the study or your access to care.

Who can I talk to about the study?

If you have any questions or require more information about this study, please contact the investigators:

Dr Andre Janse van Rensburg

University of KwaZulu-Natal

Tel: 0312601569

Email: jansevanrensburga@ukzn.ac.za

Dr Tasneem Kathree

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BIOMEDICAL RESEARCH ETHICS ADMINISTRATION

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University of KwaZulu-Natal Private Bag X 54001, Durban, 4000 KwaZulu-Natal, SOUTH AFRICA

Tel: 27 31 2602486 - Fax: 27 31 2604609

Email: BREC@ukzn.ac.za

Information sheet for Care Givers-Intervention

TITLE OF THE RESEARCH PROJECT: Feasibility of a health systems strengthening intervention to reduce hospital re-admission following acute psychiatric hospitalization among people living with severe mental illness in uMgungundlovu, KwaZulu-Natal

Information Sheet

BREC reference number: **KZNDoH reference number:**

Good Day

My name is XXX. I am working on a study led by Prof Andre Van Rensburg (Vanrensburga@ukzn.ac.za) and a research team based at the University of KwaZulu-Natal.

People living with mental illness face many challenges. In South Africa, people living with these conditions struggle to cope when living in the community, with their family or caregivers. We are unsure about the kind of help and support people living with mental illness need in the community, and would like to spend some time with you to include your inputs into coming up with services that can better support you and your family.

What is this study all about?

In this study, we have gathered information from a range of people, including people who live with mental illness, their families, the healthcare workers, organisations and government and have used that information to work with these partners to come up with a service plan that can better support people living with mental illness, especially after they leave the hospital to go stay with their families.

Why have I been invited to take part study?

We believe that voices like yours should be at the heart of decisions that impact your life and the lives of people you care about. As a caregiver of a person living with mental illness, we would like to invite you to join an exciting research opportunity so that we can learn from you and better understand what life supporting someone living with mental illness is really like and so that you can play a crucial role in the interventions needed to strengthen their care and participate in decisions that affect the research design and its outputs.

Who is doing the study?

This study is a collaboration between the University of KwaZulu-Natal, other universities, and the Department of Health.

What will happen to me in this study?

If you agree, we would like to spend some time with [INSERT SERVICE USER NAME] and his/her caregivers after he/she has left the hospital. We would also like to interview you regarding your challenges and support in the community during the care of [INSERT SERVICE USER NAME]. We would like to introduce you to a program to help the families of people living with severe mental illness to so that they do not relapse and need to be admitted to hospital. This will involve regular visits from the study researchers during the study period. With your permission, we would like to take notes and

record discussions with you, in order to be able to listen to it again later and write it down. Your name and any personal details will be removed from the recordings, and you will not be named when we write up our notes.

What are the possible benefits of participating in this study?

Taking part in the study may be of benefit to you, in that the intervention you contribute to strengthening the quality of care that people living with mental illness receive in the community. The services that we will develop will be focused on their needs, and we hope that it will meet their needs and expectations and enhance their well-being. We appreciate the time you have taken to participate and as a token to appreciation you will receive a supermarket voucher valued at R150-00 for your time. We hope that the study results will help us to improve the service provision for people living with mental illness in the community.

What are the possible drawbacks or discomforts of participating in this study?

We can see no reason why you should suffer any harm from taking part in this study, and your decision to take part or not will not affect the relationship with anybody that provides you with services.

If you agree to participate in this study, a fieldworker will spend time with you and your family, and you will be asked a number of questions about the mental health problem/s of your family member/person atht you care for in interviews. If you experience any discomfort or distress during the course of this process, related to your condition or you are thought to need treatment, you will be referred to the primary health care psychologist serving the sub-district to help you with your condition/concerns.

Will anyone know I am in the study?

All records identifying you will be kept private and only accessed by the researchers. Audio-recordings will be stored using password protected files that can only be accessed by the research team. Any quotes that are used will remain anonymous and will not be linked to you. A participant number will be used to name the electronic files containing your data. Your forms, and records associated with this study will be labelled with this number.

What if I do not want to do this?

Participation in this study is entirely voluntary, as such you are free to stop at any point without the need to give a reason. This will not have any effect on your involvement in any otherpart of the study or your access to care.

Who can I talk to about the study?

If you have any questions or require more information about this study, please contact the investigators:

Dr Andre Janse van Rensburg

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Tel: 27 31 2602486 - Fax: 27 31 2604609

Email: BREC@ukzn.ac.za

Information sheet for service users_Control

TITLE OF THE RESEARCH PROJECT: Feasibility of a health systems strengthening intervention to reduce hospital re-admission following acute psychiatric hospitalization among people living with severe mental illness in uMgungundlovu, KwaZulu-Natal

Information Sheet

Ishidi Lolwazi

BREC reference number: BREC **KZNDoH reference number: KZ Good Day**

My name is XXX. I am working on a study led by Prof Andre Van Rensburg (jansevanrensburga@ukzn.ac.za) and a research team based at the University of KwaZulu-Natal.

People living with mental illness face many challenges. In South Africa, people living with these conditions struggle to cope when living in the community, with their family or caregivers. We have developed a program of services that can better support you and your family.

Abantu abaphila nokugula kwengqondo babhekana nezinselelo eziningi. ENingizimu Afrika, abantu abaphila nalezi zimo balwela ukubhekana nezimo lapho behlala emphakathini, nomndeni wabo noma abanakekeli. Asiqiniseki ngohlobo losizo nokusekelwa kwabantu abaphila nokugula kwengqondo okudinga umphakathi, futhi ungathanda ukuchitha isikhathi nawe ukufaka okokufaka kwakho ekuza nezinsizakalo ezingakusekela kangcono wena nomndeni wakho.

What is this study all about?

In this study, we have gathered information from a range of people, including people who live with mental illness, their families, the healthcare workers, organisations and government. We used that information to work with these partners to come up with a service plan that can better support people living with mental illness, especially after they leave the hospital to go stay with their families.

Ngabe lolu cwaningo luphathelene ngani?

Kulolu cwaningo, sizoqoqa imininingwane evela ezinhlobonhlobo zabantu, kubandakanya nabantu abaphila nokugula kwengqondo, imindeni yabo, abasebenzi bezokunakekelwa kwempilo, izinhlangano nohulumeni. Ngemuva kwalokho singathanda ukusebenzisa lolo lwazi ukusebenzisana nalaba ababambisene nabo ukuza nohlelo lwensizakalo olungaxhasa kangcono abantu abaphila nokugula kwengqondo, ikakhulukazi ngemuva kokuba sebephumile esibhedlela bayohlala nemindeni yabo.

Why have I been invited to take part study?

We believe that voices like yours should be at the heart of decisions that impact your life and the livesof people you care about. As you are a person living with mental illness, we would like to invite you to join an exciting research opportunity to participate in services that may help you and your family to help to you stay on track with your medication and other helpful ways to prevent you from being admitted into hospital for your mental illness.

Kungani ngimenyiwe ukuthi ngibambe iqhaza esifundweni?

Sikholwa ukuthi amazwi afana nawe kufanele abe enhliziyweni yezinqumo ezithinta impilo yakho kanye nezimpilo zabantu obakhathalelayo. Njengoba ungumuntu ohlala nokugula kwengqondo, sithanda ukukumema ukuthi ujoyine ithuba lokucwaninga elijabulisayo ukuze sifunde kuwe futhi siqonde kangcono ukuthi impilo ngokugula kwengqondo injani ngempela nokuthi ukwazi dlala indima ebalulekile ekwakheni ukungenelela okudingekayo ukuqinisa ukunakekelwa kwakho futhi ubambe iqhaza ezinqumweni ezithinta ukwakhiwa kocwaningo nemiphumela yayo.

Who is doing the study?

This study is a collaboration between the University of KwaZulu-Natal, other universities, and the Department of Health.

Ngubani owenza isifundo?

Lolu cwaningo ukusebenzisana phakathi kweNyuvesi yaseKwaZulu-Natali, amanye amanyuvesi, noMnyango Wezempilo.

What will happen to me in this study?

If you agree, we would like to spend some time with you after you have left the hospital, to get an idea of your daily routines when you stay with family. With your permission, we would like to look at your patient file to see what kind of challenges you have been facing. Your name and any personal details will be removed from the recordings, and you will not be named when we write up our notes.

Kuzokwenzekani kimi kulolu cwaningo?

Uma uvuma, singathanda ukuchitha isikhathi nawe ngemuva kokuthi ushiye isibhedlela, ukuthola umbono wemizila yakho yansuku zonke lapho uhlala nomndeni. Sifisa ukubona inqubo yakho yansuku zonke ukuthola umbono wezinselelo obhekana nazo ngezinto ezinjengokuthatha ukwelashwa, ukuthola ukwesekwa kwabanye abantu nokuya emtholampilo. Ngalesi sikhathi sithanda futhi ukuxoxa nawe ukuthi ulalele ukuthi yimiphi imibono yakho maqondana nezinselelo zakho nokusekelwa emphakathini. Ngemvume yakho, singathanda ukuthatha amanothi futhi siqophe imibono yethu kanye nezingxoxo nawe, ukuze sikwazi ukuyilalela futhi ngokuhamba kwesikhathi futhi siyibhale phansi. Ngemvume yakho, singathanda nokubheka ifayela lakho lesiguli ukubona ukuthi hlobo luni lwezinselelo obhekane nazo. Igama lakho nanoma yimiphi imininingwane yomuntu izosuswa kokuqoshwa, futhi ngeke uqanjwe ngegama lapho sibhala amanothi ethu.

Can anything bad happen to me?

We can see no reason why you should suffer any harm from taking part in this study, and your decisionto take part or not will not affect the relationship with anybody that provides you with services.

Ngabe kukhona okubi okungenzeka kimi?

Asisiboni isizathu sokuthi kungani kufanele ulimale noma yikuphi ukubamba iqhaza kulolu cwaningo, futhi isinqumo sakho sokubamba iqhaza noma cha ngeke sithinte ubudlelwano nanoma ngubani okunikeza izinsizakalo.

Can anything good happen to me?

Taking part in the study may be of benefit to you, in that the intervention may strengthen the quality of care you receive in the community. The services that we have developed will be focused on your needs,

and we hope that it will meet your needs and expectations and enhance your well-being.

Ngabe kukhona okuhle okungenzeka kimi?

Ukubamba iqhaza ocwaningweni kungaba usizo kuwe, ngoba ukungenelela okufaka isandla kukho kuzoqinisa ikhwalithi yokunakekelwa oyithola emphakathini. Izinsizakalo esizothuthukisa zizogxila kuzidingo zakho, futhi sethemba ukuthi zizohlangabezana nezidingo zakho nokulindelwe futhi zithuthukise inhlala-kahle yakho.

Will anyone know I am in the study?

All records identifying you will be kept private and only accessed by the researchers. Audio-recordingswill be stored using password protected files that can only be accessed by the research team. Any quotes that are used will remain anonymous and will not be linked to you. A participant number will be used to name the electronic files containing your data. Your forms, and records associated with this study will be labelled with this number.

Ngabe ukhona owaziyo ukuthi ngisesifundweni?

Wonke amarekhodi akhomba ukuthi uzogcinwa ngasese futhi ufinyeleleke kuphela ngabaphenyi. Ukuqoshwa komsindo kuzogcinwa kusetshenziswa amafayela avikelwe ngephasiwedi angatholwa kuphela yiqembu lokucwaninga. Noma yiziphi izingcaphuno ezisetshenziswayo zizohlala zingaziwa futhi ngeke zixhunyaniswe nawe. Inombolo yokubamba iqhaza izosetshenziselwa ukuqamba amafayela we-elekthronikhi aqukethe idatha yakho. Amafomu akho, namarekhodi ahambisana nalolu cwaningo azobhalwa ngale nombolo.

What if I do not want to do this?

Participation in this study is entirely voluntary, as such you are free to stop at any point without the need to give a reason. This will not have any effect on your involvement in any other part of the study or your access to care.

Kuthiwani uma ngingafuni ukwenza lokhu?

Ukubamba iqhaza kulolu cwaningo kungokuzithandela ngokuphelele, ngakho-ke ukhululekile ukuma nganoma yisiphi isikhathi ngaphandle kwesidingo sokunikeza isizathu. Lokhu ngeke kube nomthelela ekuzibandakanyeni kwakho kunoma iyiphi enye ingxenye yocwaningo noma ukufinyelela kwakho ekunakekelweni.

Who can I talk to about the study?

If you have any questions or require more information about this study, please contact the investigators:

Ngubani engingakhuluma naye ngocwaningo?

Uma unemibuzo noma udinga imininingwane eminingi ngalolu cwaningo, sicela uxhumane nabaphenyi:

Dr Andre Janse van Rensburg

University of KwaZulu-Natal

Tel: 0312601569

Email: jansevanrensburga@ukzn.ac.za

Dr Tasneem Kathree

University of KwaZulu-Natal

0312601569

Kathree@ukzn.ac.za

If you have questions about your rights and are not able to resolve your concerns with the study staff, or if you have general questions about what it means to be in a research study, contact:

Uma unemibuzo ngamalungelo akho futhi ungakwazi ukuxazulula ukukhathazeka kwakho nabasebenzi bocwaningo, noma uma unemibuzo ejwayelekile yokuthi kusho ukuthini ukuba ocwaningweni lokucwaninga, thintana:

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