

# Development and Evaluation of a Rehabilitation Intervention for people with Schizophrenia in Ethiopia (RISE)



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## Introduction

In low and middle-income countries (LAMIC) schizophrenia is associated with a high disability burden and human rights violations. Evidence-based WHO guidelines for scaling-up mental healthcare advocate that community-based rehabilitation (CBR) is delivered alongside anti-psychotic medication. CBR includes health, education, livelihood, social inclusion and empowerment elements. There is evidence that CBR improves disability outcomes in people with schizophrenia in India. The feasibility, acceptability and effectiveness of CBR for schizophrenia in Ethiopia are not known.

## Aims

- Develop a CBR intervention for schizophrenia that is acceptable and feasible in Ethiopia
- Determine whether CBR + Facility-Based Care (FBC) is superior to FBC alone in reducing disability related to schizophrenia

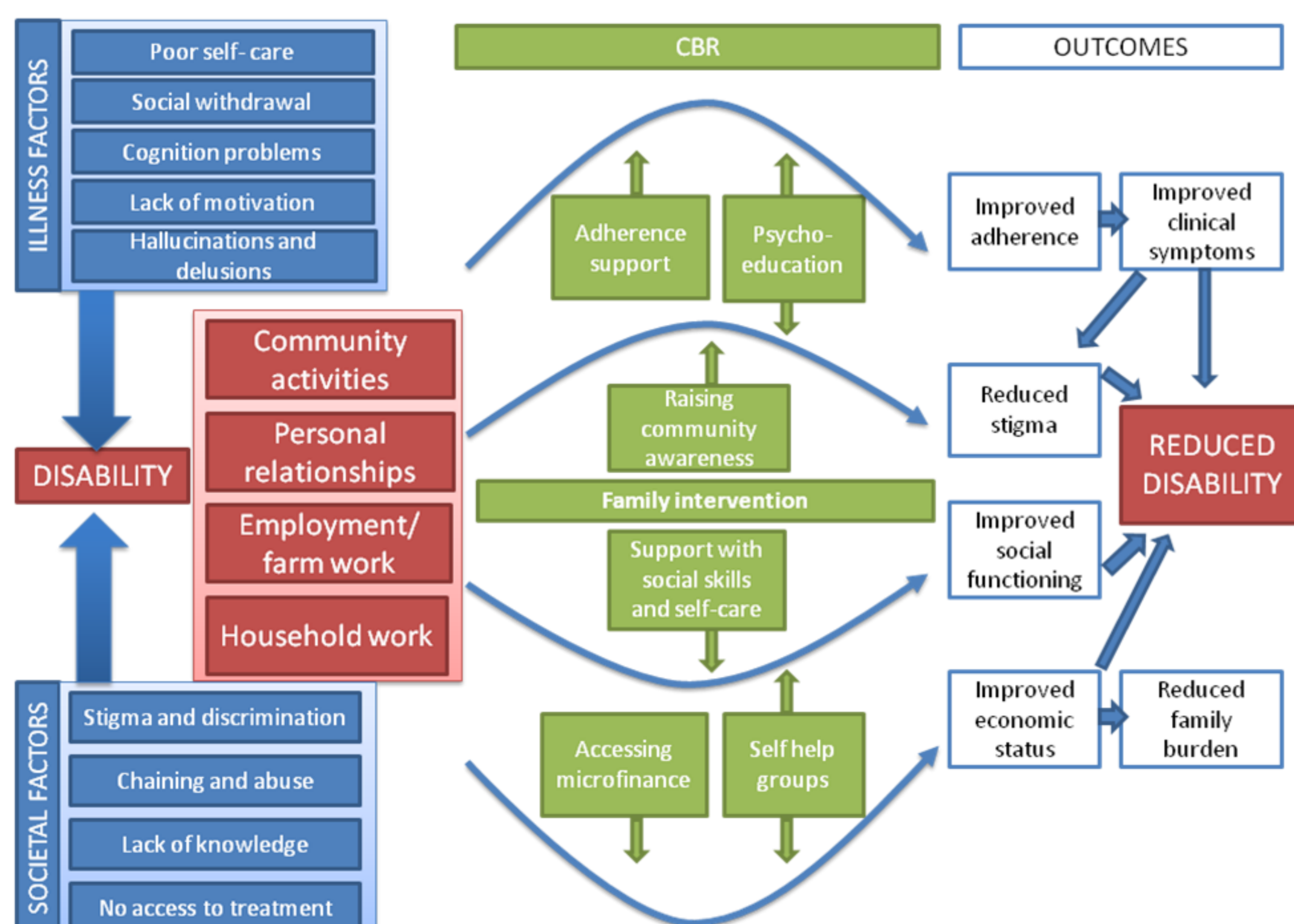
## Formative study methods

The formative study is an iterative process with six phases:  
 PHASE 1: Situational analysis of existing health services and community resources in the study setting (Sodo district, Ethiopia).  
 PHASE 2: Consult WHO CBR guidelines, and training materials of existing CBR programmes, to determine potential components of CBR for schizophrenia.  
 PHASE 3: Systematic review of effective community-based psychosocial interventions for schizophrenia in LAMIC.  
 PHASE 4: Consult stakeholders to determine acceptability and feasibility of proposed CBR components and delivery model.  
 PHASE 5: Consult experts to finalise intervention content and delivery.  
 PHASE 6: Pilot intervention and fine-tune on the basis of the results.

## Formative study results

Phases 1 to 4 are underway. There are no psycho-social or rehabilitation services for people with schizophrenia in Sodo. Potential core components of CBR and the theoretical pathways for how they may reduce disability in people with schizophrenia are shown in Figure 1.

Figure 1: Conceptual framework of CBR for schizophrenia



## Cluster-randomized trial methods

**Study design:** The design is a cluster-randomised trial with kebeles (villages) as the unit of randomization. Kebeles will be randomly allocated to receive FBC+CBR or FBC alone, stratified by health centre.

**Participants:** Participants will be identified by key informants. The main inclusion criterion is clinical diagnosis of schizophrenia with moderate-severe symptom severity.

**Interventions:** FBC will consist mainly of anti-psychotic medication prescribed in primary care. Referral to a psychiatric nurse will be available.

CBR will be delivered by trained CBR workers to people with schizophrenia and their caregivers. The CBR content and delivery model will be finalised during the formative study. Core components may include psycho-education, adherence support, self-help groups, social skills training, accessing microfinance and community awareness-raising. Sessions will be weekly initially then monthly, over 12 months.

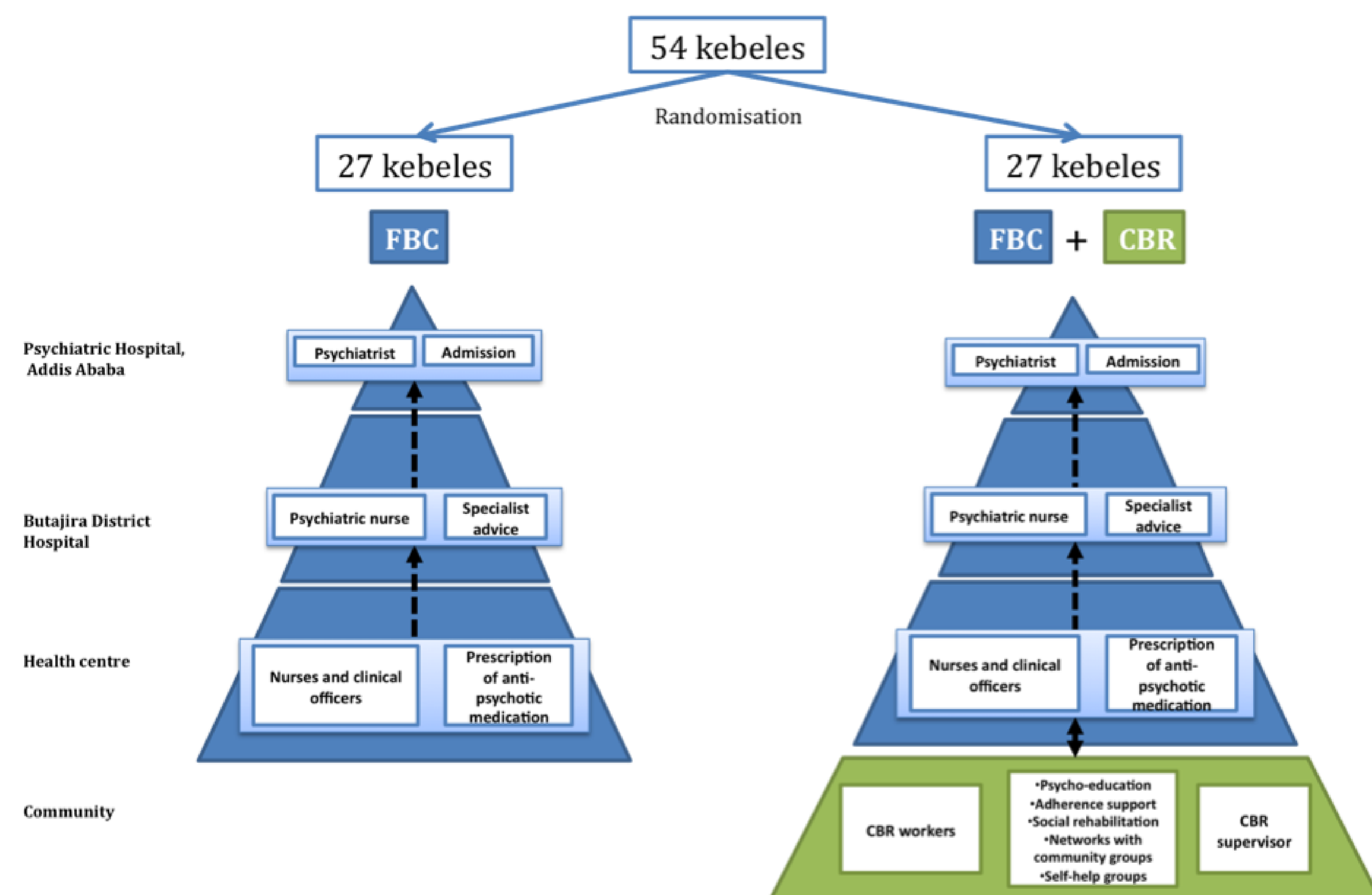
**Primary outcome:** Disability (WHO Disability Assessment Schedule 2.0) at 6 months

**Secondary outcomes:** Disability at 12 months; symptom severity, stigma, adherence, health service use and costs and family burden at 6 and 12 months.

**Sample size:** 162 participants in 54 clusters are needed to detect a 15% difference in WHODAS score with 81% power.

**Analysis:** Individual-level analysis using a mixed linear regression model.

Figure 2 – Study design of cluster-randomised trial



## Generalisability

The final RISE CBR materials will be made freely available. We anticipate they will be relevant to non-governmental organisations and Ministries of Health in the scaling up of mental healthcare in Ethiopia and other LAMICs.