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Developing and testing unconditional cash transfer strategies among young adults with first-episode psychosis in South Africa: a study protocol for a pilot randomised control trial (PRS-FEP trial)

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ABSTRACT

Introduction Access to mental health services is a challenge, especially for young people who are over-represented in the unemployment and poverty index in South Africa. Therefore, continuing care is a problem after hospital discharge for young people with first-episode psychosis (FEP) due to a lack of clinical engagement and follow-up, for which they need support, including financial, to improve their outcomes. This pilot randomised control trial (RCT) aims to assess the feasibility and acceptability of financial support, in the form of an unconditional cash transfer (UCT), among young patients with FEP to prevent relapse.

Methods and analysis This study will use a 1:1 ratio two-arm open-label pilot RCT of 60 young participants (18–29 years) with FEP in remission, who will be recruited from specialised psychiatric facilities in KwaZulu-Natal Province, South Africa. This study will implement an UCT and assess its feasibility, acceptability and preliminary clinical outcomes (ie, medication adherence, relapse, quality of life, personal and social function). The follow-up time will be 3 months, the outcomes being measured at baseline, months 1 and 3. Descriptive and conventional content analysis will be done for quantitative and qualitative data, respectively.

Ethics and dissemination The study obtained provisional approval from the Biomedical Research Ethics Committee at the University of KwaZulu-Natal(#BREC/00004117/2022). Also is registered on the South African National clinical trial registry (#DOH-27-092022-5894) and approved by the KwaZulu-Natal department of health (#NHRD Ref: KZ_2002209_033). The results from this investigation will be actively disseminated through peer-reviewed journal publications, conference presentations and stakeholder engagement.

Trial registration number DOH-27-092022-5894.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This is the first pilot randomised control trial (RCT) study that assesses the feasibility and acceptability of unconditional cash transfer (UCT) among first-episode psychosis (FEP).
⇒ The findings will inform the design of definitive RCT for UCT among FEP.
⇒ Being a hospital-based pilot study, the results cannot be generalised but give an indication of the direction of future studies.
⇒ Due to the nature of the intervention, study participants and observers will not be blinded to the group assignment.
⇒ This RCT will not show the treatment effects estimates.

INTRODUCTION

First-episode psychosis (FEP) is the first time a person shows signs of losing contact with reality, affects how a person thinks and behaves, and therefore, can severely impair everyday functioning when left untreated.[1–4] Early treatment in the course of illness raises the possibility of preventing or reducing the morbidity that rapidly occurs during the first few years of a psychotic disorder.[5 6] FEP, followed by early and correct medical interventions, results in an 80% recovery rate, with proper management being a vital factor towards single-episode psychosis.[7] Early intervention, such as improving well-being and social skills, reducing the burden on the family, and adhering to antipsychotic medication, is essential to reach clinical remission among FEP patients.[5 8]

Engagement in outpatient care after hospital discharge for FEP can be challenging for people from poor socioeconomic backgrounds, leading to poor outpatient follow-up, medication non-adherence, elevated risks of relapse and poor outcomes in psychosocial domains.[9 10] In South Africa (SA), access to mental health services for psychosis is a

challenge compounded by high poverty levels in most areas. An estimated 80% of people with mental health disorders in KwaZulu-Natal (KZN) Province, SA, do not access care due to the dearth of suitably equipped health facilities and psychiatrists and the stigma associated with such conditions.[11] Also, 6 in 10 young people (18–35 years) are unemployed and with little prospect of finding employment, and approximately 36% of children live in a house with no working adults.[12 13] There is evidence that being poor and unemployed increases the risk of psychosis[14] and that being employed improves social functioning and quality of life (QoL) in psychosis patients.[15 16]

The South African government provides social welfare grants for pensioners (60 years and older), children under 18 (paid to a parent or guardian), and those with a disability, including mental health problems. Free education and healthcare are also provided through the public schooling and healthcare system for those who need it.[17–19] However, disability grant payments to the eligible individual are often delayed.[17] The evidence suggests that cash grants are among the most impactful interventions to alleviate poverty and improve health outcomes in low-income and middle-income sub-Saharan African (SSA) countries, including SA.[17 20–22] Given the high levels of unemployment, specifically among the youth, who have little prospect of finding meaningful employment, exploring the feasibility and acceptability of unconditional cash transfer (UCT) among FEP for improving mental health outcomes is needed.

Socialdemographic characteristics and needs of people with FEP

Youth between the ages of 15–25 years are particularly vulnerable to FEP as half live under the poverty line of R604 (US$40) per month due to limited work opportunities and their parent's poor socioeconomic circumstances.[23] These patients are often unskilled or unemployed, having left school due to their symptoms and are socially isolated.[3 24–26] Most people who experience the FEP in South Africa are unfamiliar with what is happening to them, with more than one in three patients reporting consulting traditional healers before seeking medical treatment, with a higher rate in rural than urban areas.[23 27 28] Psychosis often interferes with an individual's life and increases the risks of disrupting their education, employment and social relationships.[29–31] Individuals with serious mental illness, including psychosis, have multiple basic unmet needs to function adequately, such as housing, food security, transportation and telephone, ensuring each individual's quality and dignity of life.[32] Several factors that impact their recovery from an episode of mental illness are associated with supportive care needs.[29 33] For individuals to rebuild themselves, family and friends may also require a broad range of support to meet the affected person's various needs.[29 34] However, there is limited literature on the needs of young patients following FEP, making it important to explore the nature and extent of their needs for optimal clinical care.[35 36]

Relapse in FEP

Relapse is the major challenge in the FEP and interferes with social and vocational development, with multiple relapses reducing the individual capacity to respond to subsequent treatment, increasing the cost of hospitalisation, which is estimated at R600 (US$38) per day, as well as the duration of remission, which impacts the long-term outcome.[25 37] Relapse for FEP patients due to lack of treatment exceeds 90%, of which approximately 30% occur within 1 year after experiencing the psychosis.[7 16 25 38] For young people, relapse means further disconnection from school and work. Each relapse is a traumatic experience associated with potentially serious psychosocial and functional consequences that impact their QoL.[7 25 28 39] The risks of relapse include poor adherence to anti-psychotic medication, substance abuse, comorbid psychiatric illness, medical and surgical conditions, and stressful life events, such as poverty and homelessness.[40 41]

Medication adherence in FEP

For patients with psychotic symptoms, antipsychotic drugs have proven to be effective in reducing relapse and hospitalisation rates,[42 43] and withdrawal increases their risk of relapse. Remission of psychotic symptoms occurs in 50% of individuals with FEP within the first 3 months after initiating treatment with antipsychotic medication.[5 7 25] Studies consistently demonstrate that socioeconomic challenges affect treatment uptake in FEP,[15 44 45] with individuals from poorer backgrounds exhibiting extended periods of untreated psychosis.[45] The side effect burden of antipsychotic drugs is a serious issue and requires constant medication review/adjustment by working with healthcare providers. Medication adherence (and refill) is contingent on access to and continuity of government healthcare in a community setting after hospital discharge, which can be challenging without adequate financial support.[27 28 46]

QoL in FEP

Monitoring and addressing QoL issues can increase treatment engagement and adherence in the early course of the disease and may lead to a better long-term outcome for an individual with early-stage psychotic illnesses.[47] Positive (eg, hallucinations), negative (eg, lack of social interaction) symptoms and a longer duration of untreated psychosis, are associated with poorer QoL, which is not necessarily improved with a reduction in the symptoms. Lack of social contact, unemployment, stigmatisation and social functioning difficulties interfere with improvements,[48] with social support possibly predicting a better QoL, increasing self-esteem, coping skills, resilience and decreasing stigma.[49–52]

Personal and social functions in FEP

Changes in social functioning are a critical feature in FEP and can be observed in all stages of the disorder. The evidence shows that positive and negative symptoms of FEP are adversely associated with poor social functions,

with occupational status at hospital admission being shown to predict social functioning.[53–56] The impairments in social functioning include difficulty with social interactions, maintaining relationships with family and friends, and inadequate performance in the workplace.[57]

Cash transfer interventions and health outcomes

The feasibility and acceptability of cash transfer interventions have been documented in adolescent sexual health, especially HIV prevention.[58–61] There is also evidence of the positive impact on reducing psychological distress by cash transfer interventions for common mental disorders, such as anxiety and depression in Malawi and SA[18 62 63] but not psychosis (including FEP). The cash grant can be a conditional cash transfer (CCT) or UCT,[64–72] with both being generally regarded as beneficial to mental health by addressing basic needs (eg, housing, food security, transportation, telephone) and ensuring their QoL and dignity. While CCT requires recipients to comply with specific conditions, UCT does not, and we posit that the latter is a less stressful/burdensome approach that promotes treatment uptake.[64] According to a recent systematic review, despite the potential, there is a lack of randomised evidence on the feasibility and acceptability of UCT interventions in SA and SSA to support socially vulnerable youth who experienced FEP.[73] Considering the lowest inpatient cost, we posit that addressing poverty via cash transfer (CT) may be a cost-efficient/effective, timely and impactful intervention to increase retention and medication adherence, reduce relapse, improve QoL and personal and social functions that can quickly be up-scaled to address public mental health. The proposed open-label, two-arm pilot randomised trial, entitled Poverty Reduction Strategy for FEP (PRS-FEP) trial, will address the evidence gap in the feasibility and acceptability of an UCT intervention and preliminary clinical outcomes following FEP among unemployed youth in KZN, SA. The absence of literature and evidence of tools for poverty alleviation may result in inadequate care and support for FEP, resulting in chronic conditions and long-term management, which increase the cost of care.

Aims

This study aims to pilot an UCT intervention to understand its feasibility and acceptability and to obtain preliminary data on its effect on improving mental health outcomes (medication adherence, relapse, QoL, and personal and social functions) among young patients following FEP in KZN Province, South Africa

Study objectives

1. To determine the needs of young patients following the FEP.
2. To investigate the feasibility and acceptability of UCT intervention.
3. To determine differences in relapse, medication adherence, QoL, and personal and social functions between the intervention and control groups following UCT.
4. To explore recipients' and families' experiences towards UCT intervention.

METHODS

The proposed PRS-FEP pilot randomised trial will be driven by the experienced interprofessional team of researchers from nursing, psychiatry, social work, clinical psychology, clinical trials and biostatistics/health economics. The PRS-FEP will be nested within PSYchosis MAPping in KZN (PSYMAP-ZN), a research platform that aims to generate evidence that will improve the understanding of psychosis within an SSA setting.

Study design

The PRS-FEP will use three methods

The quantitative approach to address Objective #1: is to determine young patients' needs following FEP using the Camberwell Assessment of Needs - Research (CAN-R) tool.[36] For objectives #2 and #3, an open-label, two-arm pilot randomised trial with a 3-month follow-up period will be used to assess the feasibility (retention, adoption, recruitment and assessment completion) and acceptability (perception, appropriateness, satisfaction) of UCT, with its preliminary effects on medication adherence, relapse, QoL, and personal and social functions. Regardless of group assignment, all study participants will undergo three assessments (T_1=enrolment, T_2=end of month 1, T_3=end of month 3). Lastly, objective #4 will use the qualitative approach to explore the recipients' and their families'/caregivers' experience of the intervention. The protocol for data capture will follow as per the list identified in the schedule plan.

Study setting and recruitment

This study will be conducted at specialised government psychiatric facilities located in Msunduzi Municipality, KZN. The catchment area (for PRS-FEP/PSYMAP-ZN) is also the Msunduzi Municipality in KZN, with a total population of 679 000, 80% of whom are Black Africans, the unemployment rate being more than one in three people.[74] The clinical team from the PSYMAP-ZN study will refer the potential participants to the PRS-FEP study. The principal investigator (PI) and research assistant will screen the participants for eligibility criteria (table 1). In addition, we will administer all potential study participants for PRS-FEP referred by PSYMAP-ZN with the University of California, San Diego Brief Assessment of Capacity to Consent to ensure individual's capacity to consent after being informed about the study.[75]

Study population and sample size

The study will involve 60 FEP patients from the broader PSYMAP-ZN study but will only include those aged 18–29. FEP for PRS-FEP is defined 'based on the duration of less than 6 months of antipsychotic medication use after initial psychiatric hospital visit'.[1] The sample size is based

Table 1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
► Aged 18–29 years ► In remission, that is, without positive and negative symptoms at the enrolment time or with mild symptoms(two or less positive or negative symptoms). ► In patients(7 days before discharge)or outpatients less than 6 months after discharge. ► Good English comprehension ► On antipsychotic medication for treatment for less than 6 months after the initial psychiatric hospital visit. ► Have been resident in the catchment area fo r≥6 months. ► Are unemployed ► Are able to provide consent to participate in the study	► Have severe psychotic symptoms and aggression, that is, have positive and negative symptoms ► Unable to cooperate due to any other reasons ► Have transient psychotic symptoms due to acute intoxication, as defined by ICD-11 ► Are unable to give consent to participate

ICD-11, International Classification of Diseases.

on pilot randomised control trials guidelines,[76] with the quantitative part (objectives 1, 2 and 3) involving n=30 per arm and the qualitative part (objective 4) including n=15 recipients of the UCT intervention arm with n=15 of their parents/caretakers. The inclusion and exclusion criteria are indicated in table 1.

Randomisation

An independent statistician will generate a computer-generated sequence with numbers 1–60 based on the simple randomisation method and the allocations placed in sealed, sequentially numbered envelopes. At enrolment, following baseline data collection, the PI will open the next numbered envelope and assign the participant to the control or intervention arm. As this is an open label study, study staff, clinic staff and participants will not be blinded to the allocation.

Study intervention

The intervention arm will receive the UCT, and the standard of care (SoC) includes; refilling antipsychotic medication, planning for the next visit, counselling services, and constant reminders on a scheduled visit using short message service (SMS) or call twice in the last week before a visit, with cash being provided without any conditions. The first instalment of R1350 (US$90) will be made available at the end of the first interview, with two subsequent instalments of the same amount at the beginning of the month (ie, R4050 (US$270) total for 3 months). The cash pickup will be available from selected stores near the study, and the participants will receive cash. The PI will administer the payments to study participants for this open-label trial from the selected store. The basic income support amount of R1350 (US$90) per month (adjusted for 2022 inflation rounded-up) was determined by the South African Institute for Economic Justice[77] and is valued at the upper-bound poverty line, and the control arm will receive a SoC after each interview. Cash for time reimbursement will be given in both groups, an amount of R150 per study visit according to the SA National ethics guideline.[78]

Before the UCT delivery, the team will convene the intervention adaptation by interprofessional transition advisory board (ITAB) and employ the collaborative intervention planning framework, which combines participatory planning methods, to ensure that interprofessional expertise is reflected in the UCT delivery intervention mapping procedures to structure the adaptation process.[79] The framework involves researchers and community practice partners through the ITAB to lead the intervention adaptation and planning activities. Of specific UCT programming concern is premature inpatient discharge due to lack of bed space despite significant levels of psychiatric symptomatology. If the intervention is provided to a patient under such a state, the intervention may not provide the intended benefit. UCT delivery needs to be developed and planned carefully under ITAB expert consultation about the timing of the intervention.

Trial outcomes

This study has implementation outcomes (feasibility and acceptability), as well as social and clinical outcomes (medication adherence, relapse, QoL, and personal and social functions (table 2). The outcomes will be assessed by obtaining the participants' opinions and their parents/caregivers.

Data collection

A trained research assistant (with honors-level psychology) fluent in the local KZN language (isiZulu) will assist with study assessment/interviews to allow cohort management for maximum retention from March to August 2023. The interviews will be done at specialised government psychiatric hospitals (T_1=baseline, T_2=end of month 1, T_3=end of month 3) and collect the outcome measures based on a trial schedule (table 3). At baseline, the CAN-R, household food insecurity access scale and the individual water insecurity experiences scale will be used to measure the needs of FEP, as its validity and reliability have been validated in African settings, including South Africa.[31 36 80–82] Four subdomains of feasibility and three for acceptability will be measured by a questionnaire, mainly proportion

Table 2 Proposed outcome measures for the PRS-FEP study

Trial outcomes	Subdomains	Measures
Feasibility	Adoption	Measured by obtaining the proportion of participants who qualified for UCT and successfully received three-round cash transfers during the study period.
	Retention	Measured by obtaining the proportion of participants who completed 3 months of follow-up in the intervention and control arms.
	Assessment completion	Measured by obtaining the proportion of participants who complete the interview assessment schedule visits within 3 months of follow-up in the intervention and control arms.
	Recruitment capability	Measures the average rate of recruitment. Can 30 participants be recruited in 1 month?
Acceptability	Perception	Measured from enrollment by obtaining the proportions of patients who think the cash transfer will improve disease outcomes.
	Satisfaction	Measured by obtaining the proportion of participants who receive the cash transfer and are satisfied with it.
	Appropriateness	Measured at different stages: stage 1—if UCT is an appropriate intervention for further testing, and stage 2—if the mechanism used for cash transfer is appropriate.
Relapse	Determine the proportion of participants with readmission within 3 months of follow-up after first discharge from the hospital.	
Medication adherence	Measured indirectly by using the visual analogue scale, asking the patients if they missed the pill intake for any reason or a scheduled injection. This will be validated by checking pharmacy and clinical records and pill counts.	
Quality of life (family domain)	The proportion of subjective and objective family relations quality will be measured using the Lehman Quality of Life instrument.	
Personal and social function	Measured by determining the proportion of individuals with various performance levels from the PSP scale. The domains include socially useful activities, personal and social relationships, self-care, and disturbing and aggressive behaviour.	
Recipient's and family's experiences of UCT	Explore how the UCT aims to reduce poverty and improve the mental health experienced by the recipients and families.	

PRS-FEP, Poverty Reduction Strategy for First-Episode Psychosis; PSP, Personal Social Performance; UCT, unconditional cash transfer.

and satisfaction will be measured by a modified client satisfaction questionnaire.[83 84] The social and clinical outcomes will be measured by validated tools.[43 85]

Analysis

This pilot study is not designed to assess the intervention's effectiveness but to analyse quantitative and qualitative data to establish its feasibility and acceptability. Data entry will be done using REDCap,[86] and the descriptive analysis will follow for quantitative data. The demographic characteristics will be summarised using descriptive statistics; the frequency, proportion, mean, medians and IQR will be used where appropriate. For objective 1, the frequency distribution table and proportions will be obtained for met needs, unmet needs, informal and formal support received, and the proportion of study participants who reported receiving both adequate and satisfactory support will be calculated. Descriptive analysis will be done for feasibility and acceptability outcomes, describe the proportion of participants achieving the outcomes in each arm (with a 95% CI) and use Fisher's exact test to compare the proportions in each arm. The outcome in objective 3(medication adherence, relapse, QoL, personal and social function) will be descriptive only, and no intervention effects will be estimated. Data management for qualitative data: objective 4 will be done using NVivo.12, the conventional content analysis will be done, and the categories/themes will be presented.

Data monitoring

A formal external data and safety monitoring board will not be constituted, given that the study does not involve a pharmacological agent. Our team will have a data safety monitoring plan to monitor recruitment and review every month's adverse events, mainly psychological distress. We will comply with SA Current Good Clinical Practice and Protection of Personal Information Act regulation. After data entry in REDCap, the physical forms will be stored in a locked cabinet at the specialised government psychiatric hospital research office, accessed only by the research team.

Data management

The study will be conducted in accordance with SA Current Good Clinical Practice and Protection of Personal Information Act regulation and the UKZN policy on Research Ethics. Only the PI will access a link log that connects the study number to personal identifiers. The digital and hard copy data will be kept for 5 years after study completion and destroyed with the permission of the study PI.

Ethics and dissemination

The study will commence once full ethical approval has been obtained from the UKZN Biomedical Research Ethics Committee (BREC provisional approval 00004117/2022). The study has been approved by the KZN Department of Health (KZ_2002209_033) and

Table 3 Assessment evaluation schedule

Evaluation domain	Objective	Evaluation subdomain	Tool	Baseline interview	End of month 1	End of month 3	Baseline interview	End of month 1	End of month 3
				Intervention group			Control group		
Visit no				1	2	3	1	2	3
Consent				X	X	X	X	X	X
Needs	1		Camberwell Assessment of Needs-Research Quantitative	X			X		
Feasibility	2	Adoption	Survey-Proportion Quantitative	X	X	X	X	X	X
	2	Retention	Survey-Proportion Quantitative		X	X		X	X
	2	Assessment completion	Survey-Proportion Quantitative	X	X	X	X	X	X
	2	Recruitment capability	Survey-Rate Quantitative	X	X	X	X	X	X
Acceptability	2	Perception	Questionnaire	X	X	X	X	X	X
	2	Satisfaction	Patient Satisfaction Questionnaire		X	X			
	2	Appropriateness	Questionnaire		X	X			
Quality of life assessment	3		Lehman Quality of Life (Family)	X	X	X	X	X	X
Personal and social functioning	3		Personal and Social Performance Scale	X	X	X	X	X	X
Relapse	3		Cornel Service Index		X	X	X	X	X
Medication adherence	3		Visual Analogue Scale Quantitative	X	X	X	X	X	X
Recipient's and families experience of UCT	4		In-depth interview guide Quantitative		X	X			
			Socioeconomic status, Food and Water	X	X	X	X	X	X

UCT, unconditional cash transfer.

registered with the South African National clinical trial registry (#DOH-27-092022-5894). Informed consent, oral and written, will be obtained from all study participants before data collection.

Patient and public involvement

Patients or the public were not involved in the designing of this research.

DISCUSSION

Study significance

This study will fill the current gap on the feasibility and acceptability of UCT among people with FEP and provide essential factors for large-scale implementation for further testing its efficacy on mental health outcomes. Considering the minimum inpatient cost estimate is R600 (US$38) per day, we posit that addressing poverty via UCT may be a cost-efficient/effective, timely and impactful intervention to reduce relapse for posthospital discharge that can quickly be up-scaled to address public mental health in SA.

Methodological challenges and potential risks

This study is an open-label randomised control trial, and there is a chance of encountering observation/assessor bias. However, these will be minimised as the endpoint of this trial is purely objective using validated tools, which means that the assessor cannot influence the outcomes. While participants from the control arm may feel distressed due to the difference in the cash transfer amount, a psychologist will be available and consulted on any incidents that arise due to the differences in the study arms.

Study progress and challenges

While the 3-month follow-up may be challenging for psychiatric patients, we aim to ensure maximum retention by ensuring constant reminders using SMS and calling to remind them of scheduled visits.

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