FOOD INSECURITY, WORK IMPAIRMENT AND THE IMPACT OF INTEGRATED MENTAL HEALTH CARE AMONG PEOPLE WITH SEVERE MENTAL DISORDERS IN SOUTH ETHIOPIA

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DISSERTATION FOR THE DEGREE OF DOCTOR OF PHILOSOPHY (PHD) IN MENTAL HEALTH EPIDEMIOLOGY, DEPARTMENT OF PSYCHIATRY, SCHOOL OF MEDICINE AND SCHOOL OF PUBLIC HEALTH, COLLEGE OF HEALTH SCIENCES

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Food insecurity, work impairment and the impact of integrated mental health care among people with severe mental disorders in south Ethiopia

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Acronyms and Abbreviations

AMoS	Analysis of Moment Structure
BPRS-E	Brief Psychiatric Rating Scale-Expanded version
CBR	Community-Based Rehabilitation
DALY	Disability-adjusted life years
DISC	Discrimination and Stigma scale
DSM	Diagnostic and Statistical Manual
Emerald	Emerging mental health systems in low- and middle-income countries
HIC	High income countries
HFIAS	Household Food Insecurity Access Scale
IQR	Inter-quartile range
LMICs	Low and middle-income countries
LIFE-RIFT	Longitudinal Interval Follow-up Evaluation—Range of Impaired Functioning Tool
MHCP	Mental health care plan
mhGAP	Mental health Gap Action Programme
MNS	Mental, neurological and substance use
PHC	Primary health care
PRIME	Programme for Improving Mental health carE
OSS	Oslo Social Support
OPCRIT	OPerational CRITeria for research checklist system for diagnosis of mental disorders
SMD	Severe mental disorder(s)
UN	United Nations
UN-FAO	United Nations' Food and Agricultural Organisation
WHO	World Health Organisation
WHODAS	World Health Organization Disability Assessment Schedule

Glossary: Definition of concepts

Comparison Group: The group considered to be the general population to which the households of people with SMD were matched to.

Disability: Disability refers to limitations in performing socially defined roles and tasks expected within a social-cultural and physical environment such as family, work, recreation, and self-care.

Food insecurity: Food insecurity is defined as "*uncertain access by all people, at all times, to adequate food for an active and healthy lifestyle*", UN-Food and Agricultural Organisation (FAO) (2004). It is also defined as "*lack of access to sufficient, safe and nutritious food that meets individual's dietary needs and preferences for an active and healthy life*", according to World Bank (1986).

Food security: Food security is a situation that exists when *"all people, at all times, have physical, social and economic access to sufficient, safe and nutritious food that meets their dietary needs and food preferences for an active and healthy life"*, according to UN-FAO (2002). Household food security is then understood as the application of this concept to the family level, with individuals within households as the focus of concern.

Households of people with SMD: These are the household of people with SMD who were recruited into the PRIME study.

Integrated primary mental health care: A task-sharing approach to scaling up mental health care whereby mental health care for priority conditions is integrated into the routine health care services. Primary health care workers based in health centres are trained in identification, treatment and referral of people with SMD. The intervention package relies on an evidence-based set of clinical guidelines from the WHO's mhGAP intervention guide, which includes bio-medical and psycho-educational intervention, collaborative approaches and psycho-social rehabilitation packages.

People with SMD: Individuals diagnosed with a standard tool (here OPerational CRITeria for research—OPCRIT) to manifest known symptoms of severe mental disorder, as defined below.

Psychotropic medications: In this study, this refers to medications capable of affecting the mind/mental activity, emotions and behavior, denoting medications used in the treatment of mental disorders, as per Webster's New World Medical Dictionary.

Severe mental disorder: mental and psychopathology meeting criteria for the Diagnostic and Statistical Manual-IV (DSM-IV) diagnosis of bipolar disorder, schizophrenia, schizoaffective disorder, depression with psychotic features, characterized as enduring and needing treatment.

Treatment attendance: This refers to the number of clinical appointments at PHC which were attended by a study participant with SMD.

Work impairment: functional limitation of work-related tasks resulting from a medical condition or disability is referred to as "work-related impairment" and replaces the concept of "whole person impairment", which relates more generally to a person's overall health status, according to American Medical Association's Guide.

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Abstract

Background

In many low-income countries, food insecurity is a pressing concern and thus ensuring food security for all segments of the population is a high priority. In a recent global analysis of 149 countries, the prevalence of any food insecurity ranged from 18.3% in the East Asian region to 76.1% in sub-Saharan Africa. In Ethiopia, both chronic and transitory (seasonal) food insecurity are persistent problems for a large segment of the population and in 2012, there was an 82.3% prevalence of household-level food insecurity in a zone in southern Ethiopia. Ending hunger and achieving food security is one of the United Nation's Sustainable Developmental Goals (SDG) to be achieved by 2030.

Mental illness is associated consistently with poverty, but its association with food insecurity in people with severe mental disorders (SMD; psychotic disorders and bipolar disorder) is not well understood. Primary care-based integrated mental health care supported by interventions at community and health system levels, has emerged as an important approach to address the large treatment gap for people with SMD. However, little is known about the impact of integrated mental health care on food insecurity status.

Objectives

The general objective of this study was to investigate the association between severe mental disorder and food insecurity in a rural Ethiopian district before and after improved access to mental health care.

Methods

Study Design: The study involved two designs: (1) Sub-study-1 was a cross-sectional community-based, comparative study which aimed to explore the association between SMD and food insecurity. Sub-study-2 was a cross-sectional, community-based study of factors associated with food insecurity and work impairment in people with SMD only. (2) Sub-study-3 was a before-after study which aimed to evaluate the impact of an integrated mental health care programme on food insecurity status in people with SMD when compared to the general population, over a period of 12 months.

Participants: The participants of the study were residents in Sodo district, south Ethiopia. 1) persons with SMD identified by community key informants, referred to primary care, assessed by primary care health workers who had been trained to deliver frontline mental health care, and re-assessed by a mental health specialist using a structured clinical interview (the Operational Criteria for Research interview guide) to confirm the diagnosis of psychosis or bipolar disorder, 2) respondents from households of persons with SMD, and 3) a comparison group of households which did not include a person with SMD.

Assessments: At baseline (T1), when the mental health care programme was being implemented, and at a twelve month follow-up (T2) assessment, trained lay data collectors assessed food insecurity status using a validated version of the Household Food Insecurity Access Scale (HFIAS-9). At T1 and T2, work impairment was assessed by trained psychiatric nurses using the Longitudinal Interval Follow-up Evaluation-Range of Impaired Functioning Tool. Disability was measured using the World Health Organisation Disability Assessment Schedule 2.0. A range of other demographic, socio-economic and psychosocial measures were also used.

Statistical analysis: In sub-study-1, multiple logistic regression was conducted to test the hypothesis that the presence of a household member with SMD was associated with food insecurity in that household. Potential confounders identified *a priori* were included into the model. **In sub-study-2**, multiple logistic regression was used to explore the factors associated with severe food insecurity and work-related impairment in persons with SMD. Variables included in the multivariable model were those anticipated to have associations with the outcome variables on the basis of existing literature. Potential effect modification by strata was explored using the Mantel-Haenszel test of homogeneity. **For sub-study-3**, a Poisson working model with sandwich estimators of the standard errors was used to estimate a risk ratio for change in food insecurity status in SMD cases and the comparison households between baseline and 12 months. Multiple linear regression was used to identify factors associated with change in food insecurity scores in the SMD group. To examine potential effect modification of disability between clinical attendance and food insecurity, an interaction term was included in the final multivariable model and a likelihood ratio test was used to investigate improvement in model fit. Path analysis was used to explore the possible mechanisms linking food insecurity and predictor variables.

Results

A total of 292 people with SMD, 292 respondents from households of people with SMD and 284 respondents from comparison households were included in the study at baseline. At follow-up, 239 people with SMD, 239 respondents from households of people with SMD and 273 respondents from comparison households were included in the final analysis.

Participant Characteristics: Persons with SMD were more likely to be younger, had fewer children, to have attended formal education and be female, unemployed, unmarried and not the household head than respondents from comparison households without a person with SMD.

Baseline (cross-sectional) studies: Sub-study-1: Severe household food insecurity was reported by 32.5% of people with SMD and 15.9% of respondents from comparison households: adjusted odds ratio 2.82 (95% confidence interval 1.62 to 4.91). Higher annual income was associated independently with lower odds of severe food insecurity. **Sub-study-2:** In the multivariable model in people with SMD, severe food insecurity was associated with poor social support, experience of negative discrimination, higher disability and lower household annual income, but not with symptom severity. Work impairment was associated significantly with symptom severity and disability, but not with discrimination.

Follow-up study: (Sub-study-3): Improvement in food security status 12 months after engaging with care was observed in 43.5% of households of a person with SMD compared to 30.2% of control households (adjusted risk ratio 1.68; 95%CI 1.24, 2.26). The proportion of households in the "severe food insecurity" category declined from 71/237 (29.9%) at baseline to 37/237 (15.6%) at twelve months among the SMD group; whereas it declined from 37/273 (13.5%) at baseline to 26/273 (9.5%) at twelve months among the comparison group. In people with SMD, improvement in food security status was associated with being a household head at baseline assessment, lower baseline disability and physical impairment scores. In a path model, change in symptom severity was indirectly associated with follow-up food insecurity status via an impact on reducing work impairment and discrimination ($p<0.001$).

Conclusions

People with SMD living in a rural Ethiopian district experience relatively higher levels of severe food insecurity than the general population. Moreover, the findings from this study indicate that food insecurity and work impairment in people with SMD are not just a consequence of illness

severity. Socioeconomic factors such as social support, discrimination and income emerged as important factors associated with food insecurity. Our study also indicates that improving access to mental health care can reduce food insecurity in households of people with SMD.

Recommendations

The inclusion and prioritization of people with SMD in food security programs and development opportunities, including income-generating opportunities and schemes via awareness-raising and tackling the stigma associated with mental illness should be ensured. Access to integrated mental health care should be expanded, with support for people with SMD to remain engaged in care to maximize the economic benefit. Provision of additional interventions to improve work functioning and tackle discrimination may further reduce food insecurity in this vulnerable group.

Key words: Severe mental disorder, food insecurity, disability, work impairment, integrated mental health care, psychotropics medication, improvement or change, Ethiopia

1. Introduction

1.1 Background of the study

Mental and substance use disorders were the fifth leading disorder category of global disability-adjusted life-years (DALYs) by the year 2010 (1). In 2010, mental and substance use disorders accounted for 7.4% of all DALY's worldwide and were also the leading cause of years lived with disability (YLD), accounting for 22.9% of all YLD among the top ten leading causes of total burden (1). Depressive disorders are the leading cause of DALYs (40.5%) and YLDs (42.5%) in the mental and substance use disorders sub-category (1), while schizophrenia and bipolar disorder together account for 14.4% of DALYs (1). The burden of mental and substance use disorders increased globally by 37.6% between 1990 and 2010, which for most disorders is attributable to population growth and ageing (1). This is especially relevant to low- and middle-income countries (LMICs), where more people are now surviving into adulthood and, therefore, living in the period of risk for mental disorders (2). In Ethiopia, the burden of disease from mental disorders is reported to be 11% of total disease burden in the country, largely accounted for by depression and schizophrenia (3). However, despite accounting for at least a quarter of total non-communicable disease burden, ill-health resulting from mental, neurological and substance-use (MNS) disorders remains a neglected and under-resourced element within the healthcare systems in LMICs (4).

The relationship between mental disorder and low socio-economic status is increasingly recognized; indeed, the World Health Organisation (WHO) argues that people with mental disorders are a vulnerable group who should be prioritised for inclusion in community development activities (5). However, when considering one of the most severe manifestations of poverty, that of food insecurity, most of the existing studies are concerned with food insecurity in people with common mental disorders (CMDs) (depression and anxiety) and not with severe mental disorders (SMD). SMD refers to mental disorders that are persistent and debilitating, and require long term interventions (1). Typically, SMD includes the categories of primary psychotic disorders, such as schizophrenia, and severe affective disorders, such as bipolar disorder and major depressive disorder with psychotic features.

People with SMD are subjected to diverse social disadvantages, including unemployment, human rights violations and lower earnings, which could increase their vulnerability to food insecurity. In

Ethiopia, both chronic and transitory (seasonal) food insecurity are persistent problems for a large segment of the population (6), but the burden of food insecurity in persons with SMD has not yet been investigated. Furthermore, there is a need to understand factors associated with food insecurity, and the potential mechanisms through which SMD leads to food insecurity, including via work impairment and disability. It is estimated that only 10% of persons with SMD in Ethiopia have ever received modern treatment with psychotropic medication (7). The WHO has called for scale up mental health care via applying the biopsychosocial approach in the assessment and management (pharmacological and psychosocial interventions, facilitation of rehabilitation, provision of follow-up) of people with SMD, as part of its mental health Gap Action Programme (mhGAP) (8). There is, therefore, a pressing need to examine the impact of mhGAP-based treatment of persons with SMD on their economic and livelihood status, in particular on food insecurity and work impairment levels, in order to evaluate the adequacy of such interventions.

1.1.2 Severe Mental Disorders (SMD) and the treatment gap

Severe mental disorders include psychotic disorders, such as schizophrenia, and bipolar disorders. Although there are many different forms of psychosis, schizophrenia is the best known, characterised by impairment of thought, perception, emotion, movement and behaviour, and affecting millions of people across the world (9, 10). The effect of the illness is severe in the majority of cases, frequently following a relapsing-remitting or chronic course (10) and associated with high levels of disability (11). Although the prevalence of schizophrenia is relatively low (1-2%) (12), the associated severity of impairment and risk of human rights abuses makes schizophrenia and other primary psychotic disorders a priority for intervention (8).

Bipolar disorder is a disorder in which the person cycles through uncontrollable mood states involving cycles of depression, hypomania (elevated mood) and, in some cases, psychosis (13). It is a major affective disorder characterized by a periodic exacerbation of discrete symptomatic episodes ranging from the characteristic manic mood and behavioral symptoms such as euphoria, grandiosity and impulsivity, to the dysphoric mood and behavioral symptoms of depression, anxiety, violence, suicidal ideation and attempts. Psychotic symptoms, including delusions and hallucinations, may be present in episodes of acute mania or depression (14). Bipolar disorder can lead to significant lifetime morbidity and mortality and has a worldwide distribution. Worldwide, the lifetime prevalence of bipolar spectrum disorder has been estimated to be 2.4% (15). The onset of illness is typically in young adulthood though there are often significant delays before the

diagnosis is made and effective management initiated, with growing evidence to indicate the importance of early identification (16). Further, bipolar disorder is reported to be characterized by prevalence underestimation with clinical samples but better with epidemiological household surveys (16). Bipolar disorder is commonly comorbid with anxiety disorders and substance/alcohol abuse (15). Bipolar disorder affects virtually every aspect of a patient's life, resulting in a high socioeconomic burden (17), high rates of unemployment and job-related difficulties (18).

The lifetime prevalence of schizophrenia and bipolar disorder were each reported to be 0.5% in Butajira, Ethiopia (19). Schizophrenia was also the most frequently made diagnosis amongst patients admitted to the only mental hospital in the country, accounting for 56.1% of the total cases admitted (20). Besides causing immense suffering to persons with SMD and their families, the economic cost of schizophrenia and bipolar disorder is also substantial (21). In a society where people are already struggling for survival, such as Ethiopia, the catastrophic economic impact of a chronic and disabling illness on the person and their family can easily be understood (22). People with mental health conditions are much more likely to experience disability and premature mortality, compared with the general population (5); the case being more likely higher for people with SMD. It is estimated that people with schizophrenia die 10-15 years younger than their healthy counterparts without schizophrenia (23) in high income country settings. A study from Ethiopia found even higher excess risk of mortality in people with SMD, who died more than three decades earlier than health counterparts (24). Schizophrenia and bipolar disorders are considered to be priority conditions for the WHO (8) because of the severity, the risk of affected people to be exposed to severe human rights violations, and the often-catastrophic effect on the welfare and income of family members (25).

The majority of people living with mental disorders in LMICs do not receive the treatment that they need. Between 76% and 84% of people with serious mental disorder in six LMICs in the World Mental health survey had not received treatment in the previous year (26). This represents the “treatment gap”, that is the gap between the burden of disorder in the population and the percentage of people in need of care who access evidence-based treatment (27). There is a great need for studies to quantify the burden of SMD in LMICs, particularly in socioeconomic terms,

and obtain evidence on the impact of health service interventions within the context of a low-income country.

1.2 Statement of the problem

The burden of MNS disorders is projected to grow in the next decade, in part because of the demographic and epidemiological transitions in LMICs (2). Nations with differing income levels have non-uniform availability and types of mental health care, ranging from traditional healers through psychosocial interventions to new generation medications. Although integration of mental health care into all aspects of general health care, but in particular primary health care, is recommended by the WHO, the extent to which this has been achieved to date varies across countries considerably. The almost complete absence of evaluations of scaled-up integrated care programs outside high income countries (HIC) (28) would appear as a concern (29).

In general, the process and effectiveness of scaling up mental health care has not been adequately assessed and research is needed to inform the continuing process of service reform and innovation (30). In particular, evaluation of integrated mental health care needs to consider the impact on the socioeconomic status of the affected person, something which has been little-investigated to date. This is especially true when considering the impact of treatment on food insecurity and work-related impairment in persons with SMD. A review of the impact of mental health interventions found that most were associated with improved economic outcomes, but that studies were restricted to people with depression or anxiety and did not consider the impact of interventions for people with SMD (31). It is also hard to find studies investigating the potential mechanisms by which mental health treatments lead to improved social and economic outcomes.

The issue of food insecurity, coupled with the rise in food prices in most parts of the world, has become the concern of national governments as well as the international community during the last few decades (6). Nonetheless, food security in persons with SMD has not been given due attention. There does not appear to have been any rigorous exploration of this issue among persons with SMD globally, and in Ethiopia in particular. Although some studies examining the association between common mental disorders (depression and anxiety) and food insecurity in LMICs have been carried out, none of them have investigated the impact of improved access to integrated mental health care on food security status.

The present study aims to investigate the impact of implementing a district level mental health care plan on food insecurity status in people with SMD living in rural Ethiopia, and potential mechanisms through which mental health and mental health interventions may impact upon food insecurity.

1.3 Rationale and significance of the study

Globally, severe mental disorders have a low prevalence (1-2%). However, they are associated with more enduring disability and higher social and economic costs than other mental disorders. SMDs are found to negatively affect the person's functioning across multiple domains and contribute to lower productivity, increased risk of poverty and food insecurity, increased exposure to stigma, discrimination and abuse, burden on carers, and poorer quality of life. Mental disorders have a particular impact on personal well-being, ability to perform daily activities, and social relationships (32). People suffering from schizophrenia may be disabled in various domains of personal, social, occupational and familial spheres, resulting in considerable burden to carers (33-35). In Ethiopia, caregivers of persons with SMD reported greater economic burden than that experienced by family caregivers of people with other long-term conditions (e.g. diabetes mellitus) in the same community (36). Coupled with the meagre health resources (human, material, financial) available in low-resource settings, the potential fate of persons with SMD is to have a higher likelihood of dependency, morbidity and mortality. Such a poor outcome is not inevitable if people with severe mental disorders receive the care and opportunities for rehabilitation, recovery and social integration that they need.

Several studies have examined the association between mental disorders and economic conditions, for example, poverty and food insecurity; however, these studies have usually been cross-sectional and have only investigated the association with common mental disorders but not severe mental disorders, where the association is expected to be stronger. Furthermore, there has been limited evaluation of the impact of providing mental health care on the general economic status of people with SMD, in LMICs or beyond. More fundamentally, there are no data on the prevalence of food insecurity among persons with SMD in this time of a rise in the global food-item price, despite a Food and Agricultural Organization's (FAO) report which discloses that much of Ethiopia's rural population lives in a state of chronic food insecurity (37).

Therefore, conducting of the current study in such a low health resource setting, Sodo, Ethiopia, is vital for the following reasons:

1) to provide data on the prevalence of food insecurity among people with SMD who have limited access to mental health care, compared to food insecurity in the general population, that would be vital for advocacy efforts;
2) to deliver evidence on whether evidence-based packages of mental health care for persons with SMD result in the improvement of food insecurity and work-related impairment levels; and
3) to elucidate mechanisms through which food insecurity may be alleviated in people with SMD to inform future efforts to tailor a food security intervention uniquely suited to address the challenges faced by persons with SMD.

2. Literature Review

In this part of the thesis, a systematic search and critical appraisal of the existing literature with respect to the objectives and research questions of the study will be presented.

2.1 Search Strategy

The following databases were searched: Pubmed, Medline and Google scholar from 1990. The initial search was carried out between January 2013 and September 2013 and updated in 2018. The following MeSH and free text search terms were used: "psychoses", "bipolar disorder", "schizophrenia", "disability", "work productivity/impairment", "food security/insecurity", "sub-Saharan Africa" or "developing country". In addition, the references of relevant journal articles were reviewed for further papers of relevance to the topic.

2.2 Global Burden of Psychosis

Although mental disorders may be common to all societies, the nature, prevalence, course and outcome may not be identical due to the impact of the specific sociocultural context. The prototypical primary psychotic disorder is schizophrenia, although the WHO mhGAP intervention guide uses the broader term 'psychosis' which incorporates other diagnoses, such as delusional disorder, schizoaffective disorder and affective disorders, such as depression with psychotic features (38). Schizophrenia appears to affect men and women equally, does not appear to discriminate colour, socioeconomic status or educational status, and has a similar incidence and prevalence worldwide (39). Globally, 1.1% of total DALYs lost are because of schizophrenia and 2.8% of total years lived with disability are due to schizophrenia, since the disorder is associated with early onset, long duration, and severe disability (8); increased mortality, poor quality of life and low recovery rates (40). Earlier age of onset, poor response to initial treatment, impaired premorbid adjustment, and negative symptoms have been associated with worse outcome (10). Schizophrenia often results in moderate to severe degrees of disabilities in the area of occupation and social contact (41, 42). Furthermore, schizophrenia is reported to be one of the most stigmatizing disorders, resulting in violations of human rights and discrimination in areas such as employment, housing and education (8). The burden of schizophrenia in LMICs might be expected to be even greater in light of the compounding effects of poverty, poor education and employment

opportunities, malnutrition and infection (10). Most of the burden of schizophrenia falls on economically developing regions of the world (43).

2.3 Epidemiology of SMD in Ethiopia – Schizophrenia and Bipolar Disorder

Schizophrenia and bipolar disorder are among the "priority mental illnesses" in Ethiopia, as defined within the National Mental Health Strategy of Ethiopia (22). In a methodologically robust community study from Butajira, rural Ethiopia, using standardised clinical diagnoses, schizophrenia was found to have a lifetime prevalence of 4.7/1000, a younger age of onset for females (mean age of 23.8 for males and 21 for females), and a very high male to female ratio (5:1) (19). This compares to another community study from the capital city, Addis Ababa, which relied upon non-clinician administered structured instruments and found the weighted life-time and one month prevalence of schizophrenia to be 0.4% and 0.3%, respectively (44). Being male, under 35 years of age, unmarried, educated and living in urban areas were all associated with a lifetime prevalence of schizophrenia (45). With respect to short-term outcomes, it was found that people with schizophrenia in the Butajira cohort study had significantly diminished health related quality of life, with the majority affected by significant functional impairment (46). The result of follow-up assessments conducted monthly for a mean duration of 3.4 years among people with schizophrenia in the Butajira study identified that about a third (30.8%) of them were continuously ill, while most of the remaining cohort experienced an episodic course and only 5.7% of the cases were reported to experience near-continuous complete remission. Hence, it was concluded that the course and outcome of schizophrenia in the rural Ethiopian setting appears no better than in developed countries, challenging previous studies of a better outcome in LMICs (47) and with overall less favourable outcome in Ethiopia than what has been reported from other LMICs although of more favourable course and outcome for female patients (48). Over 80% of people with schizophrenia were found to have negative symptoms and over 67% reported continuous course of the illness (19). A ten-year follow-up study among people with SMD in the same district indicated that the rate of suicide was high (49) and there was excess mortality (24); the overall incidence of completed suicide being 200.2/100,000 person-years (49).

With respect to bipolar disorder, outcome studies mostly come from the developed world and have emphasized the severe and disabling nature of the disorder and its association with a high cost and

mortality (50). In Ethiopia, in the Butajira study, the lifetime prevalence of bipolar disorder was found to be 0.5% of the general adult population, but higher (with a prevalence of 1.83%) for the isolated island community at Ziway (46). In a study conducted in a rural community in Ethiopia, bipolar I disorder cases consisted of 45.6% with a single episode, 25.7% with two episodes, and 28.3% with three or more episodes (51). Furthermore, people with bipolar disorder had more neurological dysfunction compared to healthy controls particularly in the area of sequencing of complex motor acts (51). In another study conducted in the same district on bipolar disorder, between 35% and 47% of the recent-onset cases had functional role restrictions, while 42–52% of longstanding cases had such restrictions during the follow-up period (52). With respect to social and physical functioning, deficits were also observed in 52–86% and 35–47% of recent-onset and long-standing cases, respectively, although there were improvements in function over time (52).

In summary, bipolar disorder in Ethiopia has been found to be a highly recurrent illness with chronicity in almost a third of the sample (50).

2.4 Scarcity of Mental Health Services and Treatment Gap for SMD

There is a large treatment gap for mental disorders across the globe, but the situation is particularly acute in developing regions of the world (53). Globally, it is estimated that only 25% of those who are in need have access to treatment, but with less than 10% in many LMICs (26). Those factors that adversely affect the mental and neurological health of populations, such as poverty, malnutrition, and burden of communicable disease, are concentrated largely in developing countries while the resources for addressing these needs are more available in richer countries (50). Indeed, it has been said that "Nowhere is this gap between needs and services more stark than in sub-Saharan Africa."(30). According to WHO, most LMICs have few trained and available human resources to provide adequate coverage of mental health care (8) and shortages are likely to persist (54). The low number of trained staff is compounded by distribution difficulties within countries or regions, e.g. too few staff in rural settings or too many staff in large institutional settings (8). In Ethiopia, for example, there are only around 80 psychiatrists (0.08/100,000 population), most of whom are working in the capital (22). The projected expansion of training of mental health specialists has not been able to bridge the gap (55). This scarcity of mental health specialists could clearly be one reason for the treatment gap. Low level of community awareness and a general preference for traditional and religious healing have also been reported as potential challenges to

the acceptability of integrated mental health care; however, poverty and inaccessible of services may be the biggest barriers to equitable coverage of mental healthcare (56).

Government spending on mental health in most LMICs is far lower than the needed, based on the proportionate burden of mental disorders and the availability of cost-effective and affordable interventions (4). Even when available, in part due to stigma and low awareness, in many settings, the necessary financing, infrastructure and resources are not allocated to mental health services (57). As expected, the poorest countries spend the lowest percentages of their overall health budgets on mental health (4). A study which has assessed the resource needs and costs associated with scaling up a package of essential interventions for mental health care over ten years estimated that the total expenditure in Ethiopia would need to increase by 13 times to achieve acceptable levels of coverage (58). The WHO mental health survey consortium on its part indicated that reallocation of treatment resources could substantially decrease the problem of unmet need for treatment of mental disorders among serious cases, though structural barriers exist to this reallocation (26). Similarly, it is asserted that reallocation of resources to cost-effective intervention strategies would increase health gain, save money and help implement much needed expansion of services for people with mental disorders in low resource settings (25).

In the WHO mental health Gap Action Programme (mhGAP), a task-sharing approach is recommended, whereby the management and treatment of priority mental health problems is integrated into primary health care (8). Such an approach would, in theory, enable the largest number of people to get easier and faster access to services in the shortest period of time (8). However, the extent to which primary health care workers can deliver adequate quality of care and achieve improved clinical, social and economic outcomes for people with SMD is unknown.

2.5 Disability among Persons Living with Severe Mental Disorder

Disability is an important domain in the consideration of diagnosis, severity and prognosis of mental disorders (59). Epidemiological research in community and clinical settings reveals a strong association between mental disorder and impaired occupational and social functioning (60). In people with SMD whose symptoms substantially improve over time, there are corresponding improvements in social and occupational functioning. In contrast, when symptoms do not substantially improve, there is little or no change in the level of disability (61). The link between

specific mental disorders and functional disability may be exacerbated by the co-occurrence of multiple mental disorders within the same individual (62).
There is an assertion that the concept of disability has shifted from a focus on individual impairment to recognition that disability is a more social phenomenon in the past three decades (63). Disability is a complex phenomenon, reflecting an interaction between features of a person's body and features of the society in which he or she lives (63). This notion reflects that persons with disabilities are seen as being restricted in performing daily activities because of a complex set of interrelating factors, some pertaining to the person and some pertaining to the person's environment and social/political arrangements (64).

As stated in the introductory part, mental disorders are associated with significant disability. Five of the ten leading causes of disability worldwide are in the category of mental disorders: major depression, alcohol dependence, schizophrenia, bipolar affective disorder and obsessive-compulsive disorder (65). Compared to physical ailments, mental disorders, by virtue of their very nature, display different pattern of disabilities, particularly affecting social and work-related functioning (64).

In a tertiary hospital-based study in India, conducted to assess and compare disability using the IDEAS (Indian Disability Evaluation Assessment Scale) in people with schizophrenia and obsessive-compulsive disorder, people in both groups had considerable global disability, although people with schizophrenia had significantly greater disability across all domains of IDEAS (65). In another study from India which assessed aspects of disability associated with seven mental disorders (schizophrenia, bipolar affective disorder, anxiety disorder, depression, obsessive-compulsive disorder, dementia and mental and behavioral disorders due to the use of alcohol) using IDEAS, all seven disorders studied were associated with significant disability; schizophrenia being maximally disabling (66). SMD appears to be highly disabling worldwide (67), with the level of disability tending to be associated with the severity of the disorders (66).

Social functioning is particularly affected by severe mental disorders. Social functioning is also a sub-domain of quality of life (41). Impairment of social functioning is hypothesised to be an important reason for the high levels of stigma and disability associated with severe mental disorders (68). The need to develop interventions which can improve social functioning has been noted to be important for a number of reasons (68): First, there is increasing evidence that service

users place greater value on improvements in social functioning than improvements in clinical status. Second, seeing individuals with mental disorders successfully treated and return to socially productive roles has the greatest impact on reducing stigma and may succeed where concerted efforts at improving mental health literacy have failed. Third, social functioning is seen as an increasingly important factor for reducing the overall burden of mental disorders, particularly for chronic or recurrent conditions such as schizophrenia and depression—disorders that cause very high levels of disability.

The extent to which interventions for SMD alleviate day-to-day functioning in general, and social functioning in particular, will now be considered, beginning with a brief overview of studies from high income countries and then providing a detailed appraisal of studies from low- and middle-income countries.

2.6 Impact of Interventions to Reduce Disability among Persons With Severe Mental Disorder

Psychotic disorders are associated with symptoms that involve impairment of thought, perception, emotion, movement and behaviour, leading to impairment and disability across a range of domains. Interventions to reduce symptoms are expected to also have a beneficial impact upon functioning, although that is not necessarily the case.

In a meta-analysis of 199 studies (69) focusing on psychoeducation, independent of treatment modality for people with SMD, psycho-education produced a medium effect post-treatment for reduction of relapse and a small effect size for increase in knowledge; but it had no effect on symptoms, functioning and medication adherence. Effects achieved for psycho-education targeted at people with SMD alone were not significant (69). However, in a review which examined the efficacy of psychosocial interventions for people schizophrenia (70), including 26 studies of group therapy, 18 studies of family therapy, and 11 of individual therapy, benefits in symptoms as well as social and vocational functioning were observed. This led to the conclusion that adjunctive psychosocial treatments augment the benefits of pharmacotherapy and enhance functioning in people with psychotic disorders (70).

In Table 1, studies investigating the impact of interventions for SMD upon functional outcomes are summarised. The Ethiopian studies will now be described in detail, followed by an overall critique of the studies from LMICs.

In the population-based Butajira cohort study, from south central Ethiopia, people with SMD were provided with access to psychotropic medication. The magnitude of mania and depression symptoms improved over the follow-up period, although the improvement was less marked for depression (52). In that study, sociodemographic or clinical variables were not associated with improvements in symptomatic outcome. The investigators found that between 35% and 47% of the recent-onset cases had functional role restrictions, while 42–52% of longstanding cases had such restrictions during the follow-up years. Again, the magnitude of depression and mania symptoms was associated with poor functional outcome, while male sex, rural residence and being married were associated with better functional outcome. Here, the authors concluded that, although there were improvements in function with follow-up, between one-third and one-half of cases continued to have functional deficits even while having improved access to treatment. This indicates that centralised, hospital-based mental health care may not be sufficient to improve functional deficits in people with SMD in this setting.

Table 1. Severe Mental Disorder, disability/functioning and impact of Intervention

Ref. No	Reference	Setting/ Design	Sample size	Treatment Package	Major Finding	Critique
(71)	Kebede, D, et al, 2005	Ethiopia/ community-based	271 (63 incident and 208 prevalent cases) schizophrenia	Oral or injectable neuroleptic medications, out-patient follow-up by psychiatric nurse and regular contact with outreach workers	Functioning, measured using the Short Form, 36 item questionnaire (SF-36), was significantly decreased in cases compared to the local population at baseline and follow up. Only lower negative and positive symptom scores were significantly associated with improvements in functioning after engagement in treatment. The level of functioning observed in cases from Butajira was lower than that reported for cases from developed countries.	Strengths: Community-based sample, large sample size, standardised measures Limitations: Treatment was limited only to biomedical care. Follow-up time lacked uniformity, Outcome benefits to users not stated.
(52)	Kebede, D, et al, 2006	Ethiopia/ Community -based	315 Bipolar disorder	Psychotropic medication and out-patient follow-up by psychiatric nurse and regular contact with outreach workers	Functioning was measured using SF-36. The magnitude of depression and mania symptoms was associated with poor functional outcome, while male sex, rural residence and being married were associated with better functional outcome.	Strengths: Community-based sample, large sample size, standardised measures Limitations: Specific treatments not stated, outcomes to potential beneficiaries not set out.
(72)	Odenwald, M, et al.2012	Somalia/ Community -based	33 males with psychotic disorder	Psycho-education, low-dose psychotropic medication, Monthly home visits and counselling.	Level of functioning (which was measured via carers' functioning ratings of interview) in 20 out of 33 patients improved significantly, with small differences between groups. Most patients experienced improvements in basic functioning, such as communication and self-care	Strengths: Follow-up frequency (monthly visits). Limitations: Very small sample limits interpretation. Only khat users and males studied, selection of sample not explicitly justified. Non-standardised measure of functioning.

Ref. No	Reference	Setting/ Design	Sample size	Treatment Package	Major Finding	Critique
(73)	de Jong JT. & Komproe IH, 2006	W.Africa / open study retro-spective cohort	45 SMD cases (cohort of chronic psychosis)	Depot neuroleptic treatment.	People with chronic psychosis reported a sharp decrease in symptoms paralleled by an increase in social functioning (measured by a semi-structured interview with patients & their families about social relationships) over the first 3 months. After 6-9 months this pattern stabilised and was maintained over the period from 1 to 5 years	Strengths: Frequent follow-up intervals and long follow-up. Limitations: Small sample.
(74)	Botha UA., et al, 2010	South Africa	60 people with schzophrenia	Intervention (n = 34) and control (n = 26) Modified assertive treatment service offered for intervention group	At 12-month follow-up subjects receiving the assertive intervention had significantly lower total PANSS ($p=0.02$) as well as positive ($p<0.01$) and general psychopathology ($p=0.01$) subscales' scores. The mean SOFAS (Social and Occupational Functioning Assessment Scale) score was significantly higher ($p = 0.02$)‡ .	Limitations: Small sample. Non-randomised study design meaning risk of bias.
(43)	Srinivasa, R. M. et al., 2005	Rural India, Community -based outreach programme s	100 people with untreated schizophrenia	Psychotropic medication and psychosocial support	Summary scores for psychotic symptoms and, disability (measured using World Health Organisation Disability Assessment Schedule II, 36-item version) were all reduced significantly, with particular improvement observed at the first follow-up assessment.	Strengths: Indication of advantages of outreach to remote areas. Frequent follow-up assessments (every 3 months) Limitations: Moderate sample size.
(75)	Thirthalli J, et al, 2009	Rural India, Community -based, comparativ e observation al study	190 people with schizophrenia in treatment	Community-based antipsychotic drug treatment (provided by study team or private psychiatrists).	Mean disability scores, measured using the IDEAS, and % of people classified as 'disabled' remained virtually unchanged in those who remained untreated, but showed a significant decline (indicating decrement in disability) in those who continued to receive antipsychotics and in those in whom antipsychotic treatment was initiated after 12 months of follow-up.	Strengths: Comparison group of people who did not receive treatment. Limitations: timing of outcome assessment (only at baseline & 12 months)

Table 1 (continued)

Ref. No	Reference	Setting/ Design	Sample size	Treatment Package	Major Finding	Critique
(64)	Thirthalli J. *et al, 2010*	India/ Community -based/ naturalistic design	182	People with schizophrenia receiving continuous antipsychotic treatment for the last two years compared to those who were not taking antipsychotics or taking irregular treatment in the past two years.	People with schizophrenia on antipsychotics had significantly less disability across all domains and in total IDEAS scores. Treatment status predicted disability scores even after controlling for the effects of controlling factors like age, sex, education, socio-economic status, duration of illness and alcohol dependence/ harmful use. Different levels of exposure to antipsychotics were associated with different levels of disability.	Strengths: Comparison group and validated measure of disability. Limitations: Non-randomised allocation.
(43)	Murthy RS, et al., 2005	Rural India Community -based outreach programme	100 people with untreated schizophrenia	Psychotropic medication and psychosocial support	Increases in treatment and community outreach costs over the follow-up period were accompanied by reductions in the costs of informal-care sector visits and family care-giving time. Summary score for disability along with psychotic symptoms & family burden were all reduced over the follow-up period.	Strengths: Frequent follow-up assessments Limitations: Limited sample size and lack of a comparison group.
(76)	Chatterjee S. et al., 2014	India/ Randomise d controlled trial	253 people with schizophrenia	Collaborative community-based care plus facility-based care for intervention group (n=167) vs facility-based care for the control group (n=86)	At 12 months, Disability, but not symptom scores were significantly lower in patients in the intervention group than in those in the control group (IDEAS –0·95, −1·68 to −0·23; p=0·01). However, pre-specified cut-offs for meaningful levels of change were not met. The impact on disability was more marked in the rural centre.	Strengths: multicentre, parallel group RCT design. Limitations: heterogeneous centres included

(77)	Chatterjee, S. et al (2009)	Community-based rehabilitation program	236 people with SMD	All individuals received a community-based intervention package comprising psychotropic medications, psychoeducation, adherence management, psychosocial rehabilitation and support for livelihoods.	There were significant reductions (P<0.05) in the levels of disability for the cohort, the vast majority (83.5%) of whom engaged with the programme. Lower baseline disability scores, family engagement with the programme, medication adherence and being a member of a self-help group were independent determinants of good outcomes.	Strengths: Longitudinal design. Limitations: No comparison group.
(78)	Balaji, M. et al (2012)	Community-based intervention development pilot study	Schizophrenia cases, their primary caregivers, piloted with 30 families	psycho-education; adherence management; rehabilitation; referral to community agencies; and health promotion) to be delivered by trained lay health workers supervised by specialists.	Participants found delivery by health workers acceptable. The intervention used is an acceptable and feasible intervention for treating schizophrenia in India.	Strengths: It is a multi-component community-based intervention. Limitations: pilot study, limited sample

PANSS: Positive and Negative Symptom Scale; TAU=Treatment As Usual

*The model includes outpatient care (first tier) supplemented with support from community case workers (second tier) and community rehabilitation initiatives (third tier). ‡ (SOFAS): Social and Occupational Functioning Assessment Scale measures only social and occupational functioning but eliminating symptom descriptors. ***IDEAS: Indian disability evaluation assessment scale

Overall, there have been several well-conducted studies from LMICs, mostly conducted in India. Few of these studies explicitly indicated that the instruments they are using to measure functioning are validated for local circumstances, except the studies from India, e.g. (76). Almost none of the studies had adequately examined functioning in relation to work productivity, although in some of the studies the measures used indicated impact on work (64, 76). Similarly, only few of the studies dealt with social functioning (73, 74), although the validity of the scales used were not explicitly stated. In addition, only two studies were randomised controlled trials (74, 76). However, none of these studies examined statistically the potential mechanisms linking changes in symptoms to changes in functional outcome. More importantly, the studies did not report the effect of the interventions on change in the livelihoods of the study participants.

Some of the findings used resource-intensive interventions, e.g. e.g. modified assertive treatment service (74), in combination with specialist psychiatric care which might be desirable to increase the probability of improvement regardless of resources required. Such intervention types may be useful in low-resource settings if found to be cost-effective. Some of the studies, including those which did not report use of medications (74, 78), had very small sample sizes, thus lacking precision and at risk of type two error.

In these studies from LMICs, various treatment types provided to persons with SMD were found to lead to improvements in psychotic symptoms, social, vocational, occupational and cognitive functioning, social networks, quality of life and reduction in both the overall level of disability and in various sub-domains of disability. The findings from these studies indicate that mental health interventions for persons with SMD can result in the improvement of many of the domains of functioning, although coverage of such models of care (reliant on psyciatrists in most instances) limites the population impact. Little is known of the extent to which mental health interventions integrated into routine PHC practices, with appropriate supervision and resources, can achieve the same level of impact, but the potential for population impact would be higher.

2.7 Work Productivity in Persons Living with Severe Mental Disorder

In studies from high-income countries, people with SMD have been found to have impaired occupational functioning, low levels of productivity (e.g., within paid employment, as a student, or other useful activity) and high rates of unemployment (79-81). The poor

productivity level among people with schizophrenia has long been recognized as a core component of the burden of illness and its economic cost (82, 83). In a study of the economic burden of schizophrenia in the United States in 2002, the indirect excess cost due to unemployment was found to be the largest component of the overall excess annual costs (84).

Improving the productivity level of a person with schizophrenia is an important treatment goal and was identified as the most preferred treatment outcome, more than improvement of symptoms, by clinicians, patients, their families as well as public policy makers (85). In an evaluation of the personal outcome preferences of a large sample (n= over 1200) of people treated for schizophrenia, work was identified as the fourth most preferred outcome (the strongest priorities were placed on reducing confusion and increasing energy, while social life and reducing side-effects were the least priorities) among six assessed domains, including social life, energy, symptoms, work, confusion and treatment-emergent adverse events (86). However, patients with greater preference for functional activities such as work had less preference for medical model goals such as reducing symptoms and had fewer symptoms.

Little is known about predictors of productivity levels in the treatment of people with schizophrenia, although the link between medication adherence and functional outcomes has been shown consistently (87-89). Adherence to antipsychotic treatment is associated with better long-term improvements in outcome measures including decreased risk of psychiatric hospitalization, detention, victimization, substance use, and severity of alcohol-related issues, as well as improvements in mental health and satisfaction with social life in general (88). Moreover, longer treatment duration with antipsychotic medications has been found to be associated with improved symptom severity levels (87) and greater functional outcomes in the treatment of patients with schizophrenia (90). Generally, productivity is a very important area in the treatment of schizophrenia and yet it is largely unstudied (91).

The vast majority of studies on the burden of bipolar disorder in the US indicate that burden comes largely from indirect costs, which include reduced productivity, work loss, and unemployment (17). Bipolar disorder is associated with high rates of unemployment and job-related difficulties (90). These imply the need to consider work productivity or work impairment issues in investigations which attempt to assess the impact of mental health care.

Productivity has mostly been conceptualised in Western settings to include 'useful' work, including working for pay, being a student, housekeeping, and volunteer work. In the rural Ethiopian (Gurage Zone, Sodo) context, where both sedentary agriculture and animal husbandry is practiced, these conceptualisations of productivity are applicable with the exception of volunteer work which is rare in this low-income country setting. Similar to many other predominantly rural settings in Ethiopia, most people living in the Gurage zone are either self-employed, or work for pay in the nearby area or work to earn something in kind. But, there is also a tradition of cooperative task engagement, called "*Debo*", where people from this area do activities with the sense of togetherness. In relation to this study, the productivity level of the potential participant is understood in terms of his/her current engagement level into those activities compared to people of the same age in the locality.

2.7.1 Work Productivity-Related Intervention Outcomes in Persons with Severe Mental Disorder

In high-income countries studies, such as the one studied in the USA, work productivity in people with SMD (measured by investigators on a five-point scale as 1. No useful functioning, 2. > 0 to 25% of the time, 3. > 25% to 50% of the time, 4. > 50% to 75% of the time, 5. > 75% to 100% of the time) was found to improve with treatment with antipsychotic medications (92). Productivity in this study was defined as functional activities/work including working for pay, studying, housekeeping and volunteer work. This post hoc analysis study used data from six randomized, double-blind clinical trials employing antipsychotic medication interventions on 1191 patients with schizophrenia or schizoaffective disorder. The findings indicated that chronically ill patients treated with olanzapine experienced significantly greater improvement in productivity when compared to patients treated with risperidone. Again, among first episode patients, olanzapine therapy was associated with greater improvements in productivity levels compared to haloperidol. But, significantly more chronically ill and first episode patients treated with olanzapine showed high levels of productivity (>75%-100% of the time) at the endpoint. Moreover, higher productivity levels were associated with significantly higher study completion rates and better scores on the positive, negative, disorganized thoughts, hostility and depression subscales of the Positive and Negative Symptom Scale (PANSS). Importantly, chronically ill patients who completed the studies had statistically significantly better productivity levels compared to dropouts in each of the six studies ($p < .001$) (92).

The above HIC study based its analysis on post hoc data; it also assessed the productivity level of people with SMD using a single item with five response options whose reliability and validity has not been established yet. In addition, the analysis was made on data from and there is no information as to whether the findings may generalize to people with schizophrenia treated in usual care settings.

Studies from LMICs investigating the impact of interventions for SMD on work productivity and functioning are summarised in table 2.

Table 2. Interventions for SMD and impact on work productivity

Ref.No	Author(s)	Design	Intervention Type Administered	Sample size	Major Finding/Observed Change/	Evaluation
(93)	Ran MS, et al, 2003, China	Cluster RCT	Family psycho-education intervention, Long-acting injection of haloperiodol or oral medication, or both. Control received TAU*	I-1=126I-2=103 Control=97 Recent onset & chronic cases of schizophrenia	Although not statistically significant, the number of patients who were able to work full or part-time was greater in the intervention group.	**Strengths:** Combined interventions, use of more than one intervention levels. **Limitations:** Timing of outcome assessment is early (only at 9 months)
(94)	Xiong W, et al, 1994 China	Individual RCT	Family counseling session, family group session, home visit, medication supervision	I=34 Control=29 Schizophrenia cases	The intervention group reported a significantly reduced effect of the condition on family finances during the whole follow-up period. Patients in the intervention group had significantly more months of employment than did the control group.	**Strengths:** Diverse interventions applied, Good timing of outcome assessment (at 6,12,18 months) **Limitations:** Very small sample size and risk that findings due to chance

I=Intervention *TAU=Treatment As Usual

2.7.2 Summary and Implications of the Above Findings

Various treatment modalities, including medications, family psychoeducation, psychosocial support, family counselling session, family group sessions, home visits, medication supervision and community-based antipsychotic medication treatment were found to improve work disability, duration of employment, and the productivity level of people with SMD and also reduced its effect on family finances. Some of the studies were limited by reliance on short-term outcome assessments. The measures of work productivity were also problematic, often only measuring whether or not a person attended the workplace for a certain length of time but not measuring how well they actually worked, that is, their productivity. That is, the indicators usually did not report the quantitative aspects of changes in productivity.

The above studies reflect those intervention studies conducted in either developed or fastest-growing economy counties. However, as yet there has not been any intervention study which explicitly described interventions undertaken using diverse treatment modalities and their functional and economic outcomes of persons with SMD in low-income countries like Ethiopia. Therefore, it is important to conduct a study which aims considering the functional and productivity outcomes of mental health care in low-resource settings.

2.8 Food Insecurity and Mental Health

2.8.1 Definitions

The term "food security" originated in the international development literature of the 1960s and 1970s, and at that time referred to “the ability of a country or region to assure an adequate food supplies for its current and projected population” (95). Defining food insecurity, the inverse of food security, has been a problem in the past as it is influenced by theories and policies (96); as some focus on nutritional factors, some on access factors and others on adequacy or sufficiency issues.

More traditional food security measures that rely on anthropometry or dietary intake or recall data may miss food insecure individuals—an important point as populations urbanize and diets change (96). The reviewers argued further that to define food insecurity on the basis of dietary intake and anthropometry, therefore, is potentially to confuse an outcome with the definition and would

inevitably lead to misclassification of the food insecure. Even though the term ‘‘food security’’ has been fairly well defined, because of the presence of a number of other constructs, such as hunger, malnutrition, food insufficiency, starvation, and famine, which have been used in place of food insecurity over the years but do not hold the same meaning (96), failure to recognize this point has likely contributed to the inability of development policies to solve the problem of food insecurity (97, 98).

Food insecurity is defined by Food and Agricultural Organization as “uncertain access by all people, at all times, to adequate food for an active and healthy lifestyle” (99). Food insecurity is simply the lack of food security that, at the extreme, is experienced as hunger (100, 101). Thus, famine and hunger are both rooted in food insecurity. Food security exists when all people, at all times, have physical, social and economic access to sufficient, safe and nutritious food to meet their dietary needs and food preferences for an active and healthy life (102). While food insecurity does not capture all dimensions of poverty, it may indicate poverty and is an important indicator of well-being (103). In summary, there is now consensus that the concept of food security embodies food availability, access and utilization (6).

2.8.2 Measurement of Food Insecurity

Measuring food security has been equally problematic and, often, as imprecise as that of its definition (96). Earlier, food security and insecurity measurement was approached by employing proxy measures, such as nutritional status, calorific intake or macro- and micronutrient intake, and poverty level. That is, earlier measures were not encompassing the way in which access to food is negotiated and experienced. There has been a shift in the conceptualization/thinking about food security from objective indicators to subjective perception (104) or move to perception measures to improve the disaggregated identification of food insecure sub-populations and their targetable characteristics and behaviors (105). However, recently there has been development of experience-based measurement scales that allow a more precise and valid measurement. Since the focus of food security research has shifted to the access dimension, measurement of the construct has shifted from the quantification of food availability to the ways in which access to food is negotiated and experienced (104, 105). A strategy that is gaining increased acceptance among researchers and policy makers is to develop experiential, scaled food security instruments based primarily on issues of access, but incorporating other aspects of the definition as well. Among such scales is a commonly used tool, the Household Food Insecurity Access Scale (HFIAS), USDA core food

security module (106), the Radimer Cornell Hunger Scale (107), the Hunger project scale, the Latin American and Caribbean Household Food Security Scale (ELCSA) (108), and Brazilian Household Food Security Scale, which are based on in-depth understandings of the experience of food insecurity as reflected in respondents' narratives of their experiences (109).

These tools are also reported to attempt to capture the range of expressions of food insecurity whereas earlier questionnaires focused on food insufficiency or outright hunger. Experience-based scales are underpinned by extensive processes of qualitative and ethnographic research and can be locally shaped and still reflect commonalities in the cross-cultural experience of food insecurity. Also, some scholars have used anthropological techniques to push for new ways of measuring food insecurity (110). Some researchers noted that the above newer food security measurement tools reflect three shifts in focus compared with earlier measures (111). First, current tools place less emphasis on availability and utilization and more on secure access to food (or on entitlements), Second, current tools reflect a growing concern with the adequacy and expense of proxy measures such as nutritional status, calorific intake and micronutrient intakes, in capturing food insecurity across individuals and populations and, thirdly, the shift toward subjective, experience or perception-based measurement tools recognizes that one could be food insecure or worrying about meals, skipping meals, reducing meals, but still be consuming sufficient macro and micronutrients or may have anthropometric values that reflect adequate or even over-nutrition. On the other hand, it should be noted that the recent historic rise in food prices in the world reflect both quantitative and qualitative shifts in the supply and demand side processes that ultimately determine household level food insecurity.

2.8.3. Dimensions/components of food insecurity

Four dimensions of food security have been defined: food accessibility, food availability, food utilization and stability (112).

Food access: Household food access is the ability to obtain sufficient food of guaranteed quality and quantity to meet nutritional requirements of all household members. Food access is the extent to which consumers (individuals and households), as agents, are able to obtain food for an adequate and acceptable diet; the power to exercise this ability is dynamic and derives from the amount and type of household resources and food landscapes available (112, 113). The food should be at the right place at the right time and people should have economic freedom or purchasing power to buy adequate and nutritious food (112).

Food access is individual, variable, and subjective. Food access is an important component of food security, defined as "access by all people at all times to enough food for an active, healthy life and includes at a minimum: (a) the ready availability of nutritionally adequate and safe foods, and (b) the assured ability to acquire acceptable foods in socially acceptable ways e.g., without resorting to emergency food supplies, scavenging, stealing, and other coping strategies" (114). Food access is determined by physical and financial resources as well as by social and political factors (115). Access depends normally on; income available to the household, the distribution of income within the household, the price of food and other factors worth mentioning are individual's access to market, social and institutional entitlement/rights.

Food availability: Refers to the physical presence of food which may come from own production, purchases from internal market or import from overseas (116). At a national level, food availability is a function of the combination of domestic food stocks, commercial food imports, food aid and domestic food production, as well as the underlying determinants of each of these factors.

Food utilization: Refers to ingestion and digestion of adequate and quality food for maintenance of good health. This means proper biological use of food, requiring a diet that contains sufficient energy and essential nutrients as well as knowledge of food storage, processing, basic nutrition, child care and illness management (112).

Stability of food: Refers to the continuous supply of adequate food all year round without shortages (112). To be food secure, a population, household, or individual must have access to adequate food at all times. They should not be at risk of losing access to food as a consequence of a shock (e.g., an economic or climatic crisis), or cyclically (e.g., during a particular period of the year, seasonal food insecurity). The concept of stability can therefore refer to both the availability and access dimensions of food security.

2.8.3 Important risk factors for food insecurity

1. Low Income

A key risk factor for food insecurity is low income (117); thus, interventions that aim to tackle food insecurity and its consequences on families have primarily focused on supplementing poor families' income to help them purchase nutritious foods (118). There is evidence which indicates that food insecurity disproportionately occurs among low–socioeconomic status (SES) and low-income families; however, interventions that supplement families' income or diet have not eradicated food insecurity because of non-financial factors such as the presence of mental health

problems (118). Lower earnings and income among households with a disabled member increase the likelihood of food insecurity (119).

2. Household Structures

In a study conducted in the two most populous administrative zones of Southern Ethiopia, named Sidama and Wolayta, some household structural characteristics, such as household size, age of household head, headship, marital status, marital form, major source of consumption, and operational land size owned were reported to make a significant contribution to food insecurity at the household level. Population pressure, which is approximated by household size, is known to be one of the leading causes of food insecurity in the study area (120).

3. Disability

Adults with disabilities have lower levels of educational attainment and labour force participation than their peers, resulting in a higher likelihood of living in poverty (121), thus more likely to experience a manifestation of poverty, food insecurity. It is also reported that at-risk subpopulation groups, including individuals who are physically and mentally disabled, are on the margins of inadequate nutrition (122). Moreover, individuals with disabilities can have substantial limitations with respect to food access, food preparation, shopping, and planning (119). Persons with disabilities are a population with an increased risk for food insecurity, as there is strong association between food insecurity and disability (123). More specifically, very low food insecurity, the more severe range of food insecurity characterised by disrupted eating patterns and reduced food intake, was more common among households with adults with disabilities than among other households (123). Even at similar income levels, households with a member with a disability are more likely to be food insecure than households without a member with a disability (119, 124). Vision, mental, and physical disabilities were associated with higher odds of food insecurity than hearing, self-care, and going-outside-home disabilities (123). On the other hand, because patterns of healthcare utilisation differ between persons with and without disabilities, whereby persons with disabilities have higher rates of emergency department and inpatient visits than other persons and increased rates of delayed care due to cost (125), this can affect timely recovery and work engagement.

2.8.4 Food Insecurity and Health Outcomes

Previous research suggests that food insecurity is directly related to numerous health outcomes (126). It is also documented that food insufficiency, at the individual level, is associated with not

only poor health outcomes, but also poor nutrition (127-129) and mental health status as well (130, 131) and the presence of this phenomenon at the household level suggests vulnerability to a large range of consequences including poor health status. The degree to which people have access to food influences the quantity and quality of food choices they can make, and this has an impact on quality of life, health, and illness (132, 133).

Even though much theory linking food insecurity to health has focused on reporting the nutritional outcomes of food insecurity such as nutritional status among children and adults, it is reported that insecure access to food contributes to wellbeing beyond nutritional outcomes (96). That is, food insecurity placed some individuals and households at greater risk for non-nutritional health outcomes, particularly diabetes, stress, chronic and infectious disease such as HIV/AIDS and poor mental health (96). Ethnographic work has linked the experience of food with mood disorders, symptoms of anxiety and depression, and dysthymia (134) and child behavioural disorders (118, 135-137).

Emerging research results are reporting that there are associations between mental health and food insecurity. Mental health is often associated with functional disability (137); and mental health disorders may impose a substantial drain on household resources and may lower household productivity, although some of the physical effects of insecure access to food may be mediated by caregiver mental health (96). A growing number of studies show support for a positive association between food insecurity and poor mental health in developing countries (138).

Even though some evidence to support this relationship already exists for populations in developed nations (139), in developing countries, particularly in sub-Saharan Africa, where food insecurity and exposure to stressful life events are common features (140) and where food insecurity remains an important public health issue, fewer number of studies have been undertaken concerning the association between mental health and food insecurity (141, 142). In a systematic review of studies investigating the association between food insecurity and common mental disorders, ten out of twelve of them indicated a positive relationship (143).

Generally, food insecurity and poor health outcomes are linked, with the linkages mediated through variable coping responses that are context-specific (96). The following tables attempt to unpack what is known about the relationship between food insecurity and mental health conditions in LMICs, focusing in particular on sub-Saharan Africa.

Table 3. Summary of Food Insecurity (FI) and Mental Health Conditions in sub-Saharan Africa

Ref. No	Author	Setting	Sample size	Measure of Food Insecurity	Major Finding	Critique
(139)	Hadley, C & Patil C, (2006)	Rural Tanzania	449	USDA † food security module	A strong positive correlation was observed between FI measures & Depression measures (HSCL). FI prevalence was reported to be 36%.	Strength: studying diverse communities. Limitation: cross-sectional design; female only
(140)	Hadley, C, et al., (2008)	Rural Ethiopia	902	7-item scale (validated previously in diverse settings of developing countries).	FI, stressful life events were *independently* associated with high symptoms of depression, anxiety and post-traumatic stress. FI, stressful life events and symptoms of CMD were highly prevalent.	Strength: Experience-based measure of household food insecurity. Limitation: cross-sectional design and non-validated mental health measure
(144)	Maes, KC, et al., 2010	Addis Ababa, Ethiopia	110	The 9-item Household Food insecurity Access Scale (HFIAS)	The volunteers in the urban sample did *not* report increasingly severe FI or CMD during the peak of the 2008 food crisis. Prevalence ranges from **60 to 47%** at different rounds of assessment.	Strengths: neglected population Limitations: Participants were a selected group (volunteer care providers); Studied during peak of food crisis
(145)	Sorsdahl, K, 2011	South Africa	4185	a single-item measure of food insufficiency (similar to the SASH food insufficiency item)	29% of respondents reported that their household 'sometimes' did not have enough to eat while 9% reported that they 'often' did not have enough to eat. After controlling for conventional socioeconomic and sociodemographic variables, food insufficiency was associated with having any 12-month (OR 1.44, 95% CI 1.1 to 1.9) and lifetime (OR 1.35, 95% CI 1.1 to 1.7) DSM-IV disorder.	Strengths: large sample size Limitations: Association not formed with a specific DSM category. Relied upon a single-item measure of food insufficiency.

(146)	Leyna, GH. 2005	Rural Tanzania	891	Single question adopted from the third National Health and Nutrition Examination Survey (NHANES III)	The overall prevalence of food insecurity was 25.2%. It was positively related to age, presence of children and having a health complaint among women and negatively associated with level of education among women and employment status among men.	The validity of the instrument is not described except stating being adopted.
(138)	Cole, SM & Tembo, G 2011	Rural Zambia	280	A modified 7-item scale based on local coping strategies used during food shortages	A positive and significant association between FI and poor mental health was found. FI in the dry season had a subsequent greater effect on mental health than food insecurity in the rainy season.	Strength: use of interaction term in the analysis to estimate effects; Limitation: - relatively small study

HSCL: Hopkins Symptom Checklist †USDA: US Department of Agriculture (modified version)

Implications of the above findings

The above table indicates that there is sufficient evidence for the existence of a relationship between food insecurity and mental health conditions in LMICs. Alhough the link established here is with common mental disorders, one may expect an even stronger link with SMDs mainly because of the disabling nature of SMDs. However, prevalence studies reported on food insecurity and SMDs are scarce, not only in LMICs but also in HICs. There have also been no prospective studies examining the direction of the relationship. And the directions of relationships is not well understood. This calls for the need to undertake an exploration to see the prevalence of food insecurity among persons with SMD as well as the extent to which mental health interventions for SMD impact on food insecurity levels.

Severe Mental Disorder and Food Insecurity

Studies relating SMD with food insecurity are scarce and and does not seem to have methodological rigor. A mixed methods study (qualitative and quantitative), from the United States assessed food insecurity within a convenience sample of 72 community-dwelling individuals with documented SMD (147). The study used a 30-day modified version of the US Household Food Security Questionnaire for semi-structured interviews (n=28) and focus groups (n=4) among a sub-sample of these individuals. Within the sample assessed, 45.8% were classified as food insecure, with 29.2% identified as experiencing the most severe level of food insecurity (e.g. very low food security), but selection bias is likely. In a facility-based, case-control study in India, people with SMD were reported to be more deprived in terms of food insecurity (15.1% higher) compared to their controls (148). In a qualitative study which explored perspectives of patients and caregivers of persons with SMD in Butajira, Ethiopia, on reasons for use of khat (an amphetamine-like substance used in the area) and in an area where chronic food shortage is observed, one way of curbing one's appetite was reported to be by chewing khat (9). This can imply that persons with SMD are likely to experience food insecurity in the study site.

2.9 Expanding access to mental health care

The WHO mhGAP initiative aims to expand or scale-up mental health care through integration into PHC by being grounded on the best available scientific and epidemiological evidence on packages of intervention for priority MNS conditions (8). The Ethiopian National Mental Health

Strategy has adopted the WHO's mhGAP approach of integration into PHC for priority MNS disorders, including schizophrenia and bipolar disorders (22). In support of this policy initiative, various demonstration studies have been conducted to build up evidence on how to achieve integrated care in practice, including the Programme for Improving Mental health carE (149). In a participatory theory of change workshop conducted in the study district, the need to encourage broad political support for the integration of mental health care services into primary care was suggested (150). As a consequence, an integrated district level mental health care plan, with various packages and at different levels of the district health system (community, health facility and healthcare organisation), was developed as an essential framework for the provision/implementation of integrated care in rural Ethiopia and perhaps similar LMICs (149). The planned evaluation of district mental health care plans of the PRIME consortium program included disorder-specific cohorts to assess the effects on patient outcomes (151). This PhD is nested within the SMD cohort of the PRIME-Ethiopia research program.

2.10 Theoretical and conceptual frameworks

The concept of food insecurity can be approached from various perspectives. The humanistic perspective (or needs theory), self-efficacy theory, the social causation and social selection (or social drift) hypothesis and the biopsychosocial model of mental health each provide relevant perspectives for the current study and will now be considered.

Humanistic needs theory as related to food insecurity

People have natural tendencies to fulfill their needs and attain self-actualization (152), based on a hierarchy of needs (see Figure 1). Within this framework, basic physiological needs, which include getting adequate food, need to be met before transcending to higher-order well-being or growth needs. Mental health may be affected negatively by physiological effects of food deprivation, but the priority is the restoration of access to adequate food rather than tackling mental health in isolation. It is important for people to fulfill their physiological needs before addressing other non-physiological needs such as medical or psychosocial interventions. Following fulfilment of the physiological aspect of the need for food, then comes the need for safety and security of access to food. This taps into the psychological aspect of food, that is, food (in)security needs. A person may have met current physiological needs for food but, because of unpredictability of income, farming yield or other factors affecting future access to food, they may experience mental distress. Insecurity of food access may also be balanced against health security. Scale-up of antiretroviral

therapy was hampered by people needing to prioritise their nutritional needs (e.g. selling medication for food) (153) which led to the inclusion of nutritional interventions alongside access to antiretroviral interventions (154). At a higher level in the hierarchy, lack of availability of culturally endorsed foods may also be a source of mental distress through undermining family connections, capacity to engage in social events, sense of belonging and self-esteem, even if the person has enough food to satisfy their physiological needs. Even the highest level of the hierarchy, self-actualisation, may depend on the capacity to provide food securely to one's family. In this way, it can be seen that mental health is inter-linked with nutritional and food security at each level in the hierarchy of needs. Below is Maslow's Hierarchy of Needs (155).

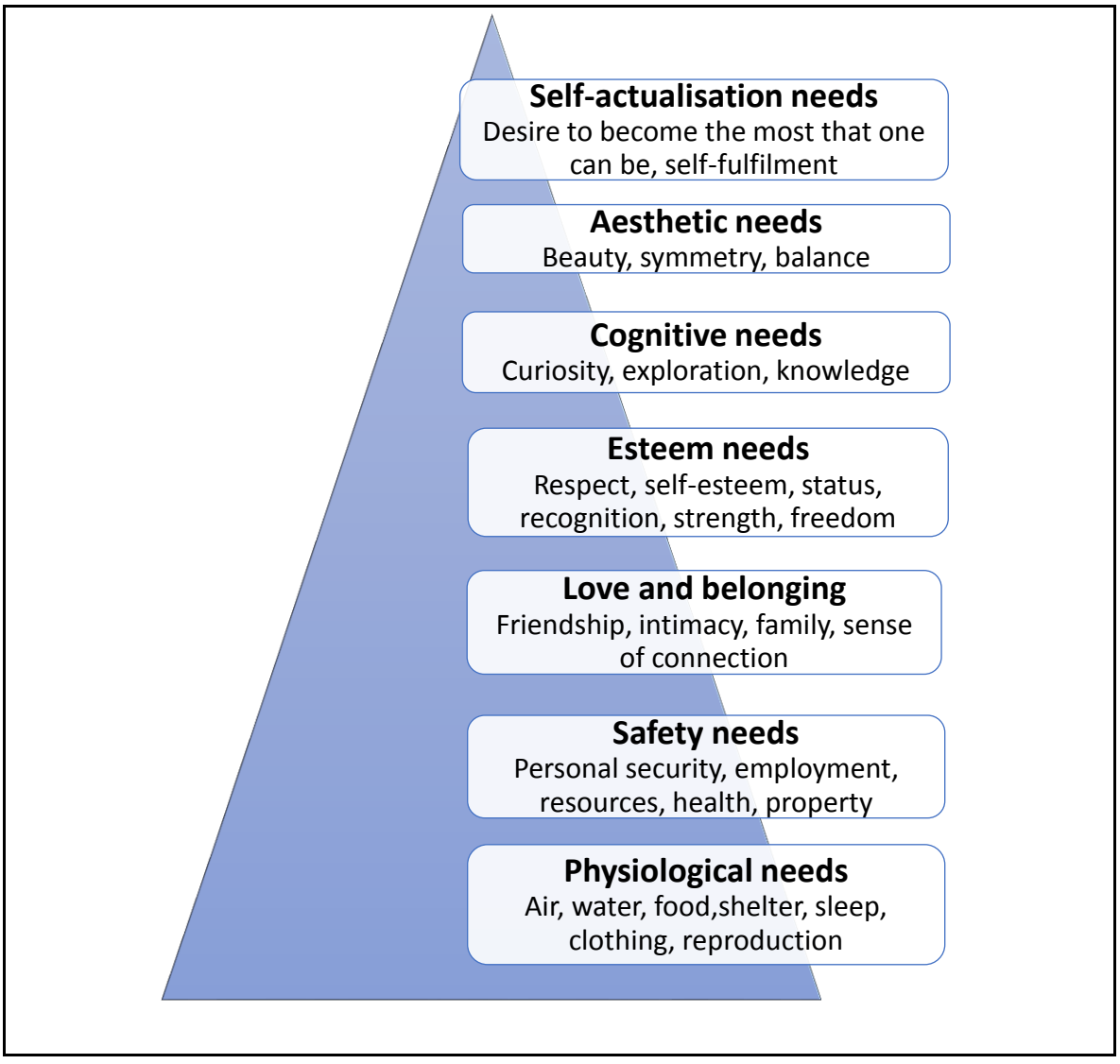


Figure 1. Maslow's hierarchy of needs

Albert Bandura's theory of self-efficacy

Self-efficacy is defined as a personal judgement of "how well one can execute courses of action required to deal with prospective situations" (156). Expectations of self-efficacy determine whether an individual will be able to exhibit coping behavior and how long effort will be sustained in the face of obstacles (157). There are indications that self-efficacy affects every area of human endeavor. By determining the beliefs a person holds regarding his or her power to affect situations, it strongly influences both the power a person actually has to face challenges competently and the choices a person is most likely to make. These effects are particularly apparent, and compelling, with regard to behaviors affecting health (158). The issue of self-efficacy is relevant to describe how it influences self-management in people with SMD. Because SMDs interfere with rational thought, feeling, and actions, people with SMD may not be able to make reasonable planning, judgement, decision-making and turn-taking when acutely unwell. Experience of stigma, discrimination and abuse can also undermine self-efficacy of a person living with SMD. Thus, self-efficacy emerges as an important concept in affecting the person's capacity to withstand adversities, such as food insecurity, and also affects their help-seeking and behaviors to promote their physical and mental health.

The social causation and social selection or social drift hypothesis

The relationship between mental health and poverty in low and middle-income countries is complex and may include both social causation and social selection, or social drift, mechanisms (159). The proponents of social causation assert that people living in poverty are at increased risk of developing mental health problems through the stress of living in conditions of deprivation, increased risk of trauma, and other negative life events, increased obstetric risks, social exclusion and food insecurity (31, 160, 161). However, social selection proponents argue that mental disorders lead to increased health expenditure, loss of employment, reduced productivity, stigma and a drift into poverty (162). Both causation and drift may be relevant to people with mental health problems, leading researchers to speak of the "vicious cycle" of poverty and mental illness. The breaking of this cycle, particularly in LMICs, is proposed to be essential to allow a person to regain mental health (143). However, interventions will be more effective if they are grounded in evidence indicating the most salient mechanisms linking SMD to food insecurity. A figure for the cycle of poverty and mental illness is given below (Figure 2) (163).

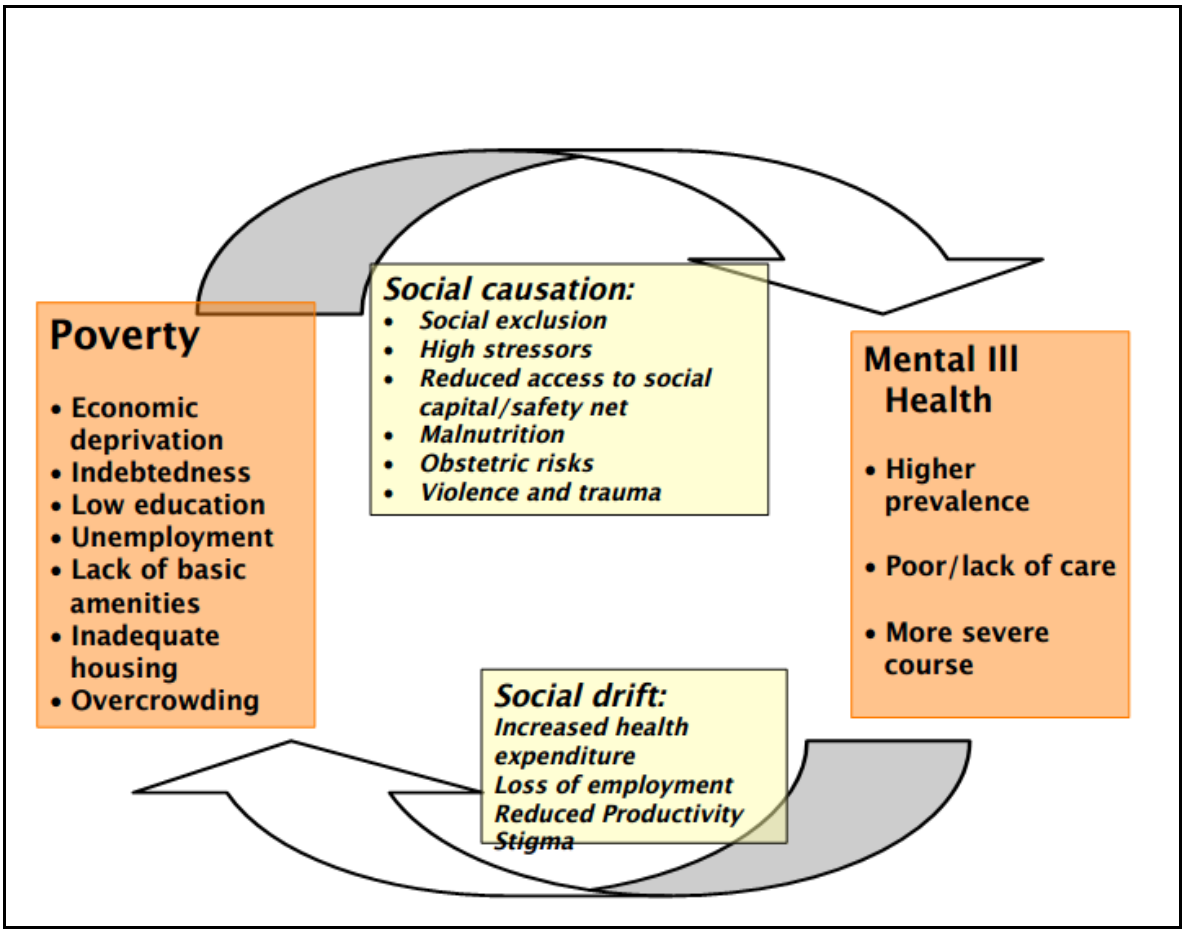


Figure 2. Cycle of poverty and mental illness

The biopsychosocial model and mental disorders

The biopsychosocial model is reported to have been an important influence on modern psychiatry (164, 165); despite its limitations (166). This model is a holistic framework that seeks to understand why a particular mental disorder has occurred in a specific individual at a particular moment in time by looking at the likely interplay between biological, psychological and social factors (167). In line with this model, interventions can be grouped into biological (mostly pharmacological), psychological and social categories, which can be tailored to an individual's needs. If coupled with responsiveness to the preferences of an affected person, such approach is likely to allow for a "person-centered" approach to treatment, which has been reported to be associated with better outcomes for a range of chronic conditions, including mental disorders (168). In addition, there have been suggestions to include the "spiritual" component to this model, having the name "bio-psycho-social-spiritual" approach, which was elaborated to be more

appropriate to the Ethiopian context (169). Likewise, the WHO mhGAP intervention guide provides evidence-based guidance for biological, psychological and social interventions for priority mental disorders, including psychosis and bipolar disorders. Biological interventions include pharmacological approaches (e.g. prescription and monitoring of antipsychotic and mood-stabiliser medication, including side effects and response to treatment), but could also include detection and management of co-morbid physical conditions and provision of nutritional support for a person found to be malnourished. Psychosocial interventions include facilitation of rehabilitation, reactivating social networks, address social stressors, provision of psychoeducation (information about the illness, available treatments and actions that the person can take to promote their own mental health), support for caregivers and encouraging linkage with community organisations that are involved in work, livelihoods and social inclusion (38). Hence, the biopsychosocial model helps to understand mental disorders in an over-arching manner.

Summary of conceptual framework

In summary, the above theoretical and conceptual frameworks/model will be used to describe and explain the association between severe mental disorder and food insecurity, disability and work impairment in this Ethiopian setting. Within this conceptual approach, the hypothesized links between exposures, outcomes, mediators and potential confounders and effect modifiers are presented in Figure 3.

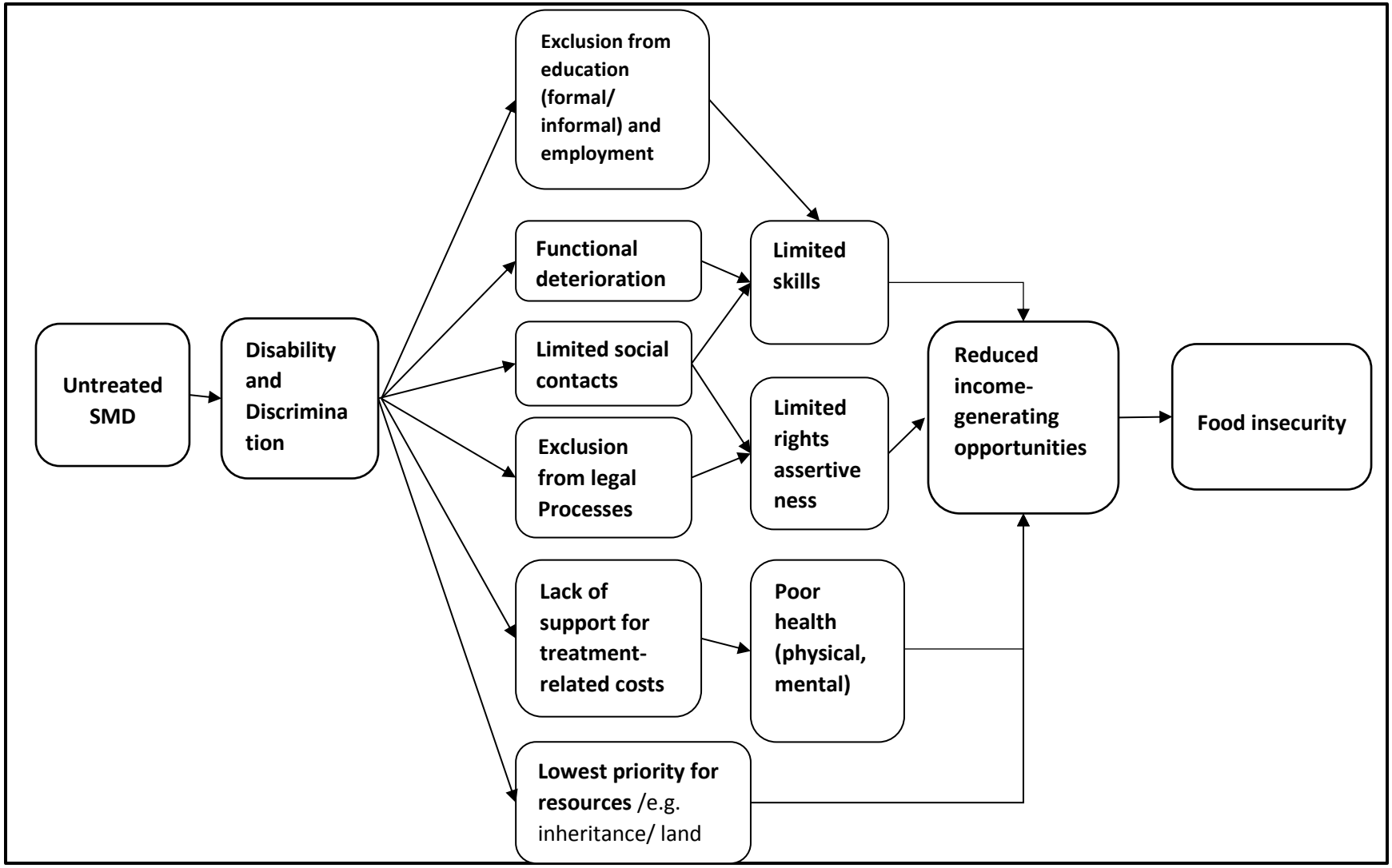
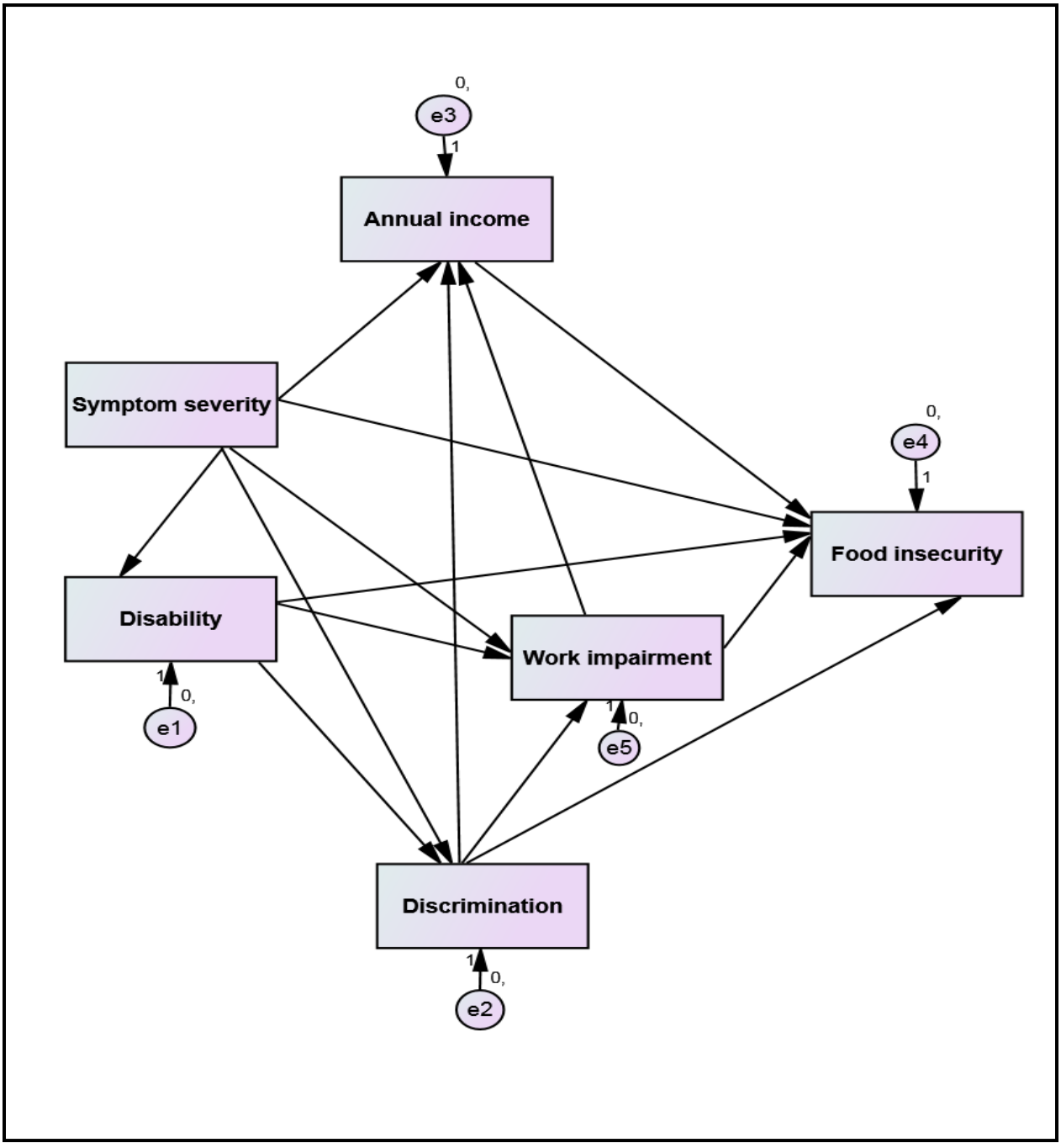


Figure 3. General conceptual model of the relationship between SMD, social conditions and food insecurity (Adapted from Yeo, R., 2001) (170)

The following figure (figure 4) depicts hypothesized factors associated with food insecurity and possible mediating roles among the variables using path diagram.



Difference in scores between baseline and 12 months were considered for all modelled variables; e1, e2, e3, e4, e5 and e6 are error terms for the respective observed endogenous variables

Figure 4. Path diagram for hypothesized factors associated with change in food insecurity

2.11 Aims of the dissertation

General objective/overall aim

The general objective of this study was to investigate the association between severe mental disorder and food insecurity in a rural Ethiopian district before and after improved access to mental health care.

2.12 Research Questions

The study sets out to answer the following research questions:

1. In a rural Ethiopian district with limited access to specialist mental health care, what is the level of food insecurity in people with SMD compared to those without SMD?
2. What are the factors associated with food insecurity and work impairment in people with SMD in a rural Ethiopian setting who have limited access to mental health care?
3. What is the impact of implementing an integrated district level mental health care plan upon food insecurity in people with SMD, beyond any secular trend, and what is the underlying mechanism for any observed impact?

Specific objectives/specific aims

The study had the following three specific objectives.

1. To compare the levels of food insecurity and associated factors in people with SMD to those without SMD in a rural Ethiopian community with limited access to specialist mental health care.
2. In people with SMD who had limited access to specialist mental health care, to investigate factors associated with food insecurity and work impairment.
3. To evaluate the impact of a multi-faceted district mental health care plan on food insecurity in people with SMD and investigate potential mechanisms for impact.

Hypothesis

This study has a separate hypothesis for the various sub-studies:

Study 1: At baseline, people with SMD will have higher food insecurity levels compared to people without SMD.

Study 2: Baseline food insecurity and work impairment in people with SMD are associated with a range of clinical (symptoms and disability) and social (social support, discrimination, income) factors.

Study 3: It is hypothesized (a) that implementation of the PRIME district level mental health care plan would result in a reduction in household food insecurity over a 12-month period of follow-up, after accounting for secular trends in food security levels in the general population, (b) that there would be a significantly greater change in mean HFIAS score in people with SMD who attend 50% or more of their follow-up appointments compared to those who attend less than 50% of scheduled appointments, and that (c) any effect of mental health care on household food insecurity status in people with SMD would be mediated by reduction in psychotic symptoms, reductions in disability and levels of work impairment, decreased negative discrimination and improved annual household income (see figure 4).

3. Methods

3.1 Setting and context

The study was carried out in Sodo district in the Gurage Zone of the Southern Nations, Nationalities and Peoples' Region (SNNPR), Ethiopia, which is located approximately 100 km from the capital city, Addis Ababa. Sodo is the second largest district of the Gurage zone, comprising 58 *kebeles* (sub-districts) (171), with a total population projection of 161,097 from 2014-2017 and nearly balanced sex proportion, of which the majority (84.6%) live in rural areas (172). Sodo is reported to have a population density/square kilometer of 166.7, which is high compared to other districts in Ethiopia (173). Within the SNNP region, there is an average household size of 4.9 people (4.2 for urban and 4.9 for rural households) (174), and a yearly average population growth of 2.9% (95). (175). Agriculture is the major means of livelihood for 90% of rural population (176). Around 55% of the population is literate (177). Amharic is the official language of the region though it is the second language for the majority of the dwellers. At the time of this study, there were eight primary care health centers that are linked to health posts which are staffed by community-based health extension workers.

It was reported that SNNPR can boast all of the inhabited environments seen elsewhere in Ethiopia: arable highlands (*dega*), midlands (*woina dega*), lowlands (*kolla*), and grazing pastures (*bereha*). But the relatively fertile and humid midland dominates (178). The most characteristic product of SNNPR is *Enset* (Ensete ventricosum or 'false banana'), a food staple unique to Ethiopia (178). Cereals are reported to be ubiquitous and are dominant in the relatively high- or low-altitude arable areas, together with smaller amounts of pulses and oilseeds and annual root crops (including sweet potatoes, Irish potatoes, and cassava) are important especially in midland areas. In the diverse ecology of SNNPR, one may also find livelihoods that rely on important cash-crops like coffee (178), ginger, chilli peppers, and the mild stimulant drug leaf khat (Catha edulis), which are grown and traded to raise supplementary cash (179).

Poverty is one of the most important concerns of the region. Due to increasing population size combined with small land size, there has been a series of food shortages, particularly the famines in 1974, 1985, 1999 and 2003. This has resulted in migration of household members from areas where the food shortage is more pronounced to the low-land zones, including the Gurage zone (95). Consequently, rural households in these areas are increasingly becoming food insecure (180).

The Sodo district is inhabited mainly by the Gurage ethnic group. The majority of Gurage peoples are Orthodox Christians, with 40 % Muslims. The Gurage are sedentary agriculturalists (181). Animal husbandry is practiced, but mainly for milk and dung. Other foods consumed include green cabbage, cheese, butter, and roasted grains, with meat consumption being very limited (181). Moreover, the Gurages are well-known for their hard work and skill as traders (182).

SNNPR is one of the regions with the lowest health service coverage in the country (180). Within the health service structure across Ethiopia, the primary health care (PHC) unit comprises a primary hospital (non-specialist doctors may or may not be available), health centres (staffed by health officers and nurses) and five satellite health posts (staffed by community-based health extension workers (HEWs). In Sodo, a primary hospital, eight public sector health centres do exist and currently, among the 58 *kebeles*, 43 of them are served by community-based HEWs. Before the launch of this study, neither mental health service nor mental health professional worker in the district. Instead, traditional healing and visiting holy water were used to be the commonest curative means.

Sodo district of Ethiopia is among the five selected LMIC settings (Ethiopia, Nepal, India, South Africa, Uganda) where PRIME (Programme for Improving Mental health care) aimed to generate evidence on the implementation and scaling up of integrated packages of care for priority mental disorders in primary and maternal health care settings (7, 27, 149). Although no epidemiological data are available from Sodo district about the magnitude and distribution of severe mental disorders, there are rich data available from the neighbouring districts of Butajira which would be expected to be generalisable to Sodo. In the Butajira area, the life time prevalence of SMDs was found to be 1.0 to 2.0% (0.5% schizophrenia/ schizoaffective disorder (10), 0.5% bipolar disorder (50) and 0.5% severe depression with psychotic features). Having the theme "improving mental health services in low-income countries," PRIME's objective (in its implementation phase April 2012—March 2015) of evaluating the feasibility, acceptability, and impact of the package of care in primary health care and maternal health care in low-resource district (or sub-district) was set. The PRIME mental health care package for people with SMD in Ethiopia was planned to be implemented at four main levels named health organization, general health care facility (clinical staff) support and other staff, maternal health care, and community levels (see appendix G).

This PhD study is nested within two projects operating in Sodo District: (1) PRIME (27), which is a multi-country implementation research programme to implement and scale-up district-level mental health care plans which integrate mental health into primary care; and (2) Emerald (Emerging mental health systems in low- and middle-income countries) project which conducted a household economic survey to investigate the socioeconomic status of, and impacts of, SMD on households with SMD linked to the PRIME cohort (183).

3.2 Design

The different study designs for the objectives in this PhD are presented in the following table

Table 4. Study aim and design for the three studies

Study	Aim	Design
Study 1	Baseline comparison of household food insecurity in people with SMD compared to the general population	Cross-sectional, community-based comparative study
Study 2	Explore factors associated with food insecurity and work impairment in people with SMD	Cross-sectional community-based study
Study 3	Evaluate the impact of integrated mental health intervention on food insecurity, and explore underlying mechanisms.	Community-based, before-after, cohort study

The methods followed for each study will now be described.

3.3. Sub-study 1: Comparison of food insecurity between households of people with SMD and the general population

Study design: comparative, cross-sectional study

The source of data for this study is primary data gathered from persons living with SMD, households of persons with SMD and the comparison general population in Sodo district at the baseline of engagement of people with SMD with PHC-based mental healthc care.

Study population: Three groups of study population were included: A) persons with SMD, B) households of person with SMD, and C) comparison households from the general population.

Eligibility criteria for people with SMD:

- Aged 18 years or older,
- Planning to stay resident in the district for the next 12 months,
- Provided informed consent (evaluated by trained psychiatric nurses) or, if lacked capacity to consent, did not refuse and guardian permission was obtained,
- Psychiatric nurse confirmed diagnosis of SMD (primary psychotic disorders such as schizophrenia, schizoaffective disorder, acute psychosis or affective disorders like bipolar disorder, major depressive disorders with psychotic features) using a standardized clinical interview, based on DSM IV (184), and
- Able to understand Amharic, the official language of Ethiopia and the working language of the study site

Eligibility criteria for respondent from household of person with SMD:

- Having a person with SMD in a household; aged 18 years or above; provided informed consent; resided in the household for a minimum of four months; household head or the older person if two household members contributed equally to household decision-making;

Eligibility criteria for control households

- No person/family member with suspected or confirmed SMD within the household; aged 18 years or above; providing informed consent.

- Matched to a household in which a person with SMD resided (on the basis of age (± 5 years), sex, village (*gott*), household position (head vs. not head) and household size, using a complete census of the district as a sampling frame (185). If more than one match was identified, the household was selected by lottery. If no respondent was identified for the first matched household after three home visits, or if they declined to participate, the next reserve was selected.

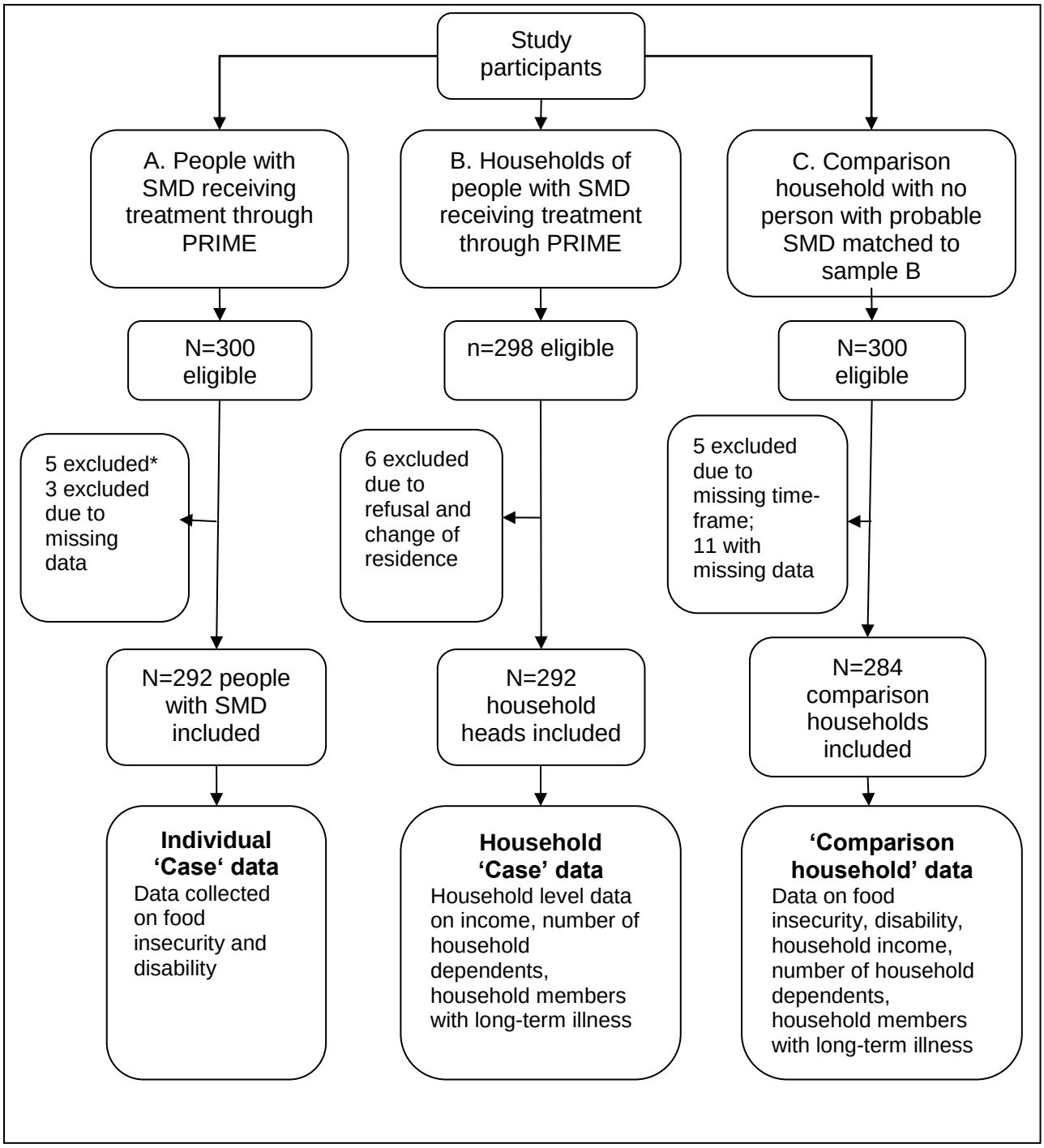


Figure 5. Participant recruitment flowchart and the nature of data

Sample size and sampling methods

Sample size and power calculation

The sample size for this study was determined by the sample sizes for the PRIME and Emerald studies which were powered to detect change in symptoms and economic status in people with SMD and their households after introduction of mental health care. The PRIME study recruited 300 people with SMD. The Emerald study recruited 300 households of people with SMD and 300 households of controls. For a baseline prevalence of food insecurity in the general population being 30%, with a sample of 267 participants per group, a difference of 12% or larger can be detected. In addition, a 10% non-response rate and loss to follow-up was considered. The ceiling of sample size (n=300) was pre-determined by the projects already running in the study site, within which this study was nested. The 30% prevalence estimate took into account household poverty headcounts reports by the government. Details of the power that this sample size afforded to detect differences in the prevalence of food insecurity are provided as follows.

Table 5 Sample size estimations for differing assumptions

Baseline prevalence of food insecurity in general population	Estimated prevalence of food insecurity in people with SMD	Sample size of people with SMD	Sample size of general population
20%	30%	313	313
	32%	225	225
	34%	171	171
30%	40%	376	376
	42%	267	267
	44%	200	200
40%	50%	408	408
	52%	287	287
	54%	213	213

* This sample size considers the 10% estimates for the non-response rate.

Note: Numbers highlighted above indicate possible sample size estimates.

Sampling methods:

People with probable SMD were identified by community-based health extension workers, community leaders and project outreach workers who had received half a day of training on common presentations of SMD for the setting (149). This key informant method has been shown

to be an effective means of community ascertainment of SMD for this setting (21). People with suspected SMD were then referred to the nearest primary health care centre and evaluated by primary care workers who had been trained in the World Health Organisation's mental health Gap Action Programme (mhGAP) base course (8, 186). For those who received a primary health care (PHC) worker diagnosis of 'psychosis' or 'bipolar disorder', a confirmatory clinical interview was conducted by a psychiatric nurse using the semi-structured Operational Criteria for Research (OPCRIT) interview guide (187). Eligible people were then recruited into the study on the basis of the criteria set beforehand (described above).

Survey instruments

The study employed both lay-interviewer administered and clinician administered instruments.

Primary outcome: Food insecurity

Food insecurity was measured using the Household Food Insecurity Access Scale (HFIAS) (188). The HFIAS was administered to people with SMD and the respondent for the control households. The HFIAS was developed to reflect three domains of the experience of inadequate household-level food access: 1) anxiety or uncertainty about food supply/access (item 1); 2) insufficient quality, which includes variety and preferences (items 2 to 4); and 3) insufficient quantity of food supply, the amount consumed and the physical consequences of insufficiency (items 5 to 9) (189). The HFIAS has been translated into Amharic (190), validated in a neighbouring district (190) and used in several research studies in Ethiopia (140, 144, 191). During piloting there were acceptability concerns about items asking about missing meals. A contextualizing lead-in statement was added, which led to improved acceptability. The HFIAS was administered by trained lay interviewers. Recommended methodology of classifying the households into four categories based on the nature of responses given to the nine HFIAS items as per the instrument developers' guide was made (192) to obtain the HFIAS categories of: food secure, mildly food insecure, moderately food insecure and severely food insecure. For data analysis, the HFIAS categories were collapsed to give two categories: (1) food secure, mildly food insecure or moderately food insecure and, (2) severely food insecure. This categorisation identified the most vulnerable group who would be the likely targets of future intervention and policy formulation.

Primary exposure: SMD

Operationally, severe mental disorder can be defined as mental and psychopathology meeting criteria for the Diagnostic and Statistical Manual-IV (DSM-IV) diagnosis of bipolar disorder, schizophrenia, schizoaffective disorder or severe depression with psychotic features characterized chiefly by their severity and persistence over time. The Operational Criteria for Research (OPCRIT) semi-structured interview was used to diagnose the presence of SMD (187). OPCRIT comprises a 90-item checklist of psychiatric symptoms, which is administered by a mental health professional and was used to generate psychiatric diagnoses according to the Diagnostic and Statistical Manual for mental disorders, version IV (187, 193). OPCRIT allows the rater to make use of all available information sources, including clinical interviews with the person and their caregiver and case records and applies operational diagnostic criteria through a computer algorithm (194). OPCRIT has been shown to have good inter-rater reliability, including among raters from different geographical and theoretical backgrounds (187, 195). OPCRIT was administered by psychiatric nurses and only administered to people with suspected SMD.

Potential mediator: functional impairment or Disability

The World Health Organization Disability Assessment Schedule 2.0 (WHODAS) was used to measure functional impairment (196). The WHODAS 2.0 is based on the International Classification of Functioning, Disability and Health (197) which can be applied to any health condition and is recommended by the DSM-V Disability Study Group as the best current measure of disability for research and routine clinical practice (198). The six domains of WHODAS are understanding and communicating, getting around, self-care, getting along with people, life activities (household or work/school) and participation in society. This measure has recently been validated for use in people with SMD in the neighboring district in rural Ethiopia (199), which shares many agro-ecological features with the present study setting. The WHODAS has both 36- and 12-item versions, with the 12-item version found to have equivalent psychometric properties to the longer version (200). In the comparison households, the 12-item version of WHODAS was used. In the sample of people with SMD, the 12-item WHODAS was extracted from the longer 36-item version. The simple WHODAS scoring method was used in this study (200).

Potential confounders

Household measures: Structured lay interviewer-administered questions were used to assess annual household income, the number of household members with a long-term illness and the number of dependents (age 17 years or less) living in the household, using items from the abbreviated version of the household survey instrument of the WHO study on global ageing and adult health which was conducted in six LMICs (201). Other potential confounders were age, sex, residence (urban or rural), household position (being a household head vs. not being a household head) and educational level of the respondent. Month of assessment was also a potential confounder due to seasonal variation in food security and this variable was taken from the initial recruitment date recorded both on the lay-interviewed and clinician-recorded document.

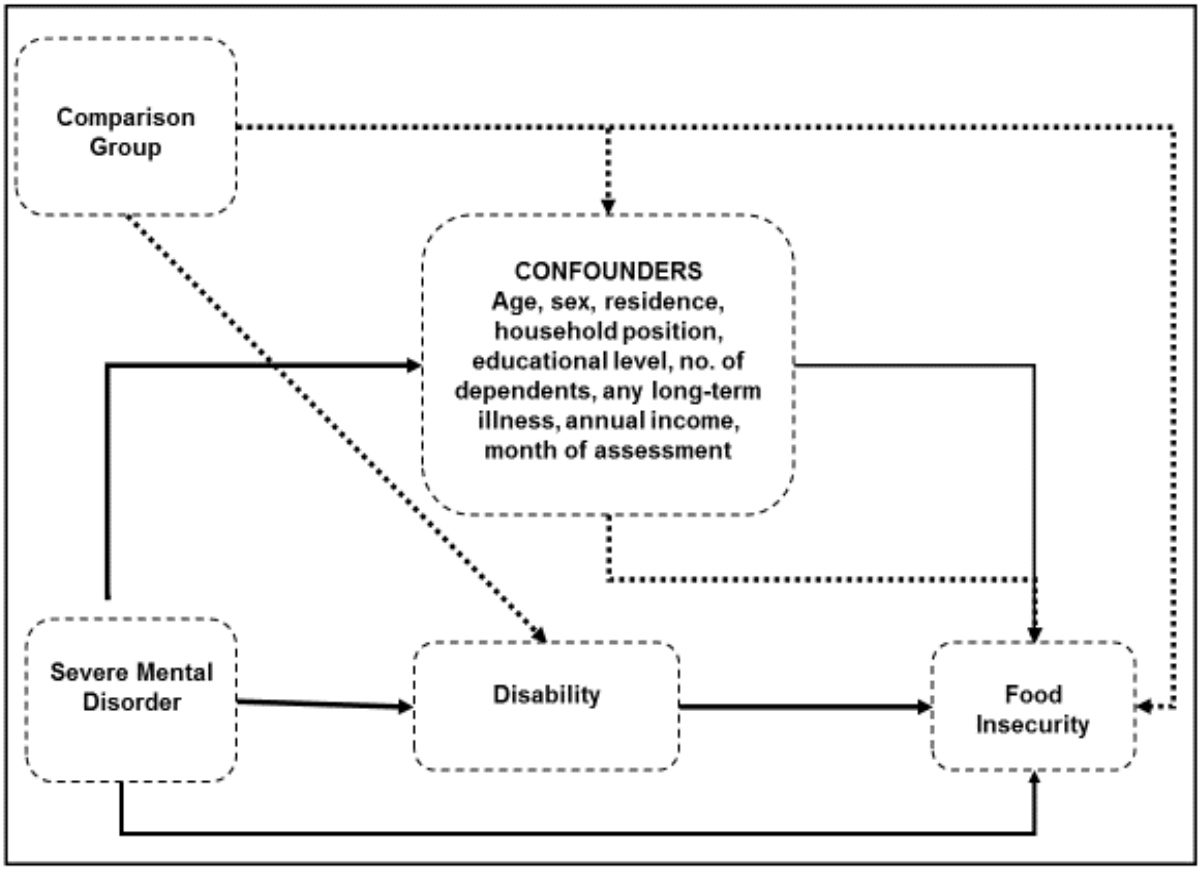


Figure 6. Conceptual model for hypothesised associations between severe mental disorder, disability and food insecurity

Training of data collectors

The lay data collectors were recruited from the study area, with a minimum educational level of tenth grade. Research assistants with Masters level psychology, public health and social work qualifications trained the data collectors for 12 days. The training covered basic interviewing skills focusing on interviewing people with SMD and their caregivers, ethical considerations when interviewing people with mental health problems, and in-depth training on the study measures. The training emphasized practice-oriented interview sessions.

Training of clinician assessors

Psychiatric nurses received seven days of training from senior Ethiopian psychiatrists in the clinician-administered measures. The training included observed interviews and feedback, but formal inter-rater reliability was not undertaken.

Data management and analysis

Double data entry was carried out using EpiData software (202). Confidentiality was ensured. Hard copies of data were stored in a secure place, while the soft copies of data were saved on password-protected computers which could only be accessed by authorized members of the research team.

Data quality assurance

To maintain data quality, the field supervisor and PI made unannounced visits to attend interviews at the site (both at health centers and households), with frequent and close supervision and cross-checks. Likewise, frequent and close supervision and cross-checking was made via actual field visits. Random quality checks of questionnaires were also made by the field supervisor and PI. Inconsistent and illogically recorded responses were corrected as much as possible on the spot after verification by PI, supervisor or PRIME research assistants.

Data analysis-study 1

Data analysis was carried out using STATA software version 13.1 (203). A conceptual model depicting hypothesized associations among the variables is presented in figure 6. The descriptive characteristics of cases (individual level data from person with SMD combined with household reports) and controls were compared using Pearson chi-squared test for categorical variables,

Kruskal-Wallis ($p<0.001$) for continuous non-normally distributed variables and two-sample t-test for continuous normally distributed variables.

Multiple logistic regression was conducted to test the hypothesis that the presence of a household member with SMD was associated with food insecurity in that household. The HFIAS total score was dichotomized into severely food insecure vs. combined categories of mild or moderate food insecurity or food secure (204). The potential confounders identified *a priori* were included into the model. In order to explore whether disability might mediate the association between SMD and food insecurity, the total WHODAS score was added into the fully adjusted model with food insecurity as the dependent variable.

A further multivariable analysis was then conducted to examine factors associated with disability (total score on the WHODAS12-item version). On inspection, a histogram of WHODAS scores indicated excess zeroes. Variance in WHODAS scores was greater than the mean score (177.48 > 13.89), indicating overdispersion. The Vuong test z-value was significant, indicating that a zero-inflated negative binomial (ZINB) model was more appropriate than the standard negative binomial model. Coefficients are on a log scale and for ease of interpretation were exponentiated.

3.4 Sub-study 2. Food insecurity and work impairment among people with severe mental disorders in Ethiopian rural district

Study design: cross-sectional study in people with SMD.

Source of data and study population: The source of data for sub-study 2 was primary data gathered from persons living with SMD in Sodo district at the baseline of engagement with PHC-based mental health care.

Eligibility criteria: The eligibility criteria used for people with SMD in study 1 were also used in this sub-study (see above).

Sample size & power calculation: The sample size and power calculation were the same as for study 1 (see above).

Sampling methods: Study 2 used the same sample of people with SMD who were recruited for study 1 (see above).

Survey instruments: Instruments used in this study are described hereunder.

Primary outcome: Food insecurity. The household food insecurity access scale (HFIAS) was used to assess food insecurity (102). Details of HFIAS description and management during analysis are provided in study 1 (see above).

Secondary outcome: Work-related impairment. This was measured using the Longitudinal Interval Follow-up Evaluation-Range of Impaired Functioning Tool (LIFE-RIFT) (205). The LIFE-RIFT is a clinician-administered tool utilizing information from the person, their caregiver and the clinician's judgment following comprehensive assessment. In this study the LIFE-RIFT was administered by psychiatric nurses. The LIFE-RIFT has been shown to be valid and reliable in high-income country settings (205, 206) and to be acceptable, feasible and have convergent validity in the Ethiopian setting (207). The LIFE-RIFT comprises four major domains: work, interpersonal relations, satisfaction, and recreation (205). The work domain covers employment, household and student sub-domains and assesses the degree to which a person's current (past week) work activities have been impaired. In this study, the analysis focused on the work domain alone.

Explanatory variables assessed by lay interviewers

Disability. The World Health Organisation Disability Assessment Schedule (WHODAS-2.0), 36-item version, which comprises six domains, was used to assess the degree of functional impairment (196). During analysis, the life activities domain was excluded from the six domains to avoid potential overlap with the work impairment measures existing in the LIFE-RIFT measure. The simple WHODAS scoring method was used in this study (200). Details about WHODAS are given in study 1 (see above).

Discrimination: Experience of negative discrimination was measured using the discrimination and stigma scale-12 (DISC-12) (208). The DISC-12 is an interviewer-administered scale comprising four sections. Only the section on 'unfair treatment' was included in this study. The DISC-12 has been shown to be a reliable, valid, acceptable and feasible tool in high-income country settings (208), but has not been adapted previously for Ethiopia. There are five response options for DISC-12: "not at all", "a little", "moderately", "a lot" and "not applicable" (209). Of the 21 items in section one, two items (unfair treatment in getting welfare benefits or disability pensions and unfair treatment in the level of privacy) were excluded due to lacking face validity or comprehensibility for the study area. We conducted exploratory factor analysis using pairwise polychoric correlation due to the missing data when the item was reported to be "not applicable". All items except item 14 (unfair treatment when getting help for physical health problems) and item 15 (unfair treatment from mental health professionals) loaded onto a single dimension. Items 14 and 15 had low frequency of endorsement (<5%) (see Appendix K-2) indicating that these are not salient indicators of discrimination in this setting. We therefore excluded items 14 and 15 and summed the remaining 17 items to give a total score indicating extent of experienced discrimination.

Socio-demographic measures

Socio-demographic characteristics, including age, sex and educational level, were obtained by self-report (see Appendix A1). Alcohol use status was measured using the ten-item alcohol use disorder identification test (AUDIT) (210), which has been adapted and used in the Ethiopian setting (211). Physical impairment was measured using the brief physical impairment checklist which was adapted by extracting items from the Washington Group General Disability Measure (212) and the Family and Wellbeing Index of physical impairment used in physical impairment

and income study (213). Annual household income, number of dependents and household members living with long-term illness was obtained from a household respondent, and assessed at baseline (201). (See sub-study 1 above).

Explanatory variables assessed by clinicians

Symptom severity was assessed using the 24-item Brief Psychiatric Rating Scale-Expanded version, BPRS-E (214), which has been translated into Amharic and used in Ethiopia previously (215). The BPRS-E is observer clinician-rated symptom scale. The BPRS-E covers four domains of symptoms of SMD (positive symptoms, negative symptoms, anxiety and depressive symptoms, and manic excitement or disorganization (214). The BPRS-E has been used widely to detect clinical improvement in response to an intervention (216). The clinical information on specific diagnosis and duration of illness was collected using the OPCRIT, as described above (187).

Potential moderator: social support

The level of social support was measured using the Oslo social support scale, OSS-3, which consists of three items covering the reported number of close friends and perceived concern and practical help received from others (217). The OSS-3 has been used in previous community and facility-based studies in an Ethiopian setting and showed good utility (185). OSS-3 total score was generated by summing up the scores as per the recommendations of the scale developers, followed by categorisation as follows: 3 to 8 “poor support”, 9 to 11 “intermediate support” and 12 to 14 “strong support” (218).

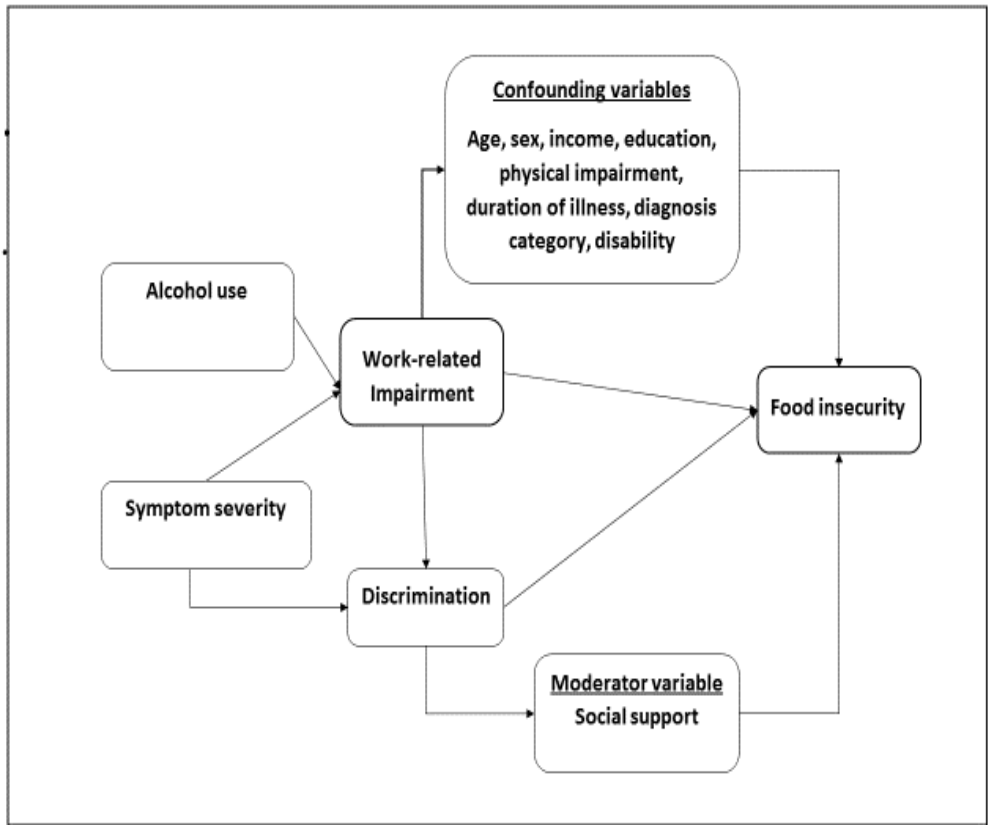


Figure 7. Hypothesized relationships between work-related impairment and food insecurity among people with SMD

Data management: (as described for study 1 above)

Data analysis— study 2

STATA software version 13.1 (203) was used for data analysis. The sociodemographic characteristics of the participants were analyzed using summary and descriptive statistics (frequencies, percentages, mean and median). Variables included in the multivariable model were those anticipated to have associations with the dependent variables on the basis of existing literature. Multiple logistic regression was used to explore the factors associated with severe food insecurity. The baseline HFIAS total score was dichotomized into severely food insecure vs. combined categories of mild or moderate food insecurity or food secure (204). Potential confounding variables identified during planning were included into the model.

Multiple logistic regression was also used to explore the factors associated with work-related impairment. Among the domains of work-impairment measure, the analysis focused on the work domain alone, as it better embodies anchors of work. During analysis, the 5 valid response options were collapsed into two as follows: “no impairment-high level”, “no impairment-satisfactory level”, “mild impairment” and “moderate impairment” considered as non-caseness (coded as 0) Vs “severe impairment” considered as caseness (coded as 1). The remaining two response options named “not applicable” and “no information” were with quite insignificant response rate and appeared not to give sense for analysis; thus excluded from the analysis. potential confounders identified at the early stage of the study were also included into the model. Potential effect modification of the association between work impairment and food insecurity as well as between disability and food insecurity by level of social support was explored using the Mantel-Haenszel test of homogeneity.

3.5 Sub-study 3: Impact of integrated primary mental health care on food insecurity in households of people with severe mental disorders in a rural Ethiopian district

Study design: pre-post study over 12 months of follow-up of people with SMD who had engaged with PHC-based mental health care.

Source of data and study population: The source of data for sub-study 3 was primary data gathered at baseline and twelve month assessments of persons living with SMD, households of persons with SMD and the comparison general population in Sodo district.

Study population: Three groups of study population who were recruited at baseline were followed-up over a year A) persons with SMD, B) households of person with SMD, and C) comparison households from the general population.

Eligibility criteria: See study 1 for the eligibility criteria to be recruited into the study. Data was included from people with SMD/households who provided data at the 12 month assessment time-point.

Sample size & power calculation: As for study 1.

Sampling methods: As for study 1.

Survey instruments: Both baseline and 12 month follow-up measures were used. The baseline assessment has been described in sub-study 1. At the 12 month follow-up time-point, the following instruments were used:

Primary outcome: Food insecurity status

The household food insecurity access scale (HFIAS) (102). Details of HFIAS description and management during analysis are provided in study 1 (see above).

Potential confounding variables

All the following measures have been used in study 1 where they are described in detail (see above):

- Information about socio-demographic characteristics (baseline measure was used).
- Season of assessment (baseline measure was used).
- Physical impairment (baseline measure was used).

- Household measures (baseline measure was used).
- Disability (baseline measure was used).

The following measures have been used in the analysis of descriptive clinical characteristics of participants in this sub-study. They have been used and described in detail in study 2 (see above):

- Symptom severity (baseline measure was used),
- Discrimination (baseline measure was used),
- Work-impairment (baseline measure was used)

Potential mediators

1) Attendance of clinical appointments (used in the multivariable model)

Data on the number of times that the person attended the PHC facility for mental health care, and medication prescribed at each appointment, were extracted from the clinical records, cross-checked with facility registers (see Appendix F for data extraction format). We hypothesized that there would be a significantly greater change in mean HFIAS score in people with SMD who attend 50% or more of their follow-up appointments compared to those who attend less than 50% of scheduled appointments. This was planned exploration of effect modification.

2) Potential mediators and predictors of change in food insecurity status in people with SMD (used both in the mean change analysis and path analysis model)

The following measures have been used and described in detail in study 2 (see above):

- Discrimination (both baseline and follow-up or T2 measure was used),
- Work impairment (both baseline and T2 measure was used),
- Symptom severity (both baseline and T2 measure was used),

The following measures have been used and described in detail in study 1 (see above):

- Disability (both baseline and T2 measure was used),
- Annual income (both baseline and T2 measure was used).

Participant recruitment and follow-up

The recruitment and eligibility criteria of participants is already provided in detail under the methods section. The recruitment and eligibility criteria used for study 1 (see above) for the three groups of study population A) persons with SMD, B) households of person with SMD, and C) comparison households from the general population, is also used here. All the three groups were reassessed after 12 months.

The mental health care programme

As part of the PRIME project, a district level mental health care plan was developed using participatory methods and involving key stakeholders (149). All health centre-based clinicians in the district (n=126), including nurses, midwives and health officers, were trained for 10 days to provide frontline care for people with SMD, depression, epilepsy and alcohol use disorders using the World Health Organization's mental health Gap Action Programme intervention guide (38, 149). This included being trained to prescribe antipsychotic medication (chlorpromazine, haloperidol or fluphenazine decanoate depot) and/or an antidepressant (amitriptyline or fluoxetine) to people with SMD and to provide psychoeducation, basic psychosocial support and ongoing review. A total of 96 community-based health extension workers were trained in community awareness-raising and outreach to engage people with SMD in ongoing care. The PRIME district level mental health care plan also included general community mobilization and awareness-raising, but no formal interventions to address food insecurity, livelihood needs or counter stigma or discrimination in the community (27). Participants were required to pay for medication unless they had obtained a 'free certificate' which is provided to the poorest households in a sub-district. Clinical supervision was provided to the PHC workers on at least a monthly basis by an experienced psychiatric nurse, with consultation by phone as needed.

Training of data collectors: (as described for study 1 above)

Training of clinician assessors: (as described for study 1 above)

Data management: (as described for study 1 above)

Data analysis— study 3

Data analysis was conducted using STATA software version 13.1 (203) and AMOS version 21.0 (219). The descriptive characteristics of people with SMD and the comparison households were compared using Pearson chi-squared test for categorical variables, Kruskal-Wallis ($p<0.001$) for continuous non-normally distributed variables and two-sample t-test for continuous normally distributed variables. The statistical significance of the indirect effects of the variables in the model was computed applying the bootstrapping method, whereby observations with non-missing data were considered for analysis. For all models, statistical tests were set at $\alpha = 0.05$ for significance, two-sided.

Primary analysis

For the primary analysis examining change in categorical food insecurity status between baseline and T2 in households of persons with SMD and comparison households, a Poisson working model with sandwich estimators of the standard error was used to estimate the risk ratio (220). HFIAS was categorized as 'improved' if the person moved to a more food secure category between baseline and T2 (e.g. from severe to moderate food insecurity) and 'non-improved' if they remained in the same category or moved to a less food secure category (e.g. from no food insecurity to mild food insecurity).

As a secondary analysis, the mean difference in change in HFIAS score between people with SMD and comparison households was modelled using multiple linear regression.

Multiple linear regression was also carried out in people with SMD to examine factors associated with change in mean food insecurity scores on the HFIAS. To examine effect modification by clinical attendance, we were unable to test the original hypothesis (see hypothesis No. 3 [b]), as only a quarter of participants (n= 60/239; 25.1%) attended for six or more monthly appointments (i.e. 50% of the follow-up period). We therefore categorized follow-up attendance into two categories: (1) the lowest tertile (1 to 4 follow-up appointments) described as 'low' attendance, and (2) the upper two tertiles (5 or more follow-up appointments) described as 'high' attendance. An interaction term for attendance category and disability score was included in the final multivariable model and likelihood ratio test used to investigate improvement in model fit.

A path model was used to investigate the direct and indirect pathways through which reduction in severity of psychotic symptoms was associated with changes in food insecurity status. The

hypothesized path model is presented in Figure 4. Acceptable fit for path models is assessed in relation to the following indices: (1) A value of 0.08 or less for Root Mean Square Error of Approximation (RMSEA) and not greater than 0.1 (221). (2) Comparative Fit Index (CFI) is truncated to fall in the range from 0 to 1 although CFI values close to 1 indicate a very good fit (222). (3) Tucker Lewis Index (TLI) between 0 and 1 is considered an acceptable range (223). Symptom severity (total score on the BPRSE) was treated as an observed exogenous variable, whereas other variables were treated as observed endogenous variables and error terms as unobserved exogenous variables.

Data quality assurance: (as for study 1)

3.6 Ethical considerations

Ethical approval was obtained from the College of Health Sciences Institutional Review Board, Addis Ababa University (Ref. 026/15/Psy) and the Human Research Ethics Committee at the Faculty of Health Sciences, University of Cape Town (HREC REF: 412/2011). Below are the ethical issues dealt with in the study.

Potential risks

Participants were made aware of the potential risks and benefits before their decision for voluntary participation. The following strategies were used to handle the potential risks.

Potential distress during interview

Study participants may have found discussing contents and even procedures of the interviews distressful. To avoid such unpleasant feelings, data collectors as well as clinician assessors were trained and supervised adequately. Interviewers and assessors were trained on the importance of establishing a good rapport with the participant. Piloting of the measures was also made to identify potentially distressing wordings.

Confidentiality

The interviews were made at places where the voices could not be heard by other parties. Hard copies of data were locked in a filing cabinet at the project office while the softcopy were stored on password-protected computers. Only authorized staff had access to the electronic copy of the data. All identifying pieces of information were removed from data after entry.

Minimization of coercion

All participants were made to be fully cognizant of the procedures involved. Informed consent was sought and recorded in writing. If the person lacked capacity to make a decision about involvement in the study, their caregiver was approached for permission. Among non-literate participants, witnessed verbal consent was sought and recorded.

Burden on local communities

The study might have been a burden on the local communities, including caregivers and PHC staff, due to time and workload. This issue was minimised by, for example, arranging assessment dates at the weekends.

Potential benefits

The research was anticipated to have potential benefits for the relevant stakeholders. Direct benefits to service users included having a confirmatory diagnostic interview and review of their treatment by a mental health specialist.

Reimbursement for participants

All study participants were reimbursed for travel and their time. Refreshments were also provided for participants and caregivers.

Treatment and referrals

To provide mental health care, all participants with SMD were encouraged to initiate and engage with mental health care (medication treatments and/or psychoeducation) as per the PRIME mental health care plan. However, they were under no obligation to engage with care. In addition, referrals for assessment by a psychiatric nurse were made for participants who have replied "yes" to an item asking about suicidal ideation to the WHO mh-GAP trained PHC staff for the SMD group whose assessment was done at health institutions.

Informed consent

Written informed consent was obtained from literate participants. For non-literate respondents, verbal consent was accompanied by a finger print in the presence of a literate witness. For people

with SMD who lacked capacity to consent and were not refusing participation, caregiver permission was obtained.

4. Results

The results of the study will be described in three sub-sections which correspond to the published article and the two manuscripts that are under review. The sub-sections are classified as Sub-study-1, Sub-study-2 and Sub-study-3. The relevant characteristics of participants and the respective findings of the sub-sections have been presented for each sub-study.

4.1 Sub-study-1: food insecurity in people with SMD in a rural Ethiopian setting: a comparative population-based study.

A total of 292/300 (97.3%) out of people with SMD and their households were included in the analysis, with five households excluded because there was more than one person with SMD living in the household and five excluded due to missing data. In the comparison households, 284/300 (94.7%) respondents were included in the analysis due to missing data.

Participant and household characteristics

The characteristics of participants are summarized in Table 6. Respondents who had SMD were less likely to be the household head and to have dependents and more likely to be female, younger and have higher disability scores, formal education and lower annual income. The timing of month of assessment for case and comparison households differed significantly: conducted during the rainy season (June to August) for 14.7% of case households and for 43.3% of the comparison group. (see Appendix L for distribution). There was no significant difference in the location of the household (rural or urban) or presence of a household member with a long-term illness (excluding the person with SMD).

Table 6. Comparison of Characteristics of households with a person with severe mental disorder (SMD) and comparison households

Characteristics	Person with Severe Mental Disorder (SMD)	Comparison households with no person with SMD	P-value**
	N (%)	**N (%)**	
Currently household head			
No	184 (63.0)	6 (2.1)	<0.001
Yes	108 (37.0)	277 (97.9)	
Educational Level			
Non-literate	116 (39.7)	99 (34.8)	<0.001
Able to read and write	37 (12.7)	88 (31.0)	
Formal education	139 (47.6)	97 (34.1)	
Sex			
Female	126 (43.1)	77 (27.1)	<0.001
Male	166 (56.9)	207 (72.9)	
Residence			
Urban	60 (20.6)	56 (19.7)	0.788
Rural	231 (79.4)	228 (80.3)	
HFIAS			
Secure/mildly/moderately food insecure	195 (67.5)	239 (84.1)	<0.001
Severely food insecure	94 (32.5)	45 (15.9)	
	Mean (Standard Deviation)	**Mean (Standard Deviation)**	
Age (years)	35.6 (13.50)	49.7 (13.86)	<0.001
Month of assessment*	4.3 (3.28)	5.5 (1.84)	<0.001
	Median (25^{th}, 75^{th} centiles)	**Median (25^{th}, 75^{th} centiles)**	
No. of members with any Long-term illness	0 (0,0)	0 (0, 0)	0.4701
No. of dependents	2 (1, 3)	2 (1, 4)	0.0001
Number of children	1 (0, 3)	4 (2, 6)	<0.001
Annual Income (ETB)	6000 (3000, 11000)	9000 (5000, 15000)	<0.001
WHODAS 2.0 total score	24 (14, 32)	2 (0, 7)	<0.001

*months numbered starting from January. ETB: Ethiopian Birr; WHODAS: World Health Organisation Disability Assessment Schedule; **P-value of Pearson Chi-squared for categorical variables, Kruskal-Wallis for continuous non-normally distributed descriptive variables and two-sample t-test with equal variances for continuous normally distributed variables

Table 7. Severe food insecurity and other factors in the univariate and fully adjusted multivariable model among persons with SMD

Characteristics	Crude Odds Ratio (95% confidence interval)	Adjusted Odds Ratio* (95% confidence interval) (n=556)
Person with SMD	**2.56 (1.71, 3.83)**	**2.82 (1.62, 4.91)**
Male Sex	1.46 (0.98, 2.15)	1.12 (0.71, 1.78)
Age (in years)	0.99 (0.98, 1.01)	1.01 (0.99, 1.03)
Urban residence	0.88 (0.55, 1.42)	0.73 (0.43, 1.25)
Able to read & write	0.78 (0.47, 1.31)	1.01 (0.56, 1.81)
Formal education	0.69 (0.45, 1.07)	0.84 (0.49, 1.43)
Current household head	**0.67 (0.45, 0.99)**	1.06 (0.61, 1.85)
Annual income	**0.99 (0.99, 0.99)**	**0.99 (0.99, 0.99)**
Number of dependents	0.90 (0.81, 1.01)	1.07 (0.93, 1.22)
Any long-term illness	1.56 (0.98, 2.28)	1.34 (0.85,2.12)
Month of assessment	0.94 (0.87, 1.01)	0.98 (0.91, 1.06)

SMD: severe mental disorder; Values in bold are statistically significant

*adjusted for all variables listed in the table

4.1.2 SMD and food insecurity

The percentage of respondents reporting severe household food insecurity was 32.5% for people with SMD and 15.9% for the control households. The median HFIAS score was higher for people with SMD (median 15, IQR 10) compared to control households (median 12, IQR 7) ($p<0.001$).

In keeping with the hypothesis, SMD was associated with severe food insecurity (adjusted OR=2.82; 95% CI 1.62, 4.91) after adjustment for potential confounders (Table 2). Higher annual income was found to be associated independently with lower odds of food insecurity.

Table 8. Univariate and fully adjusted multivariable model of food insecurity with disability included

Characteristics	Crude Odds Ratio (95% confidence interval)	Adjusted Odds Ratio* (95% confidence interval) (n=556)
Total disability score on the WHODAS	**1.06 (1.04, 1.07)**	**1.07 (1.04, 1.09)**
Person with SMD	0.78 (0.44, 1.40)	1.01 (0.51, 2.00)
Sex (male)	1.16 (0.76, 1.75)	1.09 (0.68, 1.76)
Age (in years)	1.01 (0.99, 1.02)	1.00 (0.98, 1.02)
Residence (urban)	0.82 (0.50, 1.35)	0.70 (0.41, 1.22)
Able to read and write	1.31 (0.75, 2.31)	1.35 (0.73, 2.48)
Formal education	0.87 (0.55, 1.38)	1.19 (0.68, 2.07)
Current household head	**2.21 (1.30, 3.75)**	1.80 (0.98, 3.33)
Annual income	**0.99 (0.99, 0.99)**	**0.99 (0.99, 0.99)**
Number of dependents	0.97 (0.86, 1.09)	1.07 (0.93, 1.23)
Month of assessment	0.99 (0.92, 1.06)	0.98 (0.91, 1.06)

SMD: severe mental disorder; *adjusted for all variables listed in the table
WHODAS: world health organisation disability assessment schedule
Values in bold are statistically significant

4.1.3 Exploring mediation

After including total WHODAS 12.0 score in the multivariable model with food insecurity as the dependent variable, the association between SMD and food insecurity became non-significant, indicating a possible mediating role of disability in this relationship. Annual income remained associated significantly with food insecurity even after including disability within the model.

Table 9. Zero-inflated Negative Binomial Regression model of factors associated with disability

Characteristics	WHODAS 12.0 Crude Multiplier Value (95% CI)	WHODAS 12.0 Adjusted Multiplier Value (95% CI)** (n=559)
Age (years)	**0.99 (0.98, 0.99)**	**1.01 (1.00, 1.01)**
Sex (male)	1.14 (0.96, 1.34)	1.08 (0.95, 1.23)
Residence (urban)	1.02 (0.83, 1.25)	1.04 (0.89, 1.21)
Education (formal)	0.93 (0.85, 1.02)	**0.91 (0.84, 0.98)**
Currently household head	*	**0.71 (0.61, 0.83)**
Number of dependents	**0.95 (0.91, 0.99)**	0.98 (0.94, 1.02)
Person with SMD	**3.30 (2.89, 3.77)**	**3.36 (2.83, 3.99)**
Annual income	**0.99 (0.99, 0.99)**	0.99 (0.99, 1.00)

SMD: severe mental disorder *fitting constant-only model
**adjusted for all variables listed in the table; Values in bold are statistically significant

4.1.4 Factors associated with disability

In the multivariable model, having SMD and increasing age were associated with increased disability, whereas formal education and current household head position were associated with lower disability.

4.2 Sub-study-2: Food insecurity and work impairment in people with SMD in a rural district of Ethiopia: a cross-sectional survey

A total of 282 eligible people with SMD were included in the study: 5 households had more than one person with psychosis and 15 households had missing data relevant to the analyses in this paper.

4.2.1 Descriptive characteristics

Most participants were Orthodox Christians and Gurage by ethnicity (Table 11). Fewer than half of participants had attended formal education (47.5%). Most (85.8%) participants had a diagnosis of a primary psychotic disorder, with 14.2% having an affective disorder. The median BPRS-E score (symptom severity) was 48, (interquartile range (IQR) 35, 59). The median duration of illness was 8 years (IQR 3, 20). During initial assessment, only 35.0% of participants reported that they have been taking antipsychotic medication.

Table 10. Diagnosis categories of participants with SMD

Diagnosis	N	%
Schizophrenia	197	65.7
Schizoaffective disorder	38	12.7
Schizophreniform disorder	4	1.3
Bipolar disorder*	27	9.0
Brief psychotic disorder	5	1.7
Major depressive disorder with psychotic features*	16	5.3
Acute psychosis	3	1.0
Others*	10	3.3

*categorised as affective disorders; the rest as psychotic disorders

Table 11. Sociodemographic and clinical characteristics of study participants

Characteristics	Frequency	Percent
Educational Level		
Formal education	134	47.5
No-formal education	148	52.5
Sex		
Female	122	43.3
Male	160	56.7
Residence		
Urban	59	21.0
Rural	222	79.0
Occupation		
Unemployed	87	31.1
Agriculture	70	25.0
Housewife	57	20.4
Other	66	23.5
Marital status		
Single	124	44.0
Married	97	34.4
Divorced	40	14.2
Other	21	7.4
Ethnicity		
Gurage	268	95.0
Oromo	10	3.5
Other	4	1.5
Religion		
Orthodox Christian	254	90.1
Protestant	18	6.4
Muslim	9	3.2
Others	1	0.4
Oslo Social Support	195	
Intermediate/strong support	85	69.6
Poor support		30.4
AUDIT		
No alcohol use problem (<8)	197	69.9
Hazardous use (≥ 8)	85	30.1
Diagnosis Category		
Primary psychotic disorder	242	85.8
Affective psychosis	40	14.9
	Mean	Standard Deviation
Age (years)	35.6	13.38
Month of assessment*	4.3	3.31
	Median	25^{th}, 75^{th} centiles
Number of children	3	2, 5
Annual income (ETB)‡	6000	3000, 10,750
DISC total	2	0, 7
Physical impairment total	1	0, 3
BPRS-E total	48	35, 59
Duration of illness (years)	8	3, 20

*months numbered as of January ‡ETB, Ethiopian Birr [USD ≈ 20.5 Birr (for 2015)]; AUDIT: alcohol use disorder identification test; WHODAS: World Health Organization Disability Assessment Schedule; LIFE-RIFT: Longitudinal Interval Follow-up Evaluation—Range of Impaired Functioning Tool; DISC: Discrimination and Stigma Scale; BPRS-E: Brief Psychiatric Rating Scale-Expanded version

4.2.2 Food insecurity and work impairment

One third (n= 94; 32.5%) of households reported severe food insecurity, with a median HFIAS score of 15 (IQR 10). More than half (53.6%) of the participants had severe work impairment.

Multivariable analyses

Food insecurity

In the fully adjusted model, severe food insecurity was associated with poor social support (adjusted odds ratio (aOR) 2.87; 95%CI 1.48, 5.55), negative experienced discrimination (aOR 1.08; 95%CI 1.03, 1.14), lower annual income (aOR 4.52; 95%CI 2.08, 9.81) and higher disability scores (aOR 1.02; 95%CI 1.00, 1.04), but not with symptom severity or work impairment (Table 2). Alcohol use disorder, symptom severity and physical impairment were associated with food insecurity in the crude analyses but not in the multivariable model. There was no evidence of effect modification by social support level in the association between severe food insecurity and disability (Mantel-Haenszel test of homogeneity: $p = 0.3947$).

Table 12. Factors associated with severe food insecurity in people with severe mental disorder

Characteristics	Crude Odds Ratio (95% Confidence Interval) n = 282	Adjusted Odds Ratio ‡ (95% Confidence Interval) n =261
Symptom severity (BPRS-E total score) [n = 279]	**1.02 (1.00, 1.03)**	1.01 (0.98, 1.03)
Oslo Social Support Scale [n = 277]		
Intermediate/strong social support	Reference	Reference
Poor social support	**3.42 (1.99, 5.86)**	**2.87 (1.48, 5.55)**
Alcohol use disorder identification test [n = 279]		
No alcohol use problem (<8)	Reference	Reference
Hazardous use (≥ 8)	**2.00 (1.17, 3.41)**	1.12 (0.53, 2.38)
Physical impairment total [n = 279]	**1.37 (1.15, 1.64)**	1.17 (0.93, 1.47)
Discrimination (DISC-12 total score) [n = 279]	**1.13 (1.08, 1.18)**	**1.08 (1.03, 1.14)**
Work impairment [n = 271]		
No/mild/moderate work impairment	Reference	Reference
Severe work impairment	1.30 (0.78, 2.17)	0.95 (0.46, 1.93)
Disability (WHODAS score)* [n = 279]	**1.03 (1.02, 1.04)**	**1.02 (1.00, 1.04) ±**
Age (years)	1.00 (0.98, 1.02)	1.01 (0.98, 1.03)
Sex (male) [n = 279]	0.90 (0.54, 1.49)	1.17 (0.59, 2.31)
Education [n = 279]		
Formal education	Reference	Reference
No formal education	1.06 (0.64, 1.74)	0.63 (0.31, 1.25)
Annual household income (Birr)** [n = 269]		
10000 Birr or more/year	Reference	Reference
4000-9999 Birr/year	**2.05 (1.04, 4.05)**	1.74 (0.79, 3.78)
<4000 Birr/year	**4.83 (2.47, 9.41)**	**4.52 (2.08, 9.81)**
Duration of illness (years) [n = 279]	1.00 (0.98, 1.02)	1.00 (0.97, 1.03)
Diagnosis category [n = 279]		
Affective psychosis	Reference	Reference
Primary psychotic disorder	1.57 (0.73, 3.36)	1.41 (0.56, 3.59)

BPRS-E: Brief Psychiatric Rating Scale-Expanded version; WHODAS: World Health Organization Disability Assessment Schedule; ‡adjusted for all factors listed in the table; *excluding work domain ±p = 0.021; **1 USD ≈ 20.5 Birr (for 2015); Values in bold are statistically significant

4.2.3 Work-related impairment

In the fully adjusted model (Table 13), work impairment was associated independently with symptom severity (adjusted OR 1.03; 95%CI 1.01, 1.06) and disability (adjusted OR 1.04; 95%CI 1.03, 1.06). Having no formal education was associated with work-related impairment in the crude, but not the adjusted, analyses. There was no evidence of effect modification by level of social support in the association between disability and work impairment level (Mantel-Haenszel test of homogeneity: p = 0.4593).

Table 13. Factors associated with work impairment in people with severe mental disorder

Characteristics	Crude Odds Ratio (95% Confidence Interval) n = 282	Adjusted Odds Ratio ‡ (95% Confidence Interval) n = 264
Symptom severity (BPRS-E total score) [n = 274]	**1.06 (1.04, 1.07)**	**1.03 (1.01, 1.06)**
Oslo social support scale [n = 273]		
Poor social support	Reference	Reference
Intermediate/strong social support	0.87 (0.52, 1.46)	0.73 (0.38, 1.38)
Alcohol use disorder identification test [n = 274]		
Hazardous use (≥ 8)	Reference	Reference
No alcohol use problem (<8)	0.84 (0.50, 1.41)	0.61 (0.30, 1.23)
Physical impairment total score [n = 274]	1.13 (0.95, 1.34)	0.96 (0.77, 1.18)
Age (years) [n = 274]	0.99 (0.97, 1.01)	0.98 (0.96, 1.02)
Sex (male) [n = 274]	1.07 (0.66, 1.73)	0.66 (0.34, 1.25)
Education [n = 274]		
Formal education	Reference	Reference
No formal education	**1.63 (1.01, 2.63)**	1.29 (0.69, 2.42)
Discrimination (DISC-12 total score) [n = 274]	1.00 (0.97, 1.03)	0.98 (0.94, 1.02)
Disability (WHODAS score) *	**1.05 (1.03, 1.06)**	**1.04 (1.03, 1.06)**
Annual household income (Birr)** [n = 264]		
10000 Birr or more/year	Reference	Reference
4000-9999 Birr/year	1.11 (0.62, 2.00)	1.06 (0.53, 2.13)
(<4000 Birr/year)	0.99 (0.55, 1.78)	0.96 (0.47,1.97)
Duration of illness (total years) [n = 274]	0.98 (0.97, 1.00)	1.00 (0.97, 1.03)
Diagnosis category [n = 274]		
Affective psychosis	Reference	Reference
Primary psychotic disorder	1.26 (0.64, 2.48)	0.84 (0.37, 1.89)

‡adjusted for all factors listed in the table; *without work domain during computation;
**1 USD ≈ 20.5 Birr (for 2015); Values in bold are statistically significant

4.3 Sub-study-3: Impact of the PRIME mental health care plan on food insecurity in households of people with severe mental disorders in a rural Ethiopian district: a before-after study

A total of 239 (81.8%) individual people with SMD and their household respondents and 273 (96.1%) comparison households were assessed at the T2 time-point. Reasons for loss to follow-up are presented in Figure 8. Attrition was non-differential attrition in relation to baseline characteristics (see Table 14).

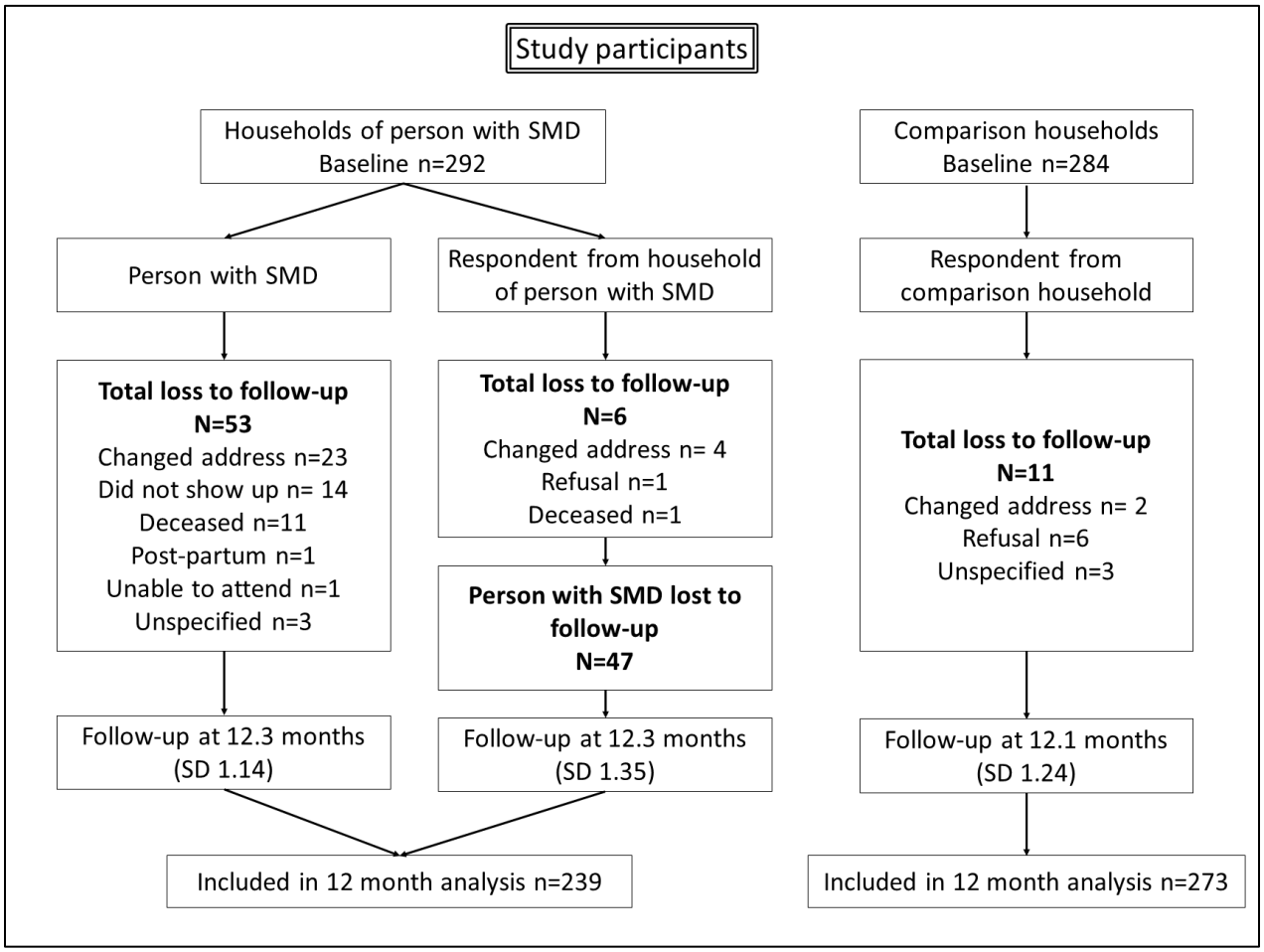


Figure 8. Flow chart of follow-up between baseline and 12 months

Table 14. Summary of the association between baseline characteristics and loss to follow-up

Baseline characteristics	Category of participants	
	SMD	Comparison
	p-value*	p-value*
Age	0.68	0.32
Sex	0.14	0.48
Food insecurity severity	0.72	0.53
Annual income	0.38	0.68
Household position	0.08	0.10
Employment	0.83	**0.00**
Marital status	0.15	0.08

SMD: severe mental disorder

*Chi-square was used for categorical variables and t-test was used for continuous variables

4.3.1 Participant characteristics

A detailed summary of participant baseline sociodemographic and clinical characteristics is presented in table 15.

Compared to respondents from households without a person with SMD, people with SMD were significantly younger, had fewer children, had higher annual income and were more likely to have attended formal education and be female, unemployed, unmarried and not the household head. In people with SMD, the median BPRSE score at baseline was 47 (IQR = 24) and 101 (35.0%) were already prescribed psychotropic medication before the time of recruitment.

Table 15. Baseline sociodemographic and clinical characteristics of study participants who were assessed at both baseline (T1) and twelve months (T2)

Characteristics	People with SMD (total n=239)	Comparison household respondent (total n=273)	P-value*
	N (%)	N (%)	
Educational Level			
Formal education	112 (46.9)	92 (33.7)	<0.002
Illiterate/no formal education	127 (53.1)	181 (66.3)	
Sex			
Female	108 (45.2)	73 (26.7)	<0.001
Male	131 (54.8)	200 (73.3)	
Residence			
Urban	44 (18.5)	53 (19.4)	0.790
Rural	194 (81.5)	220 (80.6)	
Currently household head?			
Yes	94 (39.3)	267 (98.2)	<0.001
No	145 (60.7)	5 (1.8)	
Occupation			
Unemployed	74 (31.1)	1 (0.4)	
Agriculture	58 (24.4)	174 (63.7)	<0.001
Housewife	49 (20.6)	35 (12.8)	
Other √	57 (23.9)	63 (23.1)	
Marital status			
Single	110 (46.0)	2 (0.7)	
Married	84 (35.2)	211 (77.6)	<0.001
Divorced	30 (12.6)	10 (3.7)	
Widowed	7 (2.9)	45 (16.5)	
Married but living apart	8 (3.4)	4 (1.5)	
	Mean (SD)	**Mean (SD)**	
Age (years)	35.4 (13.63)	49.6 (13.76)	<0.001
Month of assessment‡	4.3 (3.32)	5.5 (1.84)	<0.001
	Median (25^{th}, 75^{th} centiles)	**Median (25^{th}, 75^{th} centiles)**	
No. of members with any long-term illness	0 (0, 0)	0 (0, 0)	0.7485
Number of children	1 (0, 3)	4 (2, 6)	<0.001
Annual household income (ETB)	12,000 (8000, 18,000)	9000 (5000, 15,000)	<0.001
Number of dependents	2 (1, 4)	2 (1,4)	0.7783
Physical impairment total score	1 (0, 3)	-	-
Disability score (WHODAS-12)	23 (14, 32)	2 (0, 7)	<0.001
Work impairment score (LIFE-RIFT)	5 (3, 5)	-	-
Psychosis symptom severity total score (BPRS-E)	47 (35, 59)	-	-
Discrimination total score (DISC)	2 (0, 7)	-	-

*P-values of Pearson Chi-squared for categorical variables, Kruskal-Wallis for continuous non-normally distributed descriptive variables and two-sample t-test with equal variances for continuous normally distributed variables. ‡ months numbered starting from January HFIAS: Household Food Insecurity Access Scale; ETB: Ethiopian Birr; WHODAS: World Health Organization Disability Assessment Schedule; LIFE-RIFT: Longitudinal Interval Follow-up Evaluation-Range of Impaired Functioning Tool; BPRS-E: Brief Psychiatric Rating Scale-Expanded; DISC: Discrimination and Stigma Scale; SD: Standard Deviation; √ Includes: Daily laborer, government employee, run own business, student, pensioned, private firm employee and others

4.3.2 Change in food insecurity and potential mediator variables

Overall, 43.5% of households with a person with SMD experienced an improvement in food security category compared to the comparison households (30.2%). The proportion of SMD households categorized as severely food insecure declined from 29.9% (71/237) at baseline to 15.6% (37/237) at the T2 time-point in people with SMD, compared to a reduction from 13.5% (37/274) at baseline to 9.5% (26/273) at the T2 time-point in the comparison households. Households of people with SMD had a significantly greater reduction in mean food insecurity score from baseline to the T2 time-point (mean HFIAS change -2.2; 95%CI -3.13, -1.12) compared to households without a person with SMD (mean HFIAS change -0.004; 95%CI -0.63, 0.62). The difference in mean HFIAS change between the two groups is 2.2; 95%CI 1.05, 3.28; $p < 0.001$.

The change in potential mediators between T1 and T2 was as follows: symptom severity (mean BPRS-E change -5.2, 95%CI -7.82, -2.58), disability (mean WHODAS change -7.3, 95%CI -11.7, -2.78), annual income (mean change 6384.6, 95%CI 4782.53, 7986.63), discrimination (mean DISC change -2.35, 95%CI -3.26, -1.43), work impairment (mean LIFE-RIFT change -0.4, 95%CI -0.62, -0.17).

Table 16. Factors associated with improved food insecurity in people with severe mental disorder and comparison households

Characteristics		Crude risk ratio (95% confidence Interval) N=509	ǂ adjusted risk ratio (95% confidence Interval) N= 496
Sex	Male	Reference	Reference
	Female	1.04 (0.82, 1.32)	0.93 (0.72, 1.20)
Age	Number of years	1.00 (0.99, 1.01)	1.00 (0.99, 1.01)
Residence (n=508)	Urban	Reference	Reference
	Rural	1.29 (0.92, 1.80)	1.23 (0.87, 1.75)
Education	Formal	Reference	Reference
	No formal education	1.02 (0.80, 1.29)	0.99 (0.76, 1.30)
Current household position (n=508)	Not head	Reference	Reference
	Head of household	0.85 (0.67, 1.08)	1.10 (0.81, 1.48)
Season of assessment	Harvest season	Reference	Reference
	Pre-harvest season	1.01 (0.79, 1.28)	1.05 (0.82, 1.35)
Household members with any long-term illness (n=504)		1.27 (1.00, 1.61)	1.25 (0.98, 1.59)
Annual household income (n=498) (x 1000 Ethiopian Birr)		0.99 (0.99, 1.00)	0.99 (0.98, 1.01)
Number of household dependents (n=504)		0.98 (0.91, 1.05)	1.01 (0.93, 1.09)
Household SMD status	Comparison household	Reference	Reference
	Household of person with severe mental disorder	**1.44 (1.14, 1.82)**	**1.68 (1.24, 2.26)**

ǂ adjusted for all modelled variables listed in the table

4.3.3 Multivariable analysis

Food insecurity: In the fully adjusted model, change in food insecurity status over a year in people with SMD was statistically significant (adjusted risk ratio 1.68; 95%CI 1.24, 2.26), compared to the comparison group (refer to Table 16). In terms of change in mean HFIAS score (see Table 17), change in food insecurity status over a year was found to be associated with the presence of a household member with any long-term illness (adjusted mean difference [AMD] -1.71; 95%CI -3.15, -0.27) and with having a person with SMD in the household (AMD -3.36; 95%CI -4.90, -1.81).

Table 17. Factors associated with change in HFIAS score over a year in households of people with SMD and comparison households

Characteristics		Unadjusted Mean difference (95% Confidence interval)	ǂAdjusted Mean difference (95% Confidence interval) N=489
Sex [n= 502]	Male	Reference	Reference
	Female	-0.54 (-1.72, 0.64)	0.24 (-1.04, 1.52)
Age [n= 502]	Number of years	0.01 (-0.02, 0.05)	-0.01 (-0.05, 0.04)
Residence [n= 501]	Urban	Reference	Reference
	Rural	-0.14 (-1.58, 1.29)	0.10 (-1.37, 1.57)
Education [n= 502]	Formal education	Reference	Reference
	Not formal	-0.52 (-1.66, 0.64)	-0.48 (-1.80, 0.82)
Current household position [n= 501]	Not head	Reference	Reference
	Head of household	0.65 (-0.61, 1.89)	-1.53 (-3.22, 0.15)
Season of assessment [n= 502]	Harvest season	Reference	Reference
	Pre-harvest season	0.06 (-1.11, 1.23)	-0.07 (-1.27, 1.13)
Household members with any long-term illness [total score] [n= 497]	Number	**-1.69 (-3.11, -0.28)**	**-1.71 (-3.15, -0.27)**
Annual household income [n= 491]	In Ethiopian Birr	0.00 (-0.00, 0.00)	0.00 (-9.81, 0.00)
Number of household dependents [n= 497]	Number	-0.03 (-0.36, 0.29)	-0.20 (-0.57, 0.16)
Participants or case status [n= 509]	Comparison household	Reference	Reference
	Household of Person with severe mental disorders	**1.78 (1.24, 2.56)**	**-3.36 (-4.90, -1.81)**

ǂ adjusted for all variables listed in the table

Further analysis of factors associated with food insecurity in the SMD only group (Table 18) indicates that food insecurity has a statistically significant association with the respondent being a current household head (adjusted mean difference (AMD) -2.54; 95%CI -4.92, -0.16), disability simple score (AMD -0.05; 95%CI -0.09, -0.01) and physical impairment (AMD -0.93; 95%CI -1.68, -0.17). There was no evidence of effect modification by attendance at follow-up appointments.

Table 18. Factors associated with changes in food insecurity score over 12 months in people with severe mental disorder

Characteristics		Unadjusted mean difference (β)* (95% Confidence Interval) N=229	ǂAdjusted mean difference (β)* (95% Confidence Interval) N=215
Sex [n= 229]	Male	Reference	Reference
	Female	-0.98 (-2.92, 0.96)	-0.06 (-2.11, 1.98)
Age [n= 229]	Number of years	-0.2 (-0.09, 0.05)	0.02 (-0.06, 0.12)
Residence [n= 228]	Urban	Reference	Reference
	Rural	0.01 (-2.47, 2.49)	0.64 (-1.96, 3.25)
Education [n= 229]	Formal	Reference	Reference
	No formal education	-1.89 (-3.82, 0.03)	-0.73 (-2.93, 1.47)
Current household position [n= 229]	Not head	Reference	Reference
	Head of household	-1.66 (-3.62, 0.30)	**-2.54 (-4.92, -0.16)**
Season of assessment [n= 229]	Harvest season	Reference	Reference
	Pre-harvest season	-1.24 (-3.44, 0.95)	-1.30 (-3.57, 0.97)
Household members with any long-term illness [n= 224]	Number	**-2.23 (-4.41, -0.05)**	-1.83 (-4.03, 0.36)
Disability [whodas36 simple] [n= 229]	total score	**-0.06 (-0.09, -0.03)**	**-0.05 (-0.09, -0.01)**
Annual household income [n= 221]	In Ethiopian Birr	0.00 (-0.00, 0.00)	-0.00 (-0.00, 0.00)
Number of household dependents [n= 224]	Number	-0.13 (-0.68, 0.43)	-0.22 (-0.82, 0.39)
Physical impairment [n= 229]	total score	**-1.38 (-2.03, -0.73)**	**-0.93 (-1.68, -0.17)**
Work impairment (baseline maximum) [n= 224]	total score	-0.56 (-1.29, 0.17)	-0.15 (-1.01, 0.70)

*Beta coefficient (β) ǂ adjusted for all variables listed in the table

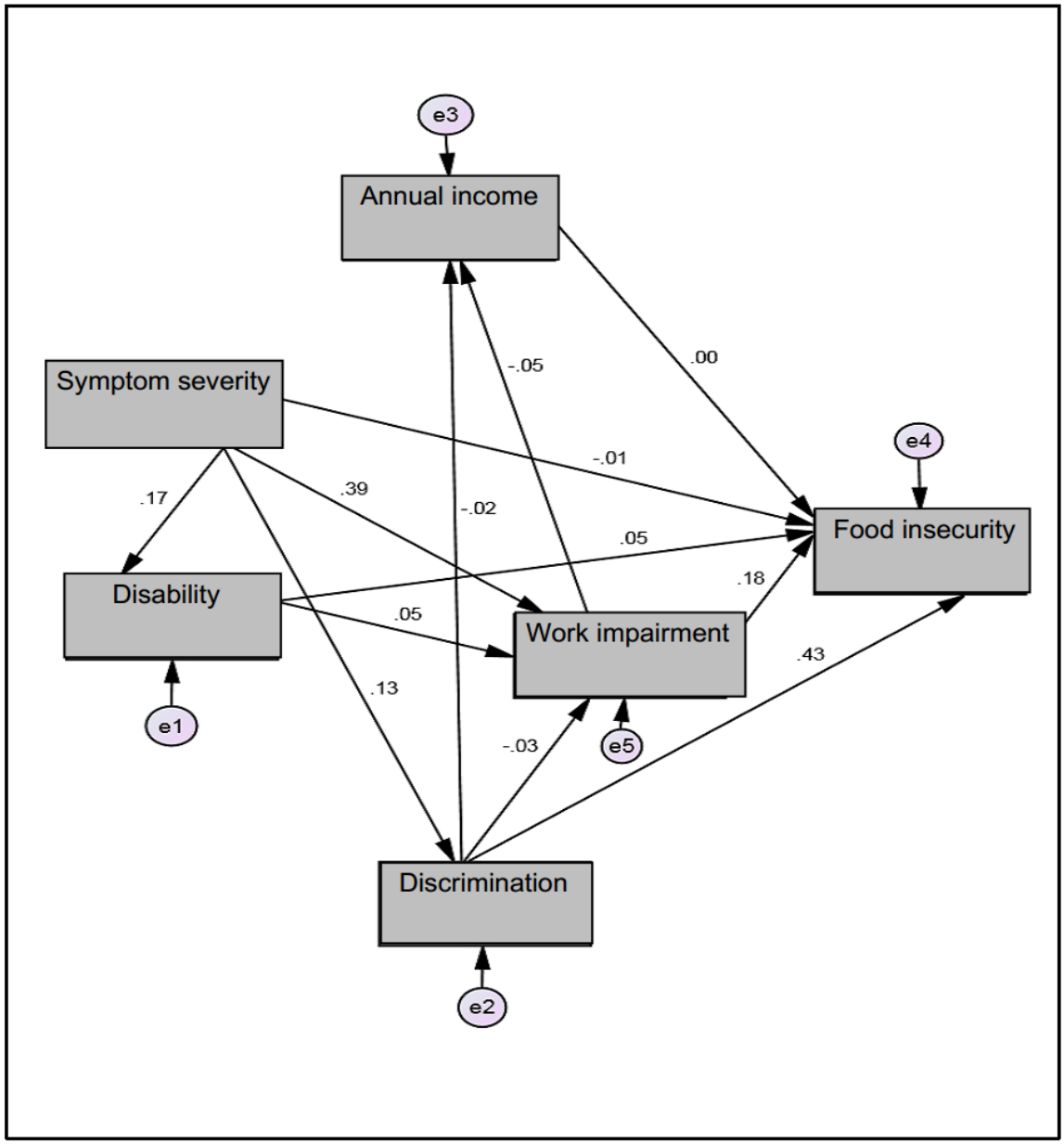
4.3.4 Path Analysis

Two of the associations in the hypothesized path diagram (disability to discrimination and symptom severity to income) were removed as they were non-significant and affected the model fit adversely. The standardised path coefficients obtained for the final path model are presented in figure 9. The model fit was acceptable for all indices: Comparative Fit Index = 0.99, Tucker Lewis Index = 0.99 and Root Mean Square Error of Approximation = 0.01, 90%CI 0.00, 0.09 (see Table 19).

Change in psychotic symptom severity was positively associated with change in disability (mean difference = 0.30, 95%CI 0.07, 0.53) and change in work impairment (mean difference = 0.03, 95%CI 0.02, 0.04). Similarly, change in discrimination (mean difference = 0.47, 95%CI 0.35, 0.59) and change in work impairment (mean difference = 0.85, 95%CI 0.26, 1.43) are positively associated with change in food insecurity. However, change in symptom severity was found to have a statistically significant indirect/mediated effect on change in food insecurity status (mean difference = 0.15, 95%CI 0.07, 0.26; $p<0.01$), through impacting on work impairment and discrimination (see Table 20). In the total effect (direct and indirect) model, symptom severity was positively associated with change in disability (mean difference = 0.22, 95%CI 0.11, 0.33), work impairment (mean difference = 0.38, 95%CI 0.26, 0.49) and discrimination (mean difference = 0.17, 95%CI 0.03, 0.32); whereas change in food insecurity was positively associated with change in discrimination (mean difference = 0.46, 95%CI 0.34, 0.58) and work impairment (mean difference = 0.16, 95%CI 0.03, 0.29).

Table 19. Goodness of fit indices summary for the direct effect default model

Indices	Indices value	
	Hypothesized model	**Fitting model**
Tucker Lewis Index (TLI) rho2	1.169	0.99
Comparative Fit Index (CFI)	1.00	0.99
Root Mean Square Error of Approximation (RMSEA)	0.00 [90%CI (0.00, 0.122)]	0.01 [90%CI (0.00, 0.09)]
Chi-square	0.26	3.11
Degrees of freedom	1	3
Probability level	0.61	0.37



Difference in scores between baseline and twelve months were considered for all modelled variables
e1, e2, e3, e4, e5 and e6 are error terms for the respective observed endogenous variables

Figure 9. Path diagram for the fitting model of factors associated with food insecurity, with standardized regression weights (path coefficients)

Table 20. Parameters for the hypothesized pathway of standardized indirect effects, using a bootstrapped model

Effect in the Pathway*		Mean difference (estimate)	95% BC** confidence interval (CI)	p-value‡
Effect of variable	**Effect on variable**			
Symptom severity	Work impairment	0.01	-0.03, 0.05	0.79
Symptom severity	Annual income	-0.02	-0.06, 0.05	0.85
Symptom severity	Food insecurity	0.15	0.07, 0.26	**<0.01**
Symptom severity	Discrimination	0.00	-0.03, 0.04	0.74
Disability	Work impairment	0.00	-0.02, 0.01	0.81
Disability	Food insecurity	0.01	-0.04, 0.09	0.58
Discrimination	Annual income	0.00	-0.01, 0.01	0.81
Discrimination	Food insecurity	-0.00	-0.03, 0.03	0.77
Work impairment	Food insecurity	0.00	-0.01, 0.01	0.83

*Twelve month baseline scores differences were considered for all modelled variables

**Bias-corrected two-tailed significance

‡ The standardized indirect (mediated) effect of other variables in the model cannot be tested for significance with p-value; hence their estimates, CI and p-values was not included in the above table.

Table 21. Parameters for the hypothesized path model with unstandardized regression weights for direct effect

Pathway		Unstandardized regression weight		p-value
From	To	Estimate	95% confidence interval	
Symptom severity	Disability	0.30	0.07, 0.53	**0.01**
Symptom severity	Work impairment	0.03	0.02, 0.04	**<0.01**
Symptom severity	Discrimination	0.04	-0.00, 0.08	0.054
Symptom severity	Food insecurity	-0.01	-0.05, 0.04	0.81
Symptom severity	Annual income	-69.45	-162.38, 23.48	0.14
Disability	Work impairment	0.00	-0.00, 0.01	0.405
Disability	Food insecurity	0.01	-0.02, 0.03	0.46
Disability	Discrimination	0.01	-0.01, 0.04	0.39
Discrimination	Annual income	-16.62	-261.86, 228.62	0.89
Discrimination	Work impairment	-0.007	-0.03, 0.02	0.63
Discrimination	Food insecurity	0.47	**0.35, 0.59**	**<0.01**
Work impairment	Annual income	-425.48	-1315.56, 1064.59	0.84
Work impairment	Food insecurity	**0.85**	**0.26, 1.43**	**0.01**
Annual income	Food insecurity	0.00	0.00, 0.00	0.95

Table 22: Path model standardized total (direct and indirect) effects in the bootstrapped model

Effect in the pathway		Estimate	95% BC confidence interval	p-value
Effect of variable	**Effect on variable**			
Symptom severity	Disability	0.22	0.11, 0.33	**<0.01**
Symptom severity	Work impairment	0.38	0.26, 0.49	**<0.01**
Symptom severity	Discrimination	0.17	0.03, 0.32	**0.01**
Symptom severity	Food insecurity	0.09	-0.07, 0.24	0.21
Symptom severity	Annual income	-0.02	-0.07, 0.03	0.47
Disability	Work impairment	0.05	-0.09, 0.17	0.51
Disability	Food insecurity	0.07	-0.06, 0.21	0.31
Disability	Annual income	-0.00	-0.02, 0.00	0.36
Discrimination	Annual income	-0.01	-0.15, 0.15	0.92
Discrimination	Work impairment	-0.02	-0.18, 0.12	0.77
Discrimination	Food insecurity	0.46	0.34, 0.58	**<0.01**
Work impairment	Annual income	-0.04	-0.16, 0.07	0.47
Work impairment	Food insecurity	0.16	0.03, 0.29	**0.02**
Annual income	Food insecurity	-0.01	-0.16, -0.01	0.84

The standardized total (direct and indirect) effect of other variables in the model cannot be tested for significance with p-value; hence their estimates and confidence intervals were not included in the above table

5. Discussion

In this study, the association between severe mental disorder and food insecurity was investigated in a rural, community-based sample in Ethiopia, both before and after implementation of a programme to improve access to mental health care. The findings will now be discussed in relation to the original hypotheses and the existing evidence base.

5.1 Food insecurity in people with SMD compared to the general population

In this community-based study conducted in rural Ethiopia, severe household food insecurity was reported by 32.5% of people with SMD and 15.9% of respondents from comparison households, which was a statistically significant difference. These findings are in keeping with findings from a small, non-representative study from the USA (147) and a facility-based case-control study from India (148) but is the first study to show this association in a rural community setting in a low-income country. Higher annual income was associated independently with lower odds of severe food insecurity. When total disability scores were added into the model, the association between SMD and food insecurity became non-significant, indicating a likely mediating role of disability.

SMD was associated with household food insecurity independently of household annual income. In this subsistence farming community, food insecurity is related to the amount of food available due to household production and not just to income. In addition to the impact of disability of the person with SMD, the opportunity costs of other household members due to engagement in caregiving activities and direct reductions in productivity of caregivers, are likely to contribute to an overall decrease in household productivity (224). In a qualitative study from the same area, respondents conceptualized disability in people with SMD as arising from a combination of direct effects of the illness, poverty and stigma (225). A recent report in a nearby district showed that lower perceived relative wealth was significantly associated with greater functional impairment (226). Stigma and discrimination extends beyond the individual person with SMD to affect the whole household (227) which may lead to decreased co-operation with community members for key farming activities and resultant decrease in food production.

5.2 Factors associated with food insecurity in people with severe mental disorder

In sub-study 2, in a multivariable model, food insecurity was associated with poor social support, lower income, negative discrimination and functional impairment in people with SMD, but was not associated directly with clinical symptom severity. In cultures valuing the needs of a group or community over an individual, such as that encountered in the rural Ethiopian setting, it is commonly assumed that high levels of social support will be provided to people with mental health or other health problems. However, about one-third of our sample reported poor social support, in keeping with previous studies of the general population in the same district (185). In a qualitative work with people with SMD from the same sample, the restrictions experienced in accessing social networks were highlighted (56). Social connectedness relies upon the capacity of a person to reciprocate; SMD may directly (via disability) and indirectly (via worsened poverty) undermine the possibility of reciprocation. People who lack interpersonal supports may then be less able to avail themselves of social opportunities which are often tied to economic opportunities, including obtaining competitive jobs and satisfactory housing (228), accessing livelihoods or obtaining financial support.

Higher perceived negative discrimination was also associated with food insecurity. Stigma and discrimination work directly against recovery in people with SMD, leading to and reinforcing social exclusion at both an individual, household and community level (229). Because of public misconceptions about SMDs, members of society may withhold opportunities (230-232) and societal prejudice can significantly exacerbate the impact that psychiatric symptoms have on social opportunities (228). In this way, the social exclusion associated with discrimination against a person or household with SMD may lead to loss of economic opportunities and financial support, and subsequent impoverishment and food insecurity. The Ethiopian Federal Ministry of Health has included mental health in the training programme to upgrade community health extension workers, including interventions to increase community awareness about the treatability of mental health problems and to counter stigmatizing attitudes (233). Previous work in Ethiopia has shown that stigmatizing attitudes in health extension workers in relation to child developmental disorders are reduced by this intervention (234).

The consequences of exposure to food insecurity in people with SMD in this setting may be profound. A previous study found that people with SMD in a rural Ethiopian district were more likely to be under-nourished compared to community controls (235). Excess mortality in people

with SMD in Ethiopia has been linked to undernutrition (24). Food insecurity is likely to also affect access to, and engagement with, care. In a qualitative study of people with SMD and their caregivers in a food-insecure area, justification for ongoing use of khat (chewing leaves containing the amphetamine-like substance cathinone) against medical advice was in part to curb one's appetite even though there was awareness that it could worsen the person's mental health (236). Formative work indicated the need for interventions to address basic needs, including food security, among people with SMD in Ethiopia to ensure equitable access to care (56, 237).

The findings from this sub-study indicate that interventions to address food insecurity need to include both expanded access to mental health care (to reduce disability) and strategies to alleviate poverty, particularly for vulnerable individuals living with SMD. Through the PRIME project, and in keeping with the policy of the Federal Ministry of Health of Ethiopia, access to mental health care is being increased through integration into PHC in this district (149).

5.3 Work impairment in people with severe mental disorder

In the multivariable model, work impairment was associated significantly with symptom severity and disability, but not with discrimination or social support. In this study, around half or more of the participants reported severe work impairment. This is noteworthy because early studies (1970s) of people with SMD in LMICs indicated that employment outcomes are more favourable when compared to people with SMD in high-income country settings (238, 239). In the International Study on Schizophrenia (ISoS), conducted in the 1980s and 1990s, the proportion of participants in LMICs diagnosed with "all psychoses" and reporting working (doing housework or paid work) was higher (79%) for most of the last two years compared with that of high-income settings (51%) (240). There was an 80% employment with some work capacity report among people with schizophrenia in a multisite study in India (241-243).

The International Pilot Study of Schizophrenia (IPSS), Determinants of Outcomes of Severe Mental Disorders (DOSMeD) and the ISoS studies have been critiqued for possible selection bias, not accounting for differential mortality and the measures used for work functioning (244, 245). In our study, use of the LIFE-RIFT measure may have enabled us to assess work impairment in a comprehensive way, based on clinician judgement and drawing on all sources of information

available (person with SMD, caregiver and clinical notes). Symptom severity and disability levels were associated strongly with work impairment, indicating that improved access to adequate mental health care may be able to support improved work functioning. There are conclusions that the severity of illness symptoms, but not the diagnosis of mental disorder, is the most significant factor in determining the level of functional impairment (246). However, in keeping with our proposed conceptual model (sub-study 2), clinical symptom severity and work impairment may not determine household food insecurity, which may require interventions tackling discrimination, social isolation and potentially income security.

5.4 Food insecurity, impact of integrated mental health care and possible mechanisms

In keeping with the hypothesis (3.1), food insecurity status improved significantly in people with SMD after implementation of district level integrated mental health care, after adjusting for secular trends in food insecurity in the general population. However, hypothesis 3.2 was not supported: increased attendance at PHC was not associated with larger gains in food insecurity status.

Change in severity of psychotic symptoms was directly associated with change in disability and work impairment, whereas change in food insecurity status was directly associated with work impairment and discrimination. However, although change in symptom severity had no direct effect on food insecurity, it did have a mediated (indirect) effect on change in food insecurity status.

There was no effect modification by number of appointments attended. In general, the level of attendance for follow-up appointments was low. A qualitative study in the district showed that poverty, unreliable medication supplies and lack of secondline options for inadequate response or intolerable side-effects, the long-term nature of the illness and the nature of SMD were barriers to ongoing engagement in care (247). In such a context, attendance for follow-up appointments may not show a dose-response relationship with improved outcomes. Indeed, as the qualitative data indicated that people tended to attended follow-up appointments when they were more unwell, we might even have expected a worse outcome in those attending for more follow-up appointments (reverse causality). Therefore, the absence of effect modification of the association between

introduction of the new mental health care programme and food insecurity outcomes is not evidence that the programme is ineffective.

Antipsychotic medication has been shown to lead to improved occupational, educational and work functioning (248, 249), a beneficial impact on productivity levels (92) and work engagement (250), as well as a reduction in symptom severity (251-253). In a follow-up study (2.5 years on average) conducted with 271 people with schizophrenia in a neighbouring Ethiopian district, significant reduction in positive symptom scores was inversely associated with improvements in physical and social functioning and role limitations in people with both recent-onset and long-standing illness, due possibly to the psychotropic medication offered free of charge to all participants (71). The salience of antipsychotic medication to improved functioning was also indicated by a randomized, controlled trial of a community-based intervention for people with schizophrenia in India (76) where improvements in functioning appeared to have been mediated by the effect of the community intervention on medication adherence.

There was a statistically significant total effect of reduced psychotic symptom severity on level of reported discrimination although the direct effect was close to significance and the indirect effect was not statistically significant. In qualitative interviews with community stakeholders during development of the district mental health care plan, stigma and discrimination was predicted to reduce when the community witnessed people with SMD show improvement with treatment (247). Feedback from the community leaders engaged in the PRIME advisory board indicated that the recovery of people who had been well-known to be incapacitated by SMD had led to more positive attitudes and support for people with SMD. This accords with findings from high-income countries that social contact interventions, whereby people gain direct exposure to people with SMD and learn about the treatability of their condition can be effective in reducing stigma and discrimination (254).

Reduction in perceived discrimination and work impairment were also independently and directly associated with improved food security. The PRIME district mental health care plan was not restricted to the facility level and prescription of psychotropic medication (149). Implementation of other components of the plan may have contributed to greater social inclusion, for example as a result of community-level activities to improve mental health awareness and reduce stigma

through training of community-based health extension workers and engagement of key community stakeholders in the advisory board. In a subsistence farming community where there is interdependence between community members, a reduction in social exclusion may result in more livelihood opportunities and access to shared community resources, thereby leading to reduced food insecurity. However, why improvement level or proportion is found better in the SMD group than the comparison, general population could be explained in terms of the possible change (improvement) in symptoms contributed for increased self-efficacy and engagement in livelihood activities, comparing to their pre-and-peri-intervention functioning/productivity level; then likely reporting improvement in their food insecurity status.

In sub-study 3, there was no association between change in household income and food insecurity level. This indicates that food insecurity is not just related to the capacity of the household to purchase necessary food. Given that most participants were subsistence farmers, the capacity of household members to work productively (free from ill-health and the need to care for ill family members) and co-operatively (not socially excluded) with other households may be the over-riding influences on food access.

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Although there was significant improvement in food insecurity in people with SMD, the 12 month level of severe food insecurity still remained higher than that of the general population (15.6% vs. 9.5%). Concerted efforts need to be made in relation to strengthening engagement in care and ensuring the affordability of psychotropic medications. A recent qualitative exploration which had targeted samples drawn from the same SMD group in the district indicated that most respondents reported improved access to care, usually equated with medication, and were motivated to remain engaged due to experienced benefits of care despite irregular psychotropic medication supply and challenges to pay for medication owing to poverty (247). Beyond this, specific interventions to alleviate food insecurity, reduce discrimination and increase livelihood opportunities may also be required alongside the PRIME integrated mental health care plan. Community-based rehabilitation could be one adjuvant approach to combining these specific interventions in LMICs (177) and is being trialled in the study district (255). In an evaluation of the BasicNeeds model of providing development interventions (e.g. income-generating activities and interventions to promote sustainable livelihoods) alongside mental health care (256, 257), improved economic status in

people with SMD was observed (258); although the study design could not distinguish the effects of mental health care alone from any added value of development interventions.

5.5 Social welfare programs relating to food insecurity in Ethiopia

Ethiopia is reported to have well-established and strong programs to address the food security needs of vulnerable groups (259, 260). In the Productive Safety Net Program, rural households facing chronic food insecurity are supported to resist financial shocks, create assets and become food self-sufficient by providing predictable transfers, as food, cash, or a combination of both (260-262) conditional upon engagement in daily labouring activities. Households of people who are "chronically sick, disabled or mentally challenged in such a way as to prevent them from undertaking work" are explicitly excluded from this scheme but considered eligible for permanent direct support and the possibility of linkages to appropriate social services, where capacity exists at the district level (263); however, the extent to which households with a person with SMD are able to access this support is unknown and likely to be low. As well as the prevailing low levels of awareness about mental health and illness, the stigma and social exclusion associated with SMD (264) are likely to act as barriers to participation in interventions to address food insecurity.

In summary, severe food insecurity and disability were increased significantly among people with SMD compared to general population controls, in support of the hypothesis for study 1. Severe work impairment was also reported to be experienced by nearly half of people with SMD. Higher improvement in food security status 12 months after engaging with care was observed in households of a person with SMD compared to comparison households. In people with SMD, improvement in food security status was associated with being a household head at baseline assessment, lower baseline disability and physical impairment scores. In a path model, change in symptom severity was indirectly associated with follow-up food insecurity status more likely via an impact on reducing work impairment and discrimination.

6. Validity and generalizability

Validity

Internal validity of a study depends on good design, conduct, analysis and sufficient sample with minimal bias. In this study we sought to maximize internal validity. The study design was selected with consideration of how the intended research idea could be addressed and testable hypotheses were specified a priori. A cross-sectional, community-based survey followed by an intervention cohort was conducted accordingly. The measures used in the study as dependent/outcome, independent/explanatory/confounding, mediator or moderator variables, were conceptualized ahead of time and their validity and usability was ensured ahead of the actual fieldwork. Hence, confounding was minimized by reviewing the literature to identify important potential confounders. Adjustments for potential confounders identified a priori were made. Adequate training was carried out for the assessors and supervisors and the frequent supervision made during data collection and entry are all activities undertaken to ensure validity.

Since the sample included in the study was ascertained in the community rather than facility-based, selection bias was reduced. Attrition during the follow-up period can introduce bias: for this reason, every effort was made to locate all people recruited into the study for follow-up assessments. The baseline characteristics of people who were assessed at follow-up and those who were lost to follow-up were compared and found to have no significant differences. Validity in the analysis was kept by proper inspection of sample distributions followed by the selection of appropriate statistical models suiting the distribution and the research questions/hypothesis. Reverse causality can be an explanation for the cross-sectional associations seen in studies 1 and 2, but we are able to explore potential causal pathways prospectively in study 3. However, given the observational nature of this study, causality cannot be concluded. The study was powered to detect relevant levels of effect.

Generalizability: It is not possible to assert that the findings of this study would be generalizable to diverse/dissimilar sociocultural settings, as its coverage is limited only to a single district which is predominantly rural. However, the findings could be generalizable to socio-cultural contexts having similar characteristics, as the present study setting comprises a range of diverse climatic conditions.

7. Strengths, limitations and challenges

Strengths

This is the first community-based study of food insecurity in households of people with SMD in a rural African setting and the first to examine the impact of provision of mental health care on the food insecurity status of people with SMD. Strengths include the community-based ascertainment of people with SMD to reduce selection bias, the use of a standardized clinical diagnostic measure to confirm the diagnosis of SMD, the use of a measure of food insecurity that has been validated in the setting, the inclusion of a community comparison sample from the general population, the prospective evaluation of change in food insecurity over time in relation to hypothesized mediators of change, the use of 12 month follow-up period to minimize seasonal effects and the large sample size with good levels of retention in the cohort.

Limitations

Although the HFIAS is a household measure, the information for the 'case' group was provided by the person with SMD. It is possible that they reported higher food insecurity levels than other household members due to less access to household resources than other household members or that they experienced greater hunger due to appetite-stimulating effects of antipsychotic medication (265); however, only closer to a third (n= 69; 29.4%) of people with SMD were already prescribed and still taking psychotropic medication at the time of baseline assessment so this is unlikely to be the full explanation. Furthermore, the HFIAS is designed to capture household-level information, with households as the focus of concern, regardless of the respondent. Failure of the HFIAS categorization into different household levels (e.g. collapsing moderate and severe together) during analysis to yield a different result is also a potential concern. Respondents may have given affirmative responses in the expectation that they would receive some kind of aid, although this would have applied to both case and comparison groups. Social desirability could also have led to minimization of the true experience of food insecurity due to the sensitivity of the topic. There may have been inadequate adjustment for seasonal variation in food insecurity.

Many of the measures relied on self-report and this may affect the validity and reliability of the measures as well as the results. There could also be a possibility of recall bias among respondents in responding to some of the measures/items. The study has failed to include important variables such as physical ill-health which is reported to be of high burden in people with SMD (266), and this could have a potential explanatory role in relation to impact on work impairment and food insecurity**.** The study also did not report medication side effects both at baseline and follow-up period which could adversely affect work capacity (267), although most participants were not taking psychotropic medication at the baseline of the study. For cross-sectional sub-study designs, the study was also not able to draw any conclusions regarding temporal relationships nor causality. Also, causality was not able to be established in study 3 although some temporal relationships were observed in a pathway manner.

The intervention sub-study has failed to identify statistically significant differences in participants' food insecurity levels based on the level of clinic attendance due possibly to the low proportion (36.4%) of attendees categorized as having "high attendance", the non-systematic recording of SMD cases treatment attendance and the potential for reverse causality. The lack of randomization of people with SMD to receive the integrated mental health care service or a comparison intervention was a limitation, but ethical considerations would have precluded the comparison being 'treatment as usual'.

Challenges

The following are some of the major challenges faced in the course of conducting this study

- Search for cases when the condition has a low prevalence,
- Length of interview duration taking into account dealing with a special population, that is, people with SMD,
- The task of matching household cases with household controls on some selected variables required continuous updating of a census conducted by the over-arching PRIME project,
- Refusals to participate by respondents, particularly comparison households,
- Non-eligible caregiver coming with the case for assessment and lay interview,
- Respondents' temporal absence from home or facility appointments,
- Study site's partly difficult topography and,
- The fieldwork across a large geographical area with varied topography.

8. Conclusions

In this study, people with SMD living in a rural Ethiopian district were found to experience higher levels of severe food insecurity than the general population. This indicates the need for the inclusion and prioritisation of people with SMD as a vulnerable group in food security programs and development opportunities, including income-generating opportunities and schemes. In turn, this requires awareness-raising and tackling the stigma which undermines inclusion of people with SMD in community aid and development activities. The finding that predominantly social factors such as poor social support, discrimination, disability and annual income were associated with food insecurity and that food insecurity in people with SMD is not just a consequence of illness severity implies amelioration of household level food insecurity may need to additionally attend to those factors. Although expanding access to care has the potential to improve clinical outcomes, reduce disability and improve the individual person's capacity to work, amelioration of household level food insecurity may need to additionally attend to social support, discrimination and access to livelihoods. Also, it is possible to note that in a situation where food items production and supply are abundant, coupled with large food items subsidizations, income alone may not have effect on household food security.On the other hand, the statistically significant mediated effect of symptoms severity via impacting on work impairment and discrimination indicates the need to focus on the primacy of symptom treatment.

The finding that work impairment is also an important experience of persons with SMD and that clinical factors such as symptoms severity and disability were associated with work impairment implies that activities targeting improvements in work capacity need to consider treatments of symptoms and disability.

The change integrated primary mental health care has brought on improvement in food insecurity levels in people with SMD, primarily via the change in symptom severity level, calls for the strengthening or expansion of the mental health integration service which is already in place through PRIME project as an important intervention practice particularly in low health resource settings, such as in LMICs. Increasing access to holistic mental health care has the potential to benefit economic outcomes, such as food insecurity, in addition to clinical and functional outcomes.

9. Recommendations

Scientific recommendations

The following areas need further research attention:

- A randomized controlled trial of differing models of expanded access to mental health care.
- This study explored the impact of integrated mental health care which has a strong focus on treatment with psychotropic medication combined with informal community interventions. The potential additional benefit of more formal, structured community and facility-based psychosocial interventions needs to be evaluated.
- Adaptation and evaluation of rehabilitation programs, including work-related schemes/models/initiatives, which suit persons with SMD who are engaged in self-employment, mainly in an Agrarian economy and rural population.
- Qualitative studies to elucidate the quantitative findings of this study.
- Stratification of the evaluation of impact of primary care-based mental health care by residence, in particular highlanders vs. lowlanders, given the variation in socio-economic status between these two geographical areas.
- Further analysis/studies in the setting may be interested in understanding more about which participants have shown improvement across demographic characteristics and specific classes of medication.

Policy recommendations

Health, social welfare (safetynet) programs need to consider the food security needs, subsidized treatments for disability, physical and work impairment needs of people with SMD. This may also include subsidized psychotropic medications as well as the fee waiver government initiative for poor households to access treatment. The need for addressing stigma and discrimination and lower social support status via implementation of contextualized mental health literacy programs is also vital. The need for working on educational/vocational training opportunities for people with SMD are also among the implications of this study. Also, the unemployment figures reported call for the design, implementation and consideration of how people with SMD could benefit from the income generation opportunities such as the recently (2017) house-approved government initiatives (e.g. the Ethiopian youth revolving fund, proclamation No. 995/2017) as part of addressing the rampant

youth (18-34 years old) unemployment via making available the financial resource needed to be funded by the federal government (268) given the mean age of the SMD cases (35 years) being closer to the upper bound of the youth period. Moreover, the need for designing a psychiatric rehabilitation training program suitable for such an overwhelmingly rural setting is of vital importance. Integration of mental health care into PHC via a model of task sharing seems to have good potential to narrow the treatment gap (8) and lead to benefits in terms of household food insecurity. Strengthening collaborative planning and implementation of rehabilitation and reintegration services for persons with SMD among relevant stakeholders working on mental health conditions such as Ministry of Health and Ministry of Labor and Social Affairs is also important.

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References

1. Whiteford H, Degenhardt L, Jürgen R, Baxter A, Ferrari A, Erskine H, et al. Global burden of disease attributable to mental and substance use disorders: findings from the Global Burden of Disease Study 2010. The Lancet. 2013.
2. Mathers C, Loncar D. Projections of global and burden of disease from 2002 to 2030 PLoS Medicine. 2006;3(e442).
3. Fekadu A, Desta M, Alem A, Prince M. A descriptive analysis of admissions to Amanuel Psychiatric Hospital in Ethiopia. Ethiopian Journal of Health Development. 2007;21(2):173-8.
4. Saxena S, Thornicroft G, Knapp M, Whiteford H. Resources for mental health: scarcity, inequity, and inefficiency. Lancet. 2007;370:878-89.
5. WHO. Mental health and development: Targeting people with mental health conditions as a vulnerable group.: WHO Press.; 2010.
6. Mengistu E, Regassa N, Yusufe A. The Levels, Determinants and Coping Mechanisms of Food Insecure Households in Southern Ethiopia: Case Study of Sidama, Wolaita and Guraghe Zones. . 2009.
7. Ethiopia P. Description of Mental Health Care Plan Intervention Packages [Unpublished Document]. In press 2013.
8. WHO. WHO-mhGAP : Mental Health Gap Action Programme : scaling up care for mental, neurological and substance use disorders. 2008.
9. Teferra S. Studies on psychotic disorders in rural Ethiopia. Umeå University Medical Dissertations. 2011;1427.
10. Shibre T. Community based studies on schizophrenia in rural Ethiopia 2002.
11. WHO. Mental health: New understanding, New hope. Geneva: 2001.
12. Tandon R, Keshavan M, Nasrallah H. Schizophrenia, "just the facts": what we know in 2008 part 1: overview. Schizophr Res. 2008;100(1-3):4-19.
13. WebMD Ws. Webster's New World Medical Dictionary, 3rd ed. Wiley publishing Inc. 2008.
14. Association AP. Diagnostic and Statistical Manual of Mental Disorders (DSM-5), 5th ed. . 2013.
15. Merikangas K, Jin R, He J-P, Kessler R, Lee S, Sampson N, et al. Prevalence and Correlates of Bipolar Spectrum Disorder in the World Mental Health Survey Initiative. Arch Gen Psychiatry. 2011;68(3):241-51.
16. Matthew T, Bressan R, Neto P, Brietzke E. Early intervention for bipolar disorder: current imperatives, future directions Revista Brasileira de Psiquiatria. 2011;33(Suppl II).
17. Wyatt R, Henter I. An economic evaluation of manic-depressive illness—1991. Soc Psychiatry Psychiatr Epidemiol. 1995;30:213-9.
18. Hirschfeld R, Lewis L, Vornik L. Perceptions and impact of bipolar disorder: how far have we really come? Results of the National Depressive and Manic- Depressive Association 2000 survey of individuals with bipolar disorder. J Clin Psychiatry. 2003;64:161-74.
19. Kebede D, Alem A, Shibre T, Negash A, Fekadu A, Fekadu D, et al. Onset and clinical course of schizophrenia in Butajira- Ethiopia: a community-based study Social Psychiatry Psychiatric Epidemiology. 2003;38:625-31.
20. Abdullahi H, Hailemariam D, Kebede D. Burden of disease analysis in rural Ethiopia. Ethiopian Medical Journal. 2001;39(4):271-81.

21. Shibre T, Kebede D, Alem A, Negash A, Kibreab S, Fekadu A, et al. An evaluation of two screening methods to identify cases with schizophrenia and affective disorders in a community survey in rural Ethiopia. Int J Soc Psychiatry 2002 sep;48(3):200-8.
22. MOH. National mental health strategy 2012/13 - 2015/16. 2012.
23. Saha S, Chant D, McGrath J. A systematic review of mortality in schizophrenia: is the differential mortality gap worsening over time? . Archives of General Psychiatry. 2007 (64):1123-31.
24. Fekadu A, Medhin G, Kebede D, Alem A, Cleare AJ, Prince, et al. Excess mortality in severe mental illness: 10-year population-based cohort study in rural Ethiopia. BJP. 2015;206:289–96.
25. Chishlom D, Saxena S. Cost effectiveness to combat neuropsychiatric conditions in sub-saharan Africa and south east asia: mathematical modeling study. BMJ. 2012;344(E609).
26. Demyttenaere K, et al;. Prevalence, severity and unmet need for treatment of mental disorders in the WHO World Mental Health Surveys. JAMA. 2004;291:2581-90.
27. Lund C, Tomlinson M, De-Silva M, Fekadu A, Shidhaye R, Jordans M, et al. PRIME: A programme to reduce the treatment gap for mental disorders in five low- and middle-income countries. PLoS Medicine. 2012;9(12):e1001359.
28. Unutzer J, Chan Y, Hafer E, Knaster J, Shields A, al. e. Quality improvement with payfor-performance incentives in integrated behavioral health care. Am J Public Health. 2012;102(e41-e45).
29. Eaton J, McCay L, Semrau M, Chatterjee S, Baingana F, Araya R, et al. Scale up of services for mental health in low-income and middle-income countries. The Lancet. 2011;378(9802):1592-603.
30. Patel V, Simbine A, Soares I, Weiss H, Wheeler E. Prevalence of severe mental and neurological disorders in Mozambique: a population-based survey. Lancet. 2007;370(9592)):1055-60.
31. Lund C, Breen A, Flisher AJ, Kakuma R, Corrigall J, Joska JA, et al. Poverty and common mental disorders in low and middle income countries: A systematic review. Social science & medicine. 2010.
32. Buist-Bouwman M, De-Graaf R, Vollebergh W, Alonso J, Bruffaerts R, Ormel J. Functional disability of mental disorders and comparison with physical disorders: a study among the general population of six European countries. 2005.
33. Chandrashekar CR, Isaac, M. K., Kapur, R. L. & Parthasarathy, R. . Management of priority mental disorders in the community. Indian Journal of Psychiatry 1981;23: 174–8.
34. Westermeyer J. Economic losses associated with chronic mental disorder in a developing country. British Journal of Psychiatry. 1984;144:475-81.
35. Sharma PSVNT, B. M. . Disability in manic depressives and schizophrenics. A comparison using WHO Disability Assessment Schedule. 1986; NIMHANS Journal 4:7–17.
36. Zergaw A, Hilemariam D, Kebede D. A longitudinal comparative analysis of economic and family caregiver burden due to bipolar disorder. Afr J Psychiatry. 2008;11:191-8.
37. FAO. Food and Agriculture Organization of the United Nations (2006) Food Security in Ethiopia. Rome: FAO. Rome: FAO, 2006.
38. WHO. mhGAP Intervention Guide - Version 2.0 for mental, neurological and substance use disorders in non-specialized health settings. 2016.
39. McGurk M. Schizophrenia is a low-incidence but burdensome disease affecting individuals uniformly across the globe 2004.
40. Keshavan MS, Shrivastava A, Gangadhar BN. Early intervention in psychotic disorders: Challenges and relevance in the Indian context. Indian J Psychiatry. 2010;52.
41. Murray C, Lopez A. The Global Burden Disease: A Comprehensive Assessment of Mortality and Disability From Disease, Injuries and Risk Factors in 1990 and Projected to 2020. Harvard University Press. 1998.
42. E. V, Nieman D, Linszen D, Becker H, Haan L, Dingemans P, et al. Disability in people clinically at high risk of psychosis. The British Journal of Psychiatry. 2010;197:278-84.

43. Srinivasa M, Chisholm D, Kumar K, Thomas T, Sekar K, Chandrashekar C. Community outreach for untreated schizophrenia in rural India: a follow-up study of symptoms, disability, family burden and costs Psychological Medicine 2005;35(03):341-51.
44. Kebede D, Alem A. Major mental disorders in Addis Ababa, Ethiopia: Schizophrenia, schizoaffective and cognitive disorders. Acta psychiatr Scand. 1999;100:11-7.
45. Kebede D, Alem A, Shibre T, Negash A, Deyessa N, Beyero T. The Sociodemographic correlate of schizophrenia in Butajira, rural Ethiopia. Schizophrenia Research. 2004;69:133-41.
46. Fekadu A, Shibreb T, Alem A, Kebedeb D, Kebreab S, Negash A, et al. Bipolar disorder among an isolated island community in Ethiopia. Journal of Affective Disorders 2004;80:1-10.
47. Alem A, Kebede D, Fekadu A, Shibre T, Fekadu D, Beyero T, et al. Clinical Course and Outcome of Schizophrenia in a Predominantly Treatment-Naïve Cohort in Rural Ethiopia. Schizophrenia Bulletin. 2009;35(3):646-54.
48. Shibre T, Medhin G, Alem A, Kebede D, Teferra S, Jacobsson L, et al. Long-term clinical course and outcome of schizophrenia in rural Ethiopia: 10-year follow-up of a population-based cohort Schizophrenia Research. 2015;161:414-20.
49. Shibre T, Hanlon C, Medhin G, Alem A, D. K, Kullgren G, et al. Suicide and suicide attempts in people with severe mental disorders in Butajira, Ethiopia: 10 year follow-up of a population-based cohort Teshome Shibre. MBC Psychiatry. 2014;14(150).
50. Fekadu A, Kebede D, Alem A, Fekadu D, Mogga S, Negash A, et al. Clinical outcome in bipolar disorder in a community-based follow-up study in Butajira, Ethiopia. . Acta Psychiatr Scand. 2006;11:426-34.
51. Negash A, Kebede D, Alem A, Melaku Z, Deyessa N, Shibre T, et al. Neurological soft signs in bipolar I disorder patients. Journal of Affective Disorders 2004;80:221-30.
52. Kebede D, Alem A, Shibre T, Deyassa N, Negash A, Beyero T, et al. Symptomatic and functional outcome of bipolar disorder in Butajira, Ethiopia Journal of Affective Disorders. 2006;90:239– 49.
53. Mbuba C, Ngugi A, Newton C, Carter J. The epilepsy treatment gap in developing countries: a systematic review of the magnitude, causes, and intervention strategies. Epilepsia. 2008;49:1491-503.
54. Warner R. Recovery from Schziophrenia New York: Routledge; 1994.
55. MoH. Health Sector Development Programme IV, 2010/11 - 2014/15. Federal Democratic Republic of Ethiopia: Addis Ababa. 2010.
56. Hailemariam M, Fekadu A, Selamu M, Medhin G, Prince M, Hanlon C. Equitable access to integrated primary mental healthcare for people with severe mental disorders in Ethiopia: a formative study. Int J Equity Health. 2016;15(121).
57. Corrigan P, Watson A, Warpinski A, Gracia G. Stigmatizing attitudes about mental illness and allocation of resources to mental health services. Community Ment Health J 2004;40(297e307).
58. Chishlom D, Lund C, Saxena S. The cost of scaling up mental health care in low-and middle-income countries BJP. 2007;191:528-35.
59. Sanderson K, Andrews G. Prevalence and severity of mental health-related disability and relationship to diagnosis. Psychiatr Serv. 2002;53(1):80-6.
60. Spitzer R, Kroenke K, Linzer M, Hahn S, Williams J, De-Gruy F, et al. Health-related quality of life in primary care patients with mental disorders: results from the PRIME-MD 1000 Study. JAMA. 1995;274:1511–7.
61. Ormel J, Von-Korff M, vanden-Brink W, Katon W, Brilman E, Oldehinkel T. Depression, anxiety and disability show synchrony of change. Am J Public Health. 1993;83:385–90.
62. Olfson M, Fireman B, Weissman M, Leon A, Sheehan D, Kathol R, et al. Mental Disorders and Disability Among Patients in a Primary Care Group Practice Am J Psychiatry. 1997;154(12).
63. Chandrashekar H, Kumar C, Prashanth N, Kasthuri P. Disabilities research in India Indian J Psychiatry 2010;52(Suppl1):S281-S5.

64. Thirthalli J, Venkatesh B, Naveen M, Venkatasubramanian G, Arunachala U, Kishore Kumar K, et al. Do antipsychotics limit disability in schizophrenia? A naturalistic comparative study in the community. Indian J Psychiatry. 2010 52(Suppl1):S281–S5.
65. Mohan I, Tandon R, Kalra H, Trivedi J. Disability assessment in mental illnesses using Indian disability evaluation assessment scale (IDEAS) Indian J Med Res 2005;121::759–63.
66. Choudhry P, Deka K, Chetia D. Disability associated with mental disorders. Indian J Psychiatry. 2006;48:95–101.
67. Keshavan M, Shrivastava A, Gangadhar B. Early intervention in psychotic disorders: Challenges and relevance in the Indian context. Indian J Psychiatry. 2010;52.
68. De Silva M, Cooper S, Li L, Lund C, Patel V. Effect of psychosocial interventions on social functioning in depression and schizophrenia: metanalysis. BJPsch. 2013.
69. Lincoln TM, Wilhelm K, Nestoriuc Y. Effectiveness of psychoeducation for relapse, symptoms, knowledge, adherence and functioning in psychotic disorders: A meta-analysis. Schizophrenia Research. 2007;96(1-3):232-45.
70. Huxley N, Rendall M, Sederer L. Psychosocial Treatments in Schizophrenia: A Review of the Past 20 Years. Journal of Nervous & Mental Disease: . 2000;188(4):187-201.
71. Kebede D, Alem A, Shibre T, Negash A, Deyessa N, Beyero T, et al. Short term symptomatic and functional outcome of schizophrenia in Butajira, Ethiopia. Schizophrenia Research. 2005;78:171-85.
72. Odenwald M, Lingenfelder B, Peschel W, Haibe F, Warsame A, Omer A, et al. A pilot study on community-based outpatient treatment for patients with chronic psychotic disorders in Somalia: Change in symptoms, functioning and co-morbid khat use. Int J Ment Health Syst. 2012;6(8).
73. De Jong J, Komproe I. A 15-year open study on a cohort of West-African out-patients with a chronic psychosis Social Psychiatry & Psychiatric Epidemiology. 2006;41(11):897-903.
74. Botha U, Koen L, Joska J, Hering L, Oosthuizen P. Assessing the efficacy of a modified assertive community-based treatment programme in a developing country. BMC Psychiatry. 2010;10(73).
75. Thirthalli J, Venkatesh B, Kishorekumar K, Arunachala U, Venkatasubramanian G, Subbakrishna D, et al. prospective comparison of course of disability in antipsychotic-treated and untreated schiziophrenia patients Acta Psychiatr Scand. 2009;119:209-17.
76. Chatterjee S, Naik S, John S, Dabholkar H, Balaji M, Koschorke M, et al. Efeectiveness of a comminity-based intervention for people with schizophrenia and their caregivers in India (COSPI): a randomised controlled trial. Lancet. 2014;383(9926):1385-94.
77. Chatterjee S, PIllai A, Jain S, COHEN A, Patel V. Outcomes of people with psychotic disorders in a community-based rehabilitation programme in rural India. Br J Psychiatry. 2009;195(5):433-9.
78. Balaji M, Chatterjee S, Koschorke M, Rangaswamy T, Chavan A, Dabholkar H, et al. The development of a lay health worker delivered collaborative community based intervention for people with schizophrenia in India. BMC Health Serv Res. 2012;16(12:42).
79. Awad A, Voruganti L. The burden of schizophrenia on caregivers: a review. Pharmacoeconomics 2008;26:149-62.
80. Lauriello J, Lenroot R, Bustillo J. Maximizing the synergy between pharmacotherapy and psychosocial therapies for schizophrenia. Psychiatr Clin North Am. 2003;26:191-211.
81. Lenroot R, Bustillo J, Lauriello J, Keith S. Integrated treatment of schizophrenia Psychiatr Serv. 2003;54:1499-507.
82. Goetzel R, Hawkins K, Ozminkowski R, Wang S. The health and productivity cost burden of the “top 10” physical and mental health conditions affecting six large U.S. employers in 1999. J Occup Environ Med. 2003;45:5-14.
83. McEvoy J. The costs of schizophrenia. 2007, 68:4-7. J Clin Psychiatry 2007;68:4-7.
84. Wu E, Birnbaum H, Shi L, Ball D, Kessler R, Moulis M, et al. The economic burden of schizophrenia in the United States in 2002. J Clin Psychiatry. 2005;66:1122-9.

85. Shumway M ST, Shern D, Pines E, Downs A, Burbine T, Beller J. Preferences for schizophrenia treatment outcomes among public policy makers, consumers, families, and providers. Psychiatr Serv 2003;54:1124-8.
86. Rosenheck R, Stroup S, Keefe R, McEvoy J, Swartz M, Perkins D, et al. Measuring outcome priorities and preferences in people with schizophrenia. Br J Psychiatry. 2005;187:529-36.
87. Weiss K, Smith T, Hull J, Piper A, Huppert J. Predictors of risk of nonadherence in outpatients with schizophrenia and other psychotic disorders Schizophr Bull. 2002;28:341-9.
88. Ascher-Svanum H FD, Zhu B, Ernst FR, Swartz MS, Swanson JW: . Medication adherence and long-term functional outcomes in the treatment of schizophrenia in usual care. . J Clin Psychiatry. 2006;67:453-60.
89. Dunayevich E, Ascher-Svanum H, Zhao F, Jacobson J, Phillips G, Dellva M, et al. Longer time to antipsychotic treatment discontinuation for any cause is associated with better functional outcomes for patients with schizophrenia, schizophreniform disorder, or schizoaffective disorder. J Clin Psychiatry. 2007;68:1163-71.
90. Dunayevich E A-SH, Zhao F, Jacobson JG, Phillips GA, Dellva MA, Green AI:. Longer time to antipsychotic treatment discontinuation for any cause is associated with better functional outcomes for patients with schizophrenia, schizophreniform disorder, or schizoaffective disorder. J Clin Psychiatry 2007;68:1163-71.
91. Liu-Seifert H, Adams D, Kinon B. Discontinuation of treatment of schizophrenic patients is driven by poor symptom response: a pooled post-hoc analysis of four atypical antipsychotic drugs. BMC Med. 2005;3:21-30.
92. Liu-Seifert H, Ascher-Svanum H, Osuntokun O, Jen K, Gomez J. Change in level of productivity in the treatment of schizophrenia with olanzapine or other antipsychotics BMC Psychiatry. 2011;11(87).
93. Ran M, Xiang M, Chan C, Chan C, Leff J, Simpson P, et al. Effectiveness of psychoeducational intervention for rural Chinese families experiencing schiziophrenia—a randomized controlled trial Social Psychiatry & Psychiatric Epidemiology. 2003;38:69-75.
94. Xiong W, Philips M, Hu X. Family-based intervention for schiziophrenia patients in China. A randomized control trial. British Journal of Psychiatry. 1994;165(239-42).
95. Mengistu E, Regassa N, Yusufe A. The Levels, Determinants and Coping Mechanisms of Food Insecure Households in Southern Ethiopia: Case Study of Sidama, Wolaita and Guraghe Zones Oslo: Drylands Coordination Group. 2009;Report no. 55.
96. Hadley C, Crooks D. Coping and the Biosocial Consequences of Food Insecurity in the 21st Century. 2012.
97. Maxwell S, Frankenberger T. Household food security:concepts, indicators, measurements: a technical review. New York: UNICEF, 1992.
98. Wiley-Exley E. Evaluations of community mental health care in low- and middle income countries: a 10-year review of the literature. Social Science & Medicine. 2007;64(6):1231-41.
99. FAO. The state of food insecurity in the world. Rome: 2004.
100. Hendriks S. The challenges facing empirical estimation of household food (in)security in South Africa. Dev South Afr. 2005;22:103-23.
101. Maxwell S. Food security: a post-modern perspective Food Policy 1996;21:155-70.
102. Coates J, Swindale A, Blinsky P. Household Food Insecurity Access Scale (HFIAS) for Measurement of Household Food Access: Indicator Guide (v.3) Washington, DC: 2007.
103. FANTA. Food and Nutrition Technical Assistance (FANTA) Dietary Diversity as a Household Food Security Indicator Washington, DC: 2002.
104. Maxwell S. The evolution of thinking about food insecurity. In: Devereux S, Maxwell S, editors. Food security in sub-Saharan Africa. London: 2001.
105. Barrett C. Measuring food insecurity Science. 2010;327:825-8.

106. Bickel G, Nord M, Price C, Hamilton W, Cook J. Guide to measuring food insecurity, revised 2000 Alexandria, VA US Department of Agriculture, Food and Nutrition Service, 2000.
107. Radimer K. Understanding hunger and developing indicators to assess it [[dissertation].]. In press 1990.
108. Perez-Escamilla R, Dessalines M, Finnigan M, Pachon H, Hromi-Fiedler A, Gupta N. Household food insecurity is associated with childhood malaria in rural Haiti. J Nutr 2009;139:2132-8.
109. Melgar-Quinonez H, Hackett M. Measuring household food security: the global experience. Revista de Nutric¸a˜o. 2008;21:27s-37s.
110. Wolfe W, Frongillo E. Understanding the experience of food insecurity among elders suggests ways to improve its measurement. J Nutr. 2003;133:2762-9.
111. Webb P, Coates J, Frongillo E, Rogers B, Swindale A, Bilinsky P. Measuring household food insecurity: why it's so important and yet so difficult to do. J Nutr. 2006;136:1404s-8s.
112. Jrad S, Nahas B, Baghasa H. Food security models. Policy breif No 33, ministry of agriculture and agrarian reform, national agricultural policy center, Syrian Arabic Republic. 2010:1-32.
113. Webber CB. Low-income households and grocery stores: Food access and availability in underserved areas. Doctoral dissertation, Cornell University, Ithaca, NY. 2005.
114. Anderson S. Core indicators of nutritional state for difficult to sample populations. Journal of Nutrition. 1990;120(11S):1557S-600S.
115. Kuwornu J, Mensah-Bonsu A, Ibrahim H. Analysis of foodstuff price volatility in Ghana: Implications for food security. Eur J Bus Manage. 2011;3:100-18.
116. Gregory P, Ingram J, Brklacich M. climate change and food security. Philos Trans R Soc B: Biol Sci. 2005;360:2139-48.
117. Ashiabi G, O'Neal K. A framework for understanding the association between food insecurity and children's developmental outcomes. Child Dev Perspect. 2008;2:71-7.
118. Melchior M, Caspi A, Howard L, Ambler A, Bolton H, Mountain N, et al. Mental Health Context of Food Insecurity: a Representative Cohort of Families With Young Children Pediatrics 2009;124(4):e564 - e72.
119. Huang J, Guo B, Kim Y. "Food Insecurity and Disability: Do Economic Resources Matter?," Social Science Research. 2010;39:111-24.
120. Hailu A, Regassa N. Correlates of Household Food Security in Densely Populated Areas of Southern Ethiopia: Does the Household Structure Matter? . Stud Home Comm Sci. 2007;1(2):85-91.
121. Brucker D, Mitra S, Chaitoo N, Mauro J. More likely to be poor whatever the measure: working-age persons with disabilities in the United States. Soc Sci Q. 2015;96(1):273e96.
122. Kregg-Byers C, Schlenk E. Implications of Food Insecurity on Global Health Policy and Nursing Practice. Journal of nursing scholarship. 2010;42(3):278-85.
123. Coleman-Jensen A, Nord M. Food insecurity among households with working-age adults with disabilities. Economic Research Report, USDA. 2013 (144).
124. Rose R, Parish S, Yoo J. "Measuring Material Hardship among the U.S. Population of Women with Disabilities Using Latent Class Analysis," Social Indicators Research. 2009;94:391-415.
125. Miller N, Kirk A, Kaiser M, Glos L. The relation between health insurance and health care disparities among adults with disabilities. Am J Public Health. 2014;104(3):e85ee93.
126. Stuff C, Szeto, Gossett, Robbins, Simpson et al. Household Food Insecurity Is Associated with Adult Health Status. The journal of nutrition. 2004.
127. Dixon L, Winkleby M, Radimer K. Dietary intakes and serum nutrients between adults from food insufficient and food-sufficient families:Third National Health and Nutrition Examination Survey. Journal of Nutrition. 2001;131:1232-46.

128. Kempson KM, Keenan DP, Sadani PS, Ridlen S, Rosato NS. Food management practices used by people with limited resources to maintain food sufficiency as reported by nutrition educators. Journal of the American Dietetic Association, . 2002;102(12):1795-9.
129. Rose DO, V. Nutrient intakes of individuals from food-insufficient households in the United States. American Journal of Public Health, . 1997;87:1956-61.
130. Heflin CM, Siefert, K., Williams, D.R. Food insufficiency and women's mental health: Findings from a 3-year panel of welfare recipients. Social Science & Medicine. 2005;61:1971-82.
131. Siefert K, Heflin, C.M., Corcoran, M.E., & Williams, D.R. Food insufficiency and physical and mental health in a longitudinal study of welfare recipients Journal of Health and Social Behavior,. 2004;45:171-86.
132. Drewnowski A, Specter SE. Poverty and obesity: The role of energy density and energy costs. American Journal of Clinical Nutrition. 2004;79(1):6-16.
133. Eikenberry N. Access to food and healthy food choice for low-income Minnesotans: A literature review. Masters thesis, University of Minnesota, Minneapolis MN. 2003.
134. Messer E. Seasonal hunger and coping strategies: an anthropological discussion. Philadelphia, PA: The University Museum, University of Pennsylvania, 1989.
135. Rose-Jacobs R, Black M, Casey P, Cook J, Cutts D, Chilton M, et al. Household food insecurity: associations with at-risk infant and toddler development. Pediatrics. 2008;121(1):65-72.
136. Kleinman RE MJ, Little M, et al. . Hunger in children in the United States: potential behavioral and emotional correlates. Pediatrics [Internet]. 1998; 101.
137. Whitaker R, Phillips S, Orzol S. Food insecurity and the risks of depression and anxiety in mothers and behavior problems in their preschool-aged Children. Pediatrics [Internet]. 2006; 118.
138. Cole S, Tembo G. The effect of food insecurity on mental health: Panel evidence from rural Zambia. Social Science & Medicine. 2011;73(7):1071–9.
139. Hadley C, Patil C. Food insecurity in rural Tanzania is associated with maternal anxiety & depression American journal of Human Biology 2006;18:359-68.
140. Hadley C, Tegegn A, Tessema F, Cowan J, Asefa M, Galea S. Food insecurity, stressful life events and symptoms of anxiety & depression in east Africa: Evidence from the Gilgel Gibe growth and development study. Journal of epidemiology and community health. 2008;62:980-6.
141. Desjarlais R, Eisenberg L, Good B, Klienman A. World mental health: problems and priorities in low-income countries. . New York, oxford university press. 1995.
142. Patel V, Klienman A. Poverty and Common Mental disorders in developing countries. 2006.
143. Lund C, De-Silva M, Plagerson S, Cooper S, Chilshom D, Das J, et al. Poverty and Mental Disorders: Breaking the cycle in low-income and middle-income countries. Lancet. 2011;378(9801):1502-14.
144. Maes K, Hadley C, Tesfaye F, Shifferaw S. Food insecurity and mental health: Surprising trends among community health volunteers in Addis Ababa, Ethiopia during the 2008 food crisis Social Science and Medicine. 2010;70(9):1450-11457.
145. Sorsdahl K, Slopen N, Siefert K, Seedat S, Stein DJ, Williams DR. Household food insufficiency and mental health in South Africa. J Epidemiol Community Health. 2011;65:426e-31.
146. Leyna G. Food insecurity: associated factors, Nutritional and health related outcomes in a Rural village, north-east Tanzania. [Maters thesis,]. Norway: University of Oslo; 2005.
147. Goetz JR. Exploring Food Insecurity Among Individuals With Serious Mental Illness: A Qualitative Study [Unpublished PHD Dissertation]: University of Kansas; 2008.
148. Trani J-S, Venkataraman H, Mishra N, Groce NE, Jadhav S, Deshpande S. Mental illness, poverty and stigma in India: a case–control study. BMJ open. 2016;5:e006355.

149. Fekadu A, Hanlon C, Medhin G, Alem A, Selamu M, Welde-Giorgis T, et al. Development of a scalable mental healthcare plan for a rural district in Ethiopia. British Journal of Psychiatry. 2016;208(S4-S12).
150. Hailemariam M, Fekadu A, Selamu M, Alem A, Medhin G, Wolde-Giorgis T, et al. Developing a mental health care plan in a low resource setting: the theory of change approach BMC Health Services Research 2015;15(429).
151. De Silva M, Rathod S, Hanlon C, Breuer E, Chisholm D, Fekadu A, et al. Evaluation of district mental healthcare plans: the PRIME consortium methodology. The British Journal of Psychiatry. 2015;s1-s8.
152. Maslow A. "A theory of human motivation". Psychological Review. 1943;50(4):370-96.
153. Oldewage-Theron W, Dicks E, Napier C. Poverty, household food insecurity and nutrition: coping strategies in an informal settlement in the Vaal Triangle, South Africa. Public Health. 2006;120(9):795–804.
154. WHO. WHO Nutrition: Nurturing Health. Regional Consultation on Nutrition and HIV/AIDS in French speaking countries in Africa Region: Evidence, lessons and recommendations for action. Ouagadougou, Burkina Faso. WHO Nutrition. 2008.
155. Maslow A. Motivation and personality. New York: Harper and Row. 1954.
156. Bandura A. "Self-efficacy mechanism in human agency". American Psychologist. 1982;37(2):122-47.
157. Stajkovic AD, Luthans F. "Self-efficacy and work-related performance: A meta-analysis". Psychological Bulletin. 1988;2(240-261).
158. Luszczynska A, Schwarzer R. "Social cognitive theory". In M. Conner & P. Norman. Predicting health behaviour. Buckingham, England: Open University Press. 2005;2nd ed. rev. ed.:127-69.
159. Dohrenwend B, Levav I, Shrout P, Schwartz S, Naveh G, Link B, et al. Socioeconomic status and psychiatric disorders: the causation-selection issue. Science. 1992;255: 946-52.
160. Patel V, Kleinman A. Poverty and common mental disorders in developing countries Bulletin of the World Health Organization. 2003;81(8):609-15.
161. Tsai A, Bangsberg D, Frongillo E, al. e. Food insecurity, depression and the modifying role of social support among people living with HIV/AIDS in rural Uganda. Soc Sci Med 2012;74:2012-9.
162. Saraceno B, Levav I, Kohn R. The public mental health significance of research on socio-economic factors in schizophrenia and major depression. World Psychiatry. 2005;4(181e185.).
163. Lund C. Poverty, Inequalities and Mental Health, with special reference to low and middle-income countries (LMIC).
164. Pilgrim D. The biopsychosocial model in Anglo-American psychiatry: past, present, and future? J Ment Health. 2002;11:585-94.
165. Ghaemi N. The rise and fall of the bio-psychosocial model. Br J Psychiatry. 2009;195:3-4.
166. Benning T. Limitations of the biopsychosocial model in psychiatry. Advances in Medical Education and Practice 2015;6:347-52.
167. Engel G. The need for a new medical model: a challenge for biomedicine. Science. 1977;196:129-36.
168. Michie S, Miles J, Weinman J. Patient-centeredness in chronic illness: what is it and does it matter? . Patient Educ Couns. 2003;51:197-206.
169. Kloos H, Zein Z. The ecology of health and disease in Ethiopia. Boulder: West view press. 1993.
170. Yeo R. Chronic Poverty and Disability. Action on Disability and Development Vallis House. 2001.
.
171. Lund C, Tomlinson M, de Silva M, Fekadu A, Shidhaye R, Jordans M, et al. PRIME: A Programme to Reduce the Treatment Gap for Mental Disorders in Five Low- and Middle-Income Countries. PL o S Medicine. 2012 12/27;9(12).

172. CSA. Population Projection of Ethiopia for All Regions At Wereda Level from 2014–2017. In Edited by Agency CS Addis Ababa: Central Statistical Agency. 2013.
173. EDH. Ethiopian demography and health. Http://www.ethiodemographyandhealth.org/snnpr.html. Retrieved on September 17, 2013.
174. CSA. CSA , Central Statistical Authority. . Addis Ababa, Ethiopia2007.
175. http://www.rippleethiopia.org/page/snnpr.
176. CSA. Summary and Statistical Report of the 2007 Population and housing census. Addis Ababa. Federal Democratic Republic of Ethiopia Population Census Commission. 2008.
177. Asher L, Hanlon C, Birhane R, Habtamu A, Eaton J, Patel V, et al. Community-based rehabilitation intervention for people with schizophrenia in Ethiopia (RISE): a 12 month mixed methods pilot study. BMC Psychiatry. 2018;18(250).
178. Ford C. The Guraghe people retrieved in 2013. Available from: http://www.carolynford.org/gurage/index.shtml.
179. USAID. Southern Nations Nationalities and People's Region (SNNPR) LIVELIHOOD PROFILES. Regional Overview. .
180. SNNPR. "The socioeconomic profile of Southern Nations, Nationalities and Peoples Region Awassa, Ethiopia.2001.
181. Wikipedia tfe. Southern Nations, Nationalities, and Peoples' Region 21 September 2015 [updated This page was last modified on 21 September 2015, at 17:17.].
182. FEWSNET U, Disaster Prevention and Preparedness Commission (DPPC), the Government of Ethiopia. Southern Nations, Nationalities, and Peoples Region (SNNPR LIVELIHOOD PROFILE), Regional Overview. December 2005.
183. Semrau M, Evans-Lacko S, Alem A, Ayuso-Mateos JL, Chisholm D, Gureje O, et al. Strengthening mental health systems in low- and middle-income countries: the Emerald programme. BMC Medicine. 2015;13(79):https://doi.org/10.1186/s12916-015-0309-4.
184. APA. DSM IV. American Psychiatric Association, Washington, DC 1995.
185. Fekadu A, Medhin G, Selamu M, Hailemariam M, Alem A, Breuer E, et al. Population level mental distress in rural Ethiopia. BMC Psychiatry. 2014;14(194):1471-244X/14/194.
186. Dua T, Barbui C, Clark N, Fleischmann A, Poznyak V, van-Ommeren M, et al. Evidence-Based Guidelines for Mental, Neurological, and Substance Use Disorders in Low- and Middle-Income Countries: Summary of WHO Recommendations. PLoS Medicine. 2011;8(11):e1001122.
187. McGuffin P, Farmer AE, Harvey I. A polydiagnostic application of operational criteria in studies of psychotic illness: development and reliability of the OPCRIT system Archives of General Psychiatry. 1991;48:764-70.
188. Coates J, Swindale A, Bilinsky P. Household Food Insecurity Access Scale (HFIAS) for measurement of Food Access: Indicator Guide. Food and Nutrition Technical Assistance (FANTA) project. Washington DC United States Agency for International Development; 2007b.
189. Swindale A, Bilinsky P. Development of a universally applicable household food insecurity measurement tool: process, current status, and outstanding issues. Journal of Nutrition. 2006;136(5):1449-52.
190. Gebreyesus SH, Lunde T, H-Mariam D, Woldehanna T, Lindtjørn B. Is the adapted Household Food Insecurity Access Scale (HFIAS) developed internationally to measure food insecurity valid in urban and rural households of Ethiopia? BMC Nutrition. 2015;1(2):doi:10.1186/2055-0928-1-2.
191. Jebena M, Taha M, Nakajima M, Lemieux A, Lemessa F, Hoffman R, et al. household food insecurity and mental distress among pregnant women in southwestern Ethiopia: a cross-sectional study design. BMC Pregnancy and Childbirth. 2015;15(250):doi: 10.1186/s12884-015-0699-5.

192. Coates J, Swindale A, Bilinsky P. Household Food Insecurity Access Scale (HFIAS) for Measurement of Food Access: Indicator Guide Washington, DC: Food and Nutrition Technical Assistance Project, Academy for Educational Development. 2006.
193. Azevedo MH, Soares MJ, Coelho I, Dourado A, Valente J, Macedo A, et al. Using consensus OPCRIT diagnoses. An efficient procedure for best-estimate lifetime diagnoses. British Journal of Psychiatry 1999;175:154-7.
194. Opcrit. Opcrit for Windows (v4), Item Checklist. 2004.
195. Williams J, Farmer AE, Ackenheil M, Kaufmann CA, McGuffin P. A multicentre inter-rater reliability study using the OPCRIT computerized diagnostic system. Psychological Medicine. 1996;26(4):775-83.
196. WHO. World Health Organisation. Disability Assessment Schedule. Geneva: 1985.
197. Üstün T, Chatterji S, Kostanjsek N, Rehm J, Kennedy C, Epping-Jordan J, et al. Developing the World Health Organization Disability Assessment Schedule 2.0. Bull World Health Organ. 2010;88:815-23.
198. Gold L. DSM-5 and the assessment of functioning: The World Health Organization Disability Assessment Schedule 2.0 (WHODAS 2.0). J Am Acad Psychiatry Law. 2014;42:173-81.
199. Habtamu K, Alem A, Medhin G, Fekadu A, Dewey M, Prince M, et al. Validation of the World Health Organization Disability Assessment Schedule in people with severe mental disorders in rural Ethiopia. Health and Quality of Life Outcomes. 2017;15(64):DOI 10.1186/s12888-015-0418-9.
200. Ustün TB, Chatterji S, Kostanjsek N, Rehm J, Kennedy C, Epping-Jordan J, et al. Developing the World Health Organization Disability Assessment Schedule 2.0. Bulletin of the World Health Organization. 2010;88( ):815-23.
201. WHO. WHO study on global ageing and adult health (SAGE). Geneva: WHO. 2013.
202. Lauritsen JM, Bruus M. EpiData (version 3). A comprehensive tool for validated entry and documentation of data. In: Association TE, editor. Odense, Denmark 2003-2008.
203. StataCorp. STATA/SE 13.1. statacorp, college station. 13.1 ed. Texas USA1985-2013.
204. ASN. Development of a universally applicable food insecurity measurement tool: process, current status, and outstanding issues 1-3. the journal of nutrition. 2006.
205. Leon AC, Solomon DA, Mueller TI, Turvey CL, Endicott J, Keller MB. The Range of Impaired Functioning Tool (LIFE–RIFT): a brief measure of functional impairment. Psychological Medicine. 1999;29(04):869-78.
206. Judd L, Akiskal H, Schettler P, Endicott J, Leon A, Solomon D, et al. psychosocial disability in the course of bipolar I and II disorder. Archives of General Psychiatry. 2005;62(12):1322-30.
207. Fekadu A. study of course and outcome of SMD in Butajira (Ethiopia) personal communication. 2017.
208. Brohan E, Clement S, Rose D, Sartorius N, Thornicroft G. Development and psychometric evaluation of the Discrimination and Stigma Scale (DISC). Psychiatry Research. 2013;208:33-40.
209. INDIGO. Discrimination and Stigma Scale. 2008.
210. WHO. WHO AUDIT: the alcohol usedisorders identification test:guidelines for use in primary care. 2nd edition Geneva: WHO. 2001.
211. Fekadu A, Hanlon C, Gebre-Eyesus E, Agedew M, Solomon H, Teferra S, et al. Burden of mental disorders and unmet needs among street homeless people in Addis Ababa, Ethiopia. BMC Med 2014;12(138).
212. UN. United Nations Statistics Division. Washington Group on Disability Statistics homepage. 2009.
213. Mirowsky J, PN H. physiacl impairment and the diminishing effects of income. Social Forces. 1996;74(3):1073-96.
214. Overall J, Gorham D. The Brief Psychiatric Rating Scale. Psychological Reports. 1962;10:799-812.

215. Zilber N, Youngmann R, Workneh F, Giel R. Development of a culturally-sensitive psychiatric screening instrument for Ethiopian populations. Nuffic, Haigud: Netherlands-Israel Development Research Project. 2004;NIRP Research for Policy Series 20(280424).
216. Gray R, Leese M, Bindman J, Becker T, Burti L, David A, et al. Adherence therapy for people with schizophrenia: European multicentre randomised controlled trial. British Journal of Psychiatry 2006;189(6):508-14.
217. Brevik J, Dalgard O. The Health Profile Inventory. . University of Oslo, Oslo. 1996.
218. Dalgard O. Explanation of OSS-3. European Public Health Information System (EUPHIX); [updated 15 August 2011]. 2008.
219. corporation I. IBM SPSS Amos 21, version 21.0. 2011.
220. Lumley T, Kronmal R, Ma S. Relative risk regression in medical research: Models, contrasts, estimators and algorithms. In: UW Biostats Working Paper Series. Washington: University of Washington. 2006.
221. Browne MW, Cudeck R. Alternative ways of assessing model fit. In Bollen, KA and Long JS (Eds.). Testing structural equation models. Newbury Park, CA. Sage. 1993:136-62.
222. Bentler P. Comparative fit indexes in structural models. Psychological Bulletin. 1990;107:238-46.
223. Bentler P, Bonnet D. Significance tests and goodness of fit in the analysis of covariance structures. Psychological Bulletin. 1980;88:588-606.
224. Flyckt L, Lothman A, Jorgenson L, Rylander A, Koering T. Burden of informal caregiving to patients with psychosis: A descriptive and methodological study. International journal of social psychiatry. 2011;59(2):137-46.
225. Habtamu K, Alem A, Hanlon C. Conceptualizing and contextualizing functioning in people with severe mental disorders in rural Ethiopia: a qualitative study. BMC Psychiatry 2015;15(34).
226. Habtamu K, Alem A, Medhin G, Fekadu A, Hanlon C. Functional impairment among people with severe and enduring mental disorder in rural Ethiopia: a cross-sectional study. Social Psychiatry and Psychiatric Epidemiology. 2018;doi: 10.1007/s00127-018-1546-6.
227. Shibre T, Negash A, Kullgren G, Kebede D, Alem A, Fekadu A, et al. Perception of stigma among family members of individuals with schizophrenia and major affective disorders in rural Ethiopia. Soc Psychiatry Psychiatr Epidemiol. 2001;36:299–303
228. Corrigan PW, Penn D. Disease and discrimination: Two paradigms that describe severe mental illness. Journal of Mental Health. 1997;6(4):355-66.
229. Lapsley H, Nikora L, Black R. “Kia Mauri Tau!”: Narratives of Recovery from Disabling Mental Health Problems, Report of the University of Waikato Mental Health Narratives Project Mental Health Commission, Wellington. 2002.
230. Nagler M. Perspectives on Disability. Health Markets Research. 1994;2nd edn.
231. Riger AL. Beyond ADA: APA’ s responsibility to disability rights. APA Monitor. 1994 December:34.
232. Stephens CL, Belisle KC. The `consumer as provider’ movement. Journal of Mental Health Administration. 1993;20:178±82.
233. OU. Increasing autism awareness in Ethiopia: The HEAT+ project. Open University. https://wwwautismspeaksorg/science/grants/increasing-autism-awareness-ethiopia-heat-project. 2018 accessed 29 january 2018.
234. Tilahun D, Hanlon C, Fekadu A, Tekola B, Baheretibeb Y, Hoekstra R. Stigma, explanatory models and unmet needs of caregivers of children with developmental disorders in a low-income African country: a cross-sectional facilitybased survey. BMC Health Services Research. 2016;16(152).
235. Lijalem M. Assessment of Nutritional Status of People with Major Mental Disorders and Their Controls, In Meskan and Marako District (Butajira), Ethiopia. MA Thesis. 2002.
236. Solomon T. Studies on psychotic disorders in rural Ethiopia. Umeå University Medical Dissertations. 2011;New Series No 1427.

237. Mall S, Hailemariam M, Selamu M, Fekadu A, Lund C, Patel V, et al. Restoring the person's life'': a qualitative study to inform development of care for people with severe mental disorders in rural Ethiopia. Epidemiology and Psychiatric Sciences. 2017;26(1):43-52.
238. WHO. Report of the International Pilot Study of Schizophrenia. Report Geneva, Switzerland. 1973;I.
239. WHO. Schizophrenia: An International Follow-up Study John Wiley & Sons, Chichester, UK. 1979.
240. Hopper K, Wanderling J. Revisiting the Developed Versus Developing Country Distinction in Course and Outcome in Schizophrenia: Results From ISoS, the WHO Collaborative Followup Project Schizophrenia Bulletin. 2000;26(4, 20).
241. ICMR. Mental Health Research in India: Technical Monograph on ICMR Mental Health Studies. New Delhi, India. Indian Council of Medical Research. 2005.
242. Verghese A, John J, Rajkumar S, Richard J, Sethi B, Trivedi J. Factors associated with the course and outcome of schizophrenia in India: results of a two-year multicentre follow-up study. Br J Psychiatry. 1989;154:499-503.
243. Thara R, Rajkumar S. Gender differences in schizophrenia: results of a follow-up study from India. Schizophr Res. 1992:65-70.
244. Cohen A, Patel V, Thara R, Gureje O. Questi oning an Axiom: Better Prog nosis for Schi zophrenia in the Developing World? Schizophrenia Bulletin. 2008;34(2):229–44.
245. Edgerton R, Cohen A. Culture and Schizophrenia: The DOSMD Challenge. British Journal of Psychiatry 1994;164:222-31.
246. Bottlender R, Strauß A, Möller H-J. Social disability in schizophrenic, schizoaffective and affective disorders 15 years after first admission. Schizophr Res. 2010;116:9-15.
247. Hailemariam M, Fekadu A, Prince M, Hanlon C. Engaging and staying engaged: a phenomenological study of barriers to equitable access to mental healthcare for people with severe mental disorders in a rural African setting. International Journal for Equity in Health. 2017;16(156):DOI 10.1186/s12939-017-0657-0.
248. Swartz M, Perkins D, Stroup T, Davis S, Capuano G, Rosenheck R, et al. Effects of Antipsychotic Medications on Psychosocial Functioning in Patients With Chronic Schizophrenia: Findings From the NIMH CATIE Study. American Journal of Psychiatry. 2007;164(3):428-36.
249. Harrow M, Jobe T, Faull R, Yang J. A 20-Year multi-followup longitudinal study assessing whether antipsychotic medications contribute to work functioning in schizophrenia. Psychiatry Research. 2017;256:267-74.
250. Wils R, Gotfredsen D, Hjorthøj C, Austin S, Albert N, Secher R, et al. Antipsychotic medication and remission of psychotic symptoms 10 years after a first-episode psychosis. Schizophrenia Research 2017;182:42-8.
251. Furukawa T, Levine S, Tanaka S, Goldberg Y, Samara M, Davis J, et al. Initial severity of schizophrenia and efficacy of antipsychotics: participant-level meta-analysis of 6 placebo-controlled studies. JAMA Psychiatry. 2015;72(1):14-21.
252. Perlis R, Welge J, Vornik L, Hirschfeld R, Keck P. Atypical antipsychotics in the treatment of mania: a meta-analysis of randomized, placebo-controlled trials. Journal of Clinical Psychiatry. 2006;67(4):509-16.
253. Zhu Y, Krause M, Huhn M, Rothe P, Schneider-Thoma J, Chaimani A, et al. Antipsychotic drugs for the acute treatment of patients with a first episode of schizophrenia: a systematic review with pairwise and network meta-analyses. Lancet Psychiatry. 2017;4(9):694-705.
254. Semrau M, Evans-Lacko S, Koschorke M, Ashenafi L, Thornicroft G. Stigma and discrimination related to mental illness in low- and middle-income countries Epidemiology and Psychiatric Sciences 2015;24:382-94.

255. Asher L, De-Silva M, Hanlon C, Weiss HA, Birhane R, Medhin G, et al. Community-based Rehabilitation Intervention for people with Schizophrenia in Ethiopia (RISE): study protocol for a cluster randomised controlled trial. BMC Trials. 2016;17(299).
256. BasicNeeds. Mental Health and Development: A Model in Practice. Leamington Spa: BasicNeeds. 2008.
257. Raja S, Underhill C, Shrestha P, Sunder U, Mannarath S, Kippen-Wood S, et al. Integrating mental health and development: a case study of the basicneeds model in Nepal. PLoS Med. 2012;9(e100126).
258. Lund C, Waruguru M, Kingori J, Kippen-Wood S, Breuer E, S. M, et al. Outcomes of the mental health and development model in rural Kenya: a 2-year prospective cohort intervention study. Int Health. 2013;5:43–50.
259. Combaz E. Social inclusion in productive safety net programmes 2013.
260. Endalew B, Muche M, Tadesse S. Assessment of Food Security Situation in Ethiopia. World Journal of Dairy & Food Sciences. 2015;10(1):37-43.
261. WFP. Productive safety net program (PSNP): Ethiopia. 2016 November 29, retrived at 4:40 PM.
262. MORAD. Government of Ethiopia (2009). Food Security Programme 2010-2014: Productive Safety Net. Addis Ababa: 2009.
263. MoA E. Productive Safety Net Programme, Phase IV Programme Implementation Manual. 2014;1.0.
264. Shibre T, Negash A, Kullgren G, Kebede D, Alem A, Fekadu A. Perception of stigma among family members of individuals with schizophrenia and major affective disorders in rural Ethiopia. Soc Psychiatry Psychiatr Epidemiol 2001;36:299-303.
265. Teferra S, Hanlon C, Beyero T, Jacobsson L, Shibre T. Perspectives on reasons for non-adherence to medication in persons with schizophrenia in Ethiopia: a qualitative study of patients, caregivers and health workers. BMC Psychiatry. 2013;13(168).
266. Cuc M, Bobes J, Cetkovich-Bakmas M, Cohen D, Itsuo Asai, Detraux J, et al. Physical illness in patients with severe mental disorders. I. Prevalence, impact of medications and disparities in health care. World Psychiatry. 2011;10(1):52-77.
267. Khalema NE, Shankar J. Perspectives on Employment Integration, Mental Illness and Disability, and Workplace Health Advances in Public Health. 2014;Article ID 258614:7.
268. FDRE E. Ethiopian Youth Revolving Fund Establishment Proclamation. Federal Negarit Gazette. 2017 (24):1-8.

Appendices

Appendix A1. Socio-demographic Information of the Study Participants (English V.)

1. Participant personal data				
102	Sex [observe the participant and fill]	male	0	SEX
		female	1	
103	Age (how old are you)	[ ] [ ]		AGE
104	Place of residence (is it urban or rural?)	urban	0	RES
		rural	1	
105	For how long did you reside in the sub-district you are living now?	[ ][ ] Years [ ][ ] months		RESDUR
106	Educational level (how is your educational level?)	Illiterate	1	EDU
		Can read & write but without formal education (e.g. church education, basic education)	2	
		Attended formal education	3	
107	If attended formal education, up to what grade level did you attend?	[ ][ ] Years		EDUYR
108	Employment status (what is the means of earning income or work type you spend the day working?)	Agriculture	1	EMP
		Private firm employee	2	
		Self-employee	3	
		Volunteer worker	4	
		House-wife	5	
		Unemployee	6	
		Student	7	
		Pensioner	8	
		Government employee	9	
		Daily laborer	10	
		others, specify	77	
109	How do you describe your family's living status (income)?	Very low	1	REINC
		Low	2	
		Medium	3	
		High	4	
		Very high	5	
110	Marital status (how is your current marital status?) **[if**	Single	1	MARIT
		Married	2	

	the response is 1, 3 and 4, skip to Q. no. 113]	Divorced	3	
		Partner deceased	4	
		Married but living in separated due to work or other reasons	5	
		cohabiting	6	
111	Spouse employment status (what is the means of earning income or work type your spouse spend the day working?) **[only those who are married and whose spouse is alive to be asked]**	Agriculture	1	EMPSP
		Private firm employee	2	
		Self-employee	3	
		Volunteer worker	4	
		House-wife	5	
		Unemployee	6	
		Student	7	
		Pensioner	8	
		Government employee	9	
		Daily laborer	10	
		others, specify	77	
112	Educational level (how is your educational level?)	Illiterate	1	SEDL
		Can read & write but without formal education (e.g. church education, basic education)	2	
		Attended formal education	3	
113	Religion (what is your religion?)	Orthodox Christian	1	**RELIG**
		Muslim	2	
		protestant	3	
		others, specify _____	4	
114	Ethnicity (what is your ethnicity?)	Gurage	1	**ETHNIC**
		Oromo	2	
		Amhara	3	
		others, specify_____	4	
115	Number of family members (including you, how many persons live in your home)?	[ ] [ ]		
116	Are you pregnant (for female participants only)?	No	0	**PREG**
		Yes	1	
		does not refer to me	66	
		I do not know	888	
117	Do you have kids (including biological and adoptees)? **[if yes, skip to Q.119]**	No	0	KIDS
		Yes	1	

118	How many kids do you have?	[ ] [ ]		KIDSNO
119	How old is your last child?	[ ][ ] Years minutes		KIDYR
120	How long (in minutes) do you travel to reach the nearest health center?	[ ] [ ] [ ] Minutes		DFHC
	Were you household head before mental illness onset?	No	0	
120	Are you currently household head?	No	1	HHOHC
		Yes	1	

Appendix A2. Socio-demographic Information of the Study Participants (Amharic V.)

1. የተሳታፊ ግላዊ መረጃ				
102	ፆታ [የተጠያቂውን ፆታ አይተው ይመዝግቡ]	ወንድ	0	SEX
		ሴት	1	
103	እድሜ (ስንት አመትዎ ነው)	[ ] [ ]		AGE
104	መኖሪያ ስፍራ (የሚኖሩበት ቦታ የከተማ ወይስ የገጠር ቀበሌ ነው?)	የከተማ	0	RES
		የገጠር	1	
105	አሁን ባሉበት ቀበሌ ለምን ያህል ጊዜ ቆዩ?	**[ ] [ ] ዓመት** **[ ][ ] ወር**		RESDUR
106	የትምህርት ሁኔታ (የትምህርት ደረጃዎ ምንድን ነው?)	ምንም ያልተማሩ	1	EDU
		ማንበብና መፃፍ የሚችል ግን መደበኛ ትምህርት የሌለው (ለምሳሌ የቄስ ትምህርት፣ መሰረተ ትምህርት የተማረ)	2	
		መደበኛ ትምህርት ተከታትያለሁ	3	
107	መደበኛ ትምህርት ከተከታተሉ፡ እስከ ስንተኛ ክፍል ለምን ያህል አመታት ተምረዋል?	**[ ] [ ] ዓመት**		EDUYR
108	ስራ (ገቢ የሚያገኙበት ወይም ቀንዎን የሚያሳልፉበት ስራዎ ምንድንነው?)	ግብርና	1	EMP
		የግል ድርጅት ተቀጣሪ	2	
		የግል ስራ	3	
		በጎ ፈቃደኛ ስራ	4	
		የቤት እመቤት	5	
		ስራ አጥ	6	
		ተማሪ	7	
		ጡረተኛ	8	
		የመንግስት ሰራተኛ	9	

		የቀን/ የጉልበት ስራ	10	
		ሌላ [ይገለፅ]	77	
109	አሁን እየኖሩበት ያለው ቤተሰብ የገቢ (የኑሮ) ሁኔታ እንዴት ይገልፁታል?	በጣም ዝቅተኛ	1	REINC
		ዝቅተኛ	2	
		መካከለኛ	3	
		ከፍተኛ	4	
		በጣም ከፍተኛ	5	
110	የጋብቻ ሁኔታ (በአሁኑ ወቅት የትዳር ሁኔታዎ እንዴት ነው?) *[ምላሹ 1, 3 እና 4 ከሆነ ወደ ጥያቄ 113 ይለፉ]*	ያላገባ	1	MARIT
		ያገባ	2	
		በፍቺ የተለያየ	3	
		በሞት የተለየ	4	
		ያገባ ግን በስራ ወይም በሌላ ምክንያት አብሮ የማይኖር	5	
		ያለ ህጋዊ ጋብቻ አብሮ የሚኖር	6	
111	የባለቤትዎ ስራ (ገቢ የሚያገኙበት ወይም ቀናቸውን የሚያሳልፉበት ስራቸው ምንድን ነው?) *[ባለትዳር ለሆነ እና የትዳር ኢጋሩ/ሯ በህይወት ላለ ተጠያቂ ብቻ የሚጠየቅ]*	ግብርና	1	EMPSP
		የግል ድርጅት ተቀጣሪ	2	
		የግል ስራ	3	
		በጎ ፈቃደኛ ስራ	4	
		የቤት እመቤት	5	
		ስራ አጥ	6	
		ተማሪ	7	
		ጡረተኛ	8	
		የመንግስት ሰራተኛ	9	
		የቀን/ የጉልበት ስራ	10	
		ሌላ [ይገለፅ]	77	
112	የባለቤትዎ የትምህርት ሁኔታ (የትምህርት ደረጃቸው ምንድን ነው?)	ምንም ያልተማረ	1	SEDL
		ማንበብና መፃፍ የሚችል ግን መደበኛ ትምህርት የሌለው (ለምሳሌ የቄስ ትምህርት፣ መሰረተትምህርት የተማረ)	2	
		መደበኛ ትምህርት የተከታተለ	3	
113	ሀይማኖት (ሀይማኖትዎ ምንድን ነው?)	ኦርቶዶክስ ክርስቲያን	1	RELIG
		ሙስሊም	2	
		ፕሮቴስታንት	3	
		ሌላ ካለ ይገለጽ_____	4	
114	ብሔር (ብሔርዎ ምንድን ነው?)	ጉራጌ	1	ETHNIC
		ኦሮሞ	2	
		አማራ	3	
		ሌላ ካለ ይገለጽ_____	4	

115	የቤተሰብ መጠን (እርሶን ጨምሮ በቤትዎ ስንት ሰው ይኖራል?)	[ ] [ ]		
116	ነፍሰ-ጡር ነዎት? (ለሴት ተጠያቂ ብቻ)	አይ	0	PREG
		አዎን	1	
		አይመለከተኝም	66	
		አላውቅም	888	
117	ልጆች(የወለዱ እና የማደጎ ልጅን ጨምሮ) አለዎት? *[ምላሹ አይ ከሆነ ወደ ጥያቄ ዘ9 ይለፉ]*	አይ	0	KIDS
		አዎን	1	
118	ስንት ልጆች አለዎት?	[ ][ ]		KIDSNO
119	የመጨረሻው/ ትንሹ ልጅዎ እድሜው ስንት ነው?	[ ][ ] አመት		KIDYR
120	ለእርስዎ ቅርብ ወደሆነዉ የጤና ጣቢያ ለመድረስ ምን ያህል ደቂቃዎች ይጓዛሉ?	[ ][ ][ ] ደቂቃ		DFHC
	ህመሙ ከመጀመሩ በፊት የቤተሰቦ አስተዳዳሪ (አባወራ/እማወራ) ነበሩ?	አይ	0	
120	በአሁኑ ሰአት የቤተሰቦ አስተዳዳሪ(አባወራ/እማወራ) ነዎት?	አይ	1	HHOHC
		አዎን	1	

Appendix B1: Household Food Insecurity Access Scale HFIAS-9 (English version)

For each of the following questions, consider what has happened in the past 30 days. Please, answer whether this has happened never, rarely, sometimes or often in the past 30 days.

S.No.	Question	Response option			
		Never	Rarely	sometimes	often
1.	Did you worry that your household would not have enough food?	1	2	3	4
2.	Were you or any household member not able to eat the kinds of foods you preferred because of a lack of resources?	1	2	3	4
3.	Did you or any household member eat just a few kinds of food day after day due to a lack of resources?	1	2	3	4
4.	Did you or any household member eat food that you preferred not to eat because of lack of resources to obtain other types of food?	1	2	3	4
5.	Did you or any household member eat a smaller meal that you felt you needed because there was not enough food?	1	2	3	4
6.	Did you or any household member eat fewer meals in a day because there was not enough food?	1	2	3	4
7.	Was there ever no food at all in your household because there were not resources to get more?	1	2	3	4
8.	Did you or any household member go to sleep at night hungry because there was not enough food?	1	2	3	4
9.	Did you or any household member go a whole day without eating anything because there was not enough food?	1	2	3	4

Appendix B2: Household Food Insecurity Access Scale HFIAS-9 (Amharic version)

አሁን ደግሞ ስለራስዎና ስለቤተሰብ- የምግብ ዋስትና ሁኔታ (የአመጋገባችሁ ሁኔታ ማለትም መግኘት/አለመግኘቱን፡ **መጠኑን፡ ዓይነቱን፡ ሰዓቱን...ወ**^{2} ኮ) እጠይቆታለሁ፡፡

ለሚከተሉት ጥያቄዎች ያለፉ ሰላሳ ቀናትን ግምት ውስጥ ያስገቡ፡፡ እባክዎን ስለ ክስተቱ ¾ላም፤ በጣም አልፎ አልፎ፤ አልፎ አልፎ፤ ወይም ሁልጊዜ የሚሉትን አማራጮች በመምረጥ ይመልሱ፡፡					
ተ. ቁ	□ጸቁ	አማራጭ መልሶች			
		¾ላም	በ× ም አልፎ አልፎ	አልፎ አልፎ	ሁል□^{2}
1.	አንዳንድ ሰዎች ለቤተሰቤ በቂ ምግብ አይኖርም የሚል ስጋት አላቸው፤ እርስዎ ለቤተሰቤ በቂ ምግብ አይኖርም የሚል ስጋት ነበረብዎ?	1	2	3	4
2.	አንዳንድ ሰዎች የመረጡትን ምግብ ማግኘት ያቅታቸዋል፤ በአቅም • ኣጥረት ምክንያት • ኣርስ- ወ□ም ሌላ ¾ቤተሰብዎ አባል የመረጣችሁትን ምግብ ማ□ኘት አቅቷችሁ ነበር?	1	2	3	4
3.	አንዳንድ ሰዎች ጥቂት ተመሳሳይ ምግቦችን ብቻ በየቀኑ (በተ□ፉፉሚ) ለመመ□በ ÃÑÅÇ ሉ፤ በአቅም እጥረት ምክንያት እርስዎ ወ□ም ¾ቤተሰብዎ አባል ጥቂት ተመሳሳይ ምግቦችን ብቻ በየቀኑ (በተደጋጋሚ) ለመመገብ ተገዳችሁ ነበር?	1	2	3	4
4.	አንዳንድ ሰዎች የማይፈልጉትን ምግብ ለመመገብ የሚገደዱበት ሁኔታ አለ፤ በአቅም እጥረት ምክንያት እርስዎ ወ□ም የቤተሰብዎ አባል የማትፈልጉትን ምግብ ለመመገብ ተገዳችሁ ነበር?	1	2	3	4
5.	አንዳንድ ሰዎች በቂ ምግብ ባለመኖሩ ምክንያት መጠኑ ያነሰ ም□ብ ለመመ□ብ ÃÑÅÅ ሉ፤ በቂ ምግብ ባለመኖሩ ምክንያት እርስዎ ወ□ም ¾ቤተሰብዎ አባል መጠኑ ያነሰ ምግብ ለመመገብ ተ□ጸችሁ ነበር?	1	2	3	4
6.	አንዳንድ ሰዎች በቂ ምግብ ባለመኖሩ ምክንያት በቀን ውስጥ ጥቂት Ñ^2 ብቻ ለመመገብ ይገደዳሉ፤ በቂ ምግብ ባለመኖሩ ምክንያት እርስዎ ወይም የቤተሰብዎ አባል በቀን ውስጥ ጥቂት Ñ^2 ብቻ ለመመገብ ተገዳችሁ ነበር?	1	2	3	4
7.	በአንዳንድ ሰዎች ቤት ውስጥ ምንም ምግብ የማይኖርበት ወቅት አለ፤ በአቅም እጥረት ምክንያት በቤትዎ ውስጥ ምንም ምግብ ያልነበረበት ወቅት ነበር?	1	2	3	4
8.	አንዳንድ ሰዎች ምግብ ባለመኖሩ ምክንያት ምግብ ሳ□በሉ ማታ/ለሊት ወደ መኝታ ለመሄት ÃÑÅÇ ሉ፤ ምግብ ባለመኖሩ ምክንያት እርስዎ ወይም የቤተሰብዎ አባል ምግብ ሳትበሉ ማታ/ለሊት ወደ መኝታ ለመሄድ ተገዳችሁ ነበር?	1	2	3	4
9.	አንዳንድ ሰዎች በቂ ምግብ ባለመኖሩ ምክንያት ቀኑን ሙሉ ምንም ምግብ ሳይመገቡ ሲውሉ ይስተወላሉ፤ በቂ ም□ብ ባለመኖሩ ምክንያት እርስዎ ወይም የቤተሰብዎ አባል ቀኑን ሙሉ ምንም ምግብ ሳትመገቡ ውላችሁ ታውቃላችሁ?	1	2	3	4

Appendix C1: WHODAS 2.0 36-item version (English)

SECTION 1: DISABILITY (WHO DAS (DISABILITY ASSESSMENT SCHEDULE) 2.0 – 36 ITEM

Note to the interviewer: ONLY PATIENT RESPONSES SHOULD BE USED TO COMPLETE THIS INSTRUMENT

Note to the interviewer: Hand flashcard 1 to respondent and explain the following

The next few questions are about difficulties people have because of health conditions. By health condition I mean diseases or illnesses, other health problems that may be short or long lasting, injuries, mental or emotional problems and problems with alcohol or drugs.

I remind you to keep all of your health problems in mind as you answer the questions.

When I ask you about difficulties in doing an activity think about

- Increased effort
- Discomfort or pain
- Slowness
- Changes in the way you do the activity

Note to the interviewer: give the following extra information to the respondent

When answering, I'd like you to think back over the last 30 days. I also would like you to answer these questions thinking about how much difficulty you have, on average over the past 30 days, while doing the activity as you usually do it.

Hand flashcard #2 to interviewee and read scale aloud. Then give the following additional explanations to the respondent

Use the following scale when responding.

1. None 2. Mild 3. Moderate 4. Severe 5. Extreme or cannot do.

Note to the interviewer: Flashcards #1 and #2 should remain visible to the respondent throughout the interview

1. Cognition

I am going to ask you some questions about communication and thinking activities.

Use the above mentioned five scales for disability assessment when responding. These are

1. None 2. Mild 3. Moderate 4. Severe 5. Extreme or cannot do.

In the past 30 days, how much difficulty did you have in:			
101.1		None	1

	Concentrating on doing something for ten minutes?	Mild	2
		Moderate	3
		Severe	4
		Extreme or cannot do	5
101.2	Remembering to do important things?	None	1
		Mild	2
		Moderate	3
		Severe	4
		Extreme or cannot do	5
101.3	Analysing and finding solutions to problems in day-to-day life?	None	1
		Mild	2
		Moderate	3
		Severe	4
		Extreme or cannot do	5
101.4	Learning a new task, for example, learning how to get to a new place?	None	1
		Mild	2
		Moderate	3
		Severe	4
		Extreme or cannot do	5
101.5	Generally understanding what people say?	None	1
		Mild	2
		Moderate	3
		Severe	4
		Extreme or cannot do	5
101.6	Starting and maintaining a conversation?	None	1
		Mild	2

		Moderate	3
		Severe	4
		Extreme or cannot do	5

2. Mobility

Now am going to ask you problems associated with mobility

In the past 30 days, how much difficulty did you have in:			
102.1	Standing for long periods such as 30 minutes?	None	1
		Mild	2
		Moderate	3
		Severe	4
		Extreme or cannot do	5
102.2	Standing up from sitting down?	None	1
		Mild	2
		Moderate	3
		Severe	4
		Extreme or cannot do	5
102.3	Moving around inside your home?	None	1
		Mild	2
		Moderate	3
		Severe	4
		Extreme or cannot do	5
102.4	Getting out of your home?	None	1
		Mild	2
		Moderate	3
		Severe	4
		Extreme or cannot do	5

102.5	Walking a long distance such as a kilometre [or equivalent]?	None	1
		Mild	2
		Moderate	3
		Severe	4
		Extreme or cannot do	5

3. Self-care

   Now, I am going to ask you problems associated with self care

In the past 30 days, how much difficulty did you have in:			
103.1	Washing your whole body?	None	1
		Mild	2
		Moderate	3
		Severe	4
		Extreme or cannot do	5
103.2	Getting dressed?	None	1
		Mild	2
		Moderate	3
		Severe	4
		Extreme or cannot do	5
103.3	Eating?	None	1
		Mild	2
		Moderate	3
		Severe	4
		Extreme or cannot do	5
103.4	Staying by yourself for a few days?	None	1
		Mild	2
		Moderate	3

		Severe	4
		Extreme or cannot do	5

4. Getting along

Now I am going to ask you problems associated with getting along with other people. Remember that I am going to ask only difficulties that might be encountered with this due to a health condition. This means, diseases or illnesses, other health problems that may be short or long lasting, injuries, mental or emotional problems and problems with alcohol or drugs.

Show the respondent flash card #1 and #2 and read			
In the past 30 days, how much difficulty did you have in:			
104.1	Dealing with people you do not know?	None	1
		Mild	2
		Moderate	3
		Severe	4
		Extreme or cannot do	5
104.2	Maintaining a friendship?	None	1
		Mild	2
		Moderate	3
		Severe	4
		Extreme or cannot do	5
104.3	Getting along with people who are close to you?	None	1
		Mild	2
		Moderate	3
		Severe	4
		Extreme or cannot do	5
104.4	Making new friends?	None	1
		Mild	2

		Moderate	3
		Severe	4
		Extreme or cannot do	5
104.5	Sexual activities?	None	1
		Mild	2
		Moderate	3
		Severe	4
		Extreme or cannot do	5

5. Life activities

5(1). Taking care of your household responsibilities

The next questions are intended to elicit respondents' appraisal of any difficulty they encounter in maintaining the household and in caring for family members or other people they are close to. These activities are those that people do on most days; they include: cooking, cleaning, going to the market or shops and taking care of other people and protecting your property.

Show the respondent flash card #1 and #2 and read			
In the past 30 days, how much difficulty did you have in:			
105.1	Taking care of your household responsibilities?	None	1
		Mild	2
		Moderate	3
		Severe	4
		Extreme/cannot do	5
105.2	Doing most important household tasks well?	None	1
		Mild	2
		Moderate	3
		Severe	4
		Extreme/cannot do	5

105.3	Getting all the household work done that you needed to do?	None	1
		Mild	2
		Moderate	3
		Severe	4
		Extreme/cannot do	5
105.4	Getting your household work done as quickly as needed?	None	1
		Mild	2
		Moderate	3
		Severe	4
		Extreme/cannot do	5

If the respondents give above 'none' (greater than 1) for the level of difficulty within questions 105.1 – 105.4, ask the following. [→if all the responses are none, go to 5(2)]

105.01	In the past 30 days, for how many days were you totally unable to carry out your usual house work because of any health condition?	_____ days	

5(2) work/school

Now I am going to ask you about your work or school.

Show the respondent flash card #1 and #2 and read

In the past 30 days, how much difficulty did you have in:			
105.5	Your day-to-day work/school?	None	1
		Mild	2
		Moderate	3
		Severe	4
		Extreme or cannot do	5
105.6	Doing your most important work/school tasks well?	None	1
		Mild	2

		Moderate	3
		Severe	4
		Extreme or cannot do	5
105.7	Getting all the work done that you need to do?	None	1
		Mild	2
		Moderate	3
		Severe	4
		Extreme or cannot do	5
105.8	Getting your work done as quickly as needed?	None	1
		Mild	2
		Moderate	3
		Severe	4
		Extreme or cannot do	5

If the respondents give above 'none' (greater than 1) for the level of difficulty within questions 105.5 – 105.8, ask the following. [→if all the responses are none, go to 5(2)]			
105.02	In the past 30 days, for how many days did you miss work for half days or more than that becaue of any health condition?	_____days	

105.9	Did you obligated to work less than what you are expected or less than usual?	No	1
		Yes	2
105.10	Is you income decreased because of your illness?	No	1
		Yes	2

6. Participation

Now I am going to ask you about your participation in the community and the impact of your health condition on your and your families community life. Some of these problems might have stayed more than a month. However, when you give response to the following questions, please focus only on the past 30 days.

I remind you again to keep all of your health problems in mind as you answer the questions

In the past 30 days			
106.1		None	1

	How much of a problem did you have joining in community activities (for example, festivities, religious or other activities) in the same way anyone else can?	Mild	2
		Moderate	3
		Severe	4
		Extreme or cannot do	5
106.2	How much of a problem did you have because of barriers or hindrances in the world around you?	None	1
		Mild	2
		Moderate	3
		Severe	4
		Extreme or cannot do	5
106.3	How much of a problem did you have living with dignity because of the attitudes and actions of others?	None	1
		Mild	2
		Moderate	3
		Severe	4
		Extreme or cannot do	5
106.4	How much time did you spend on your health condition, or its consequences?	None	1
		Mild	2
		Moderate	3
		Severe	4
		Extreme or cannot do	5
106.5	How much have you been emotionally affected by your health condition?	None	1
		Mild	2
		Moderate	3
		Severe	4
		Extreme or cannot do	5
106.6	How much has your health been a drain on the financial resources of you or your family?	None	1
		Mild	2

		Moderate	3
		Severe	4
		Extreme or cannot do	5
106.7	How much of a problem did your family have because of your health problems?	None	1
		Mild	2
		Moderate	3
		Severe	4
		Extreme or cannot do	5
106.8	How much of a problem did you have in doing things by yourself for relaxation or pleasure?	None	1
		Mild	2
		Moderate	3
		Severe	4
		Extreme or cannot do	5

107.1	Overall, in the past 30 days, how many days were these difficulties present?	_____ days
107.2	In the past 30 days, for how many days were you totally unable to carry out your usual activities or work because of any health condition?	_____ days
107.3	In the past 30 days, not counting the days that you were totally unable, for how many days did you cut back or reduce your usual activities or work because of any health condition?	_____days

Appendix C2: WHODAS 2.0 36-item (Amharic V.)

የአለም ጤና ድርጅት የእክል መጠይቅ (WHODAS- 2.0)

መግቢያ

ለጠያቂ ማስታዎሻ፡ ካርድ ቁጥር አንድን ለተጠያቂ በመስጠት የሚከተለውን ማብራሪያ ስጥ ::

ይህ ቃለመጠይቅ ሰዎች በጤና እክል ምክንያት ስለሚኖራቸው ችግር ይሆናል። የጤና እክል ስል በሽታ ወይም ህመም፤ ሌሎች ለአጭር ወይም ለረጅም ጊዜ የሚቆዩ የጤና ችግሮች፤ ጉዳቶች፤ የአዕምሮ ወይም የመንፈስ መታወክ እንዲሁም ከመጠጥ እና ከዕጽ ጋር የተገናኙ ችግሮችን ይሆናል። ቃለመጠይቁ ውስጥ ያሉ ጥያቄዎችን ሲመልሱ ሁሉንም የጤና ችግርዎን እንዲያስቡ እፈልጋለሁ።

<u>ለጠያቂ ማስታወሻ</u>፡ ካርድ ቁጥር አንድን አመልክት ወይም ለተጠያቂው አንብብ እና የሚከተለውን ማብራሪያ ስጥ።

"አንድን ተግባር ለማከናወን መቸገር" ማለት

- ስራውን ለማከናወን ተጨማሪ ጥረት ሲያስፈልግ
- ስራውን ለማከናወን አለመመቸት ወይም የሕመም ስሜት ሲፈጥር
- ስራውን ለማከናውን ብዙ ጊዜ ሲፈጅ
- ስራውን ለማከናወን ቀድሞ ከሚሰሩበት ሌላ መንገድ ለመጠቀም ሲገደዱ ማለት ነው።

እንግዲህ አንድን ተግባር ለማከናወን ስለገጠመወት ችግር ስጠይቅዎት እነዚህን ሊያሰቡ መልስ ይስጡ።

<u>ለጠያቂ ማስተዋሻ፡</u> ለተጠያቂው የሚከተለውን ተጨማሪ ማብራሪያ ስጥ።

ጥያቄዎቹን ሲመልሱ ያለፈውን አንድ ወር እያስታወሱ ይሁን። እንዲሁም አነዚህን ጥያቄዎች ሲመልሱ በአማካይ ባለፈው እንድ ወር ብዙ ጊዜ የሚያከናውኑትን ስራ ለመፈፀም ምን ያህል ችግር ይገጥምዎት እንደነበር እያሰቡ ይሁን።

ካርድ ቁጥር ሁለትን ለመላሹ ስጥና ድምጽህን ከፍ አድርገህ መስፈርቶቹን አንብብላቸው። በመቀጠልም የሚከተለውን ተጨማሪ ማብራሪያ ስጥ።

ጥያቄዎቹን ሲመልሱ እነዚህን አምስት የችግር ወይም የእክል ደረጃዎች ይጠቀሙ።

1. ምንም ችግር የለም 2. አነስተኛ ችግር 3. መካከለኛ ችግር 4. ከፍተኛ ችግር
5. በጣም ከፍተኛ ችግር ወይም ፈፅሞ መስራት አለመቻል

<u>ለጠያቂ ማስታወሻ</u>፡ መጠይቁ እስኪጠናቀቅ ድረስ ካርድ ቁጥር አንድ እና ካርድ ቁጥር ሁለት ለመላሹ እንደሚታዩ መሆን አለባቸው።

<u>ለጠያቂ ማስታወሻ</u>፡ ለመላሹ ካርድ ቁጥር አንድንና ካርድ ቁጥር ሁለትን አሳይ።

1. ነገሮችን መረዳት

ነገሮችን ስለመረዳትና ከሰዎች ጋር ያለዎትን መግባባት በተመለከተ አንዳንድ ጥያቄዎች አቀርብለዎታለሁ፡፡ ጥያቄዎቹን ሲመልሱ ከላይ የጠቀስኩልዎትን አምስቱን የችግር ወይም የእክል ደረጃዎች ይጠቀሙ፡፡ እነዚህም

1. ምንም ችግር የለም 2. አነስተኛ ችግር 3. መካከለኛ ችግር 4. ከፍተኛ ችግር
5. በጣም ከፍተኛ ችግር ወይም ፈፅሞ መስራት አለመቻል

	ባለፈው አንድ ወር ጊዜ ውስጥ	ምንም	አነስተኛ	መካከለኛ	ከፍተኛ	በጣም ከፍተኛ
D1.1	በሚሰሩት ስራ ላይ **ለጥቂት ጊዜ (ለ10 ደቂቃ) ያህል ትኩረት ማድረግ** ምን ያህል ይቸግርዎት ነበር?	1	2	3	4	5
D1.2	**ማድረግ የሚፈልጓቸውን ነገሮች አስታውሰው ለማድረግ** ምን ያህል ይቸግርዎት ነበር?	1	2	3	4	5
D1.3	**በእለት ተእለት ሕይወትዎ ውስጥ የሚገጥምዎትን ችግሮች መንስኤ ለመለየትና መፍትሄ ለመፈለግ** ምን ያህል ይቸግርዎት ነበር?	1	2	3	4	5
D1.4	**አዲስ ነገር ወይም ስራ ለመማር** ምን ያህል ይቸግርዎት ነበር? (ለምሳሌ፡ የእርሻ ስራ፤ ባልትና፤ የእጅ ስራ ወዘተ...)	1	2	3	4	5
D1.5	**በአጠቃላይ ሰዎች የሚሉትን ለመረዳት** ምን ያህል ይቸግርዎት ነበር?	1	2	3	4	5
D1.6	**ከሰዎች ጋር ንግግር ለመጀመርና እስከመጨረሻው ለመቆየት** ምን ያህል ይቸግርዎት ነበር?	1	2	3	4	5

2. እንቅስቃሴ

ለመላሹ ካርድ ቁጥር አንድንና ካርድ ቁጥር ሁለትን አሳይ፡፡

አሁን ደግሞ **ከእንቅስቃሴ ጋር የተያያዙ** ችግሮችን እጠይቅዎጣለሁ፡፡

	ባለፈው አንድ ወር ጊዜ ውስጥ	ምንም	አነስተኛ	መካከለኛ	ከፍተኛ	በጣም ከፍተኛ
D2.1	ረዘም ላለ ጊዜ **ቆሞ መቆየት** ምን ያህል ይቸግርዎት ነበር? (ለምሳሌ፡ ለግማሽ ሰዓት)	1	2	3	4	5
D2.2	**ከተቀመጡበት ለመነሳት** ምን ያህል ይቸግርዎት ነበር?	1	2	3	4	5
D2.3	**እቤትዎ ውስጥ መዘዋወር** ምን ያህል ይቸግርዎት ነበር	1	2	3	4	5
D2.4	**ከቤትዎ ለመውጣት** ምን ያህል ይቸግርዎት ነበር?	1	2	3	4	5
D2.5	**የተወሰነ ርቀት መንገድ ለመጓዝ** ምን ያህል ይቸግርዎት ነበር? (ለምሳሌ፡ የሩብ ሰዓት መንገድ ወይም አንድ ኪሎ ሜትር)	1	2	3	4	5

3. <u>እራስን መንከባከብ ወይም መጠበቅ</u>

አሁን እራስዎትን በመንከባከብ ረገድ የሚገጥምዎትን ችግር የተመለከቱ ጥያቄዎች እጠይቅዎታለሁ፡፡

	ባለፈው አንድ ወር ጊዜ ውስጥ	ምንም	አነስተኛ	መካከለኛ	ከፍተኛ	በጣም ከፍተኛ
D3.1	<u>**ሰውነትዎን መታጠብ**</u> ምን ያህል ይቸግርዎት ነበር?	1	2	3	4	5
D3.2	<u>**ልብስዎትን ለመልበስ**</u> ምን ያህል ይቸግርዎት ነበር?	1	2	3	4	5
D3.3	<u>**ምግብ ለመመገብ**</u> ምን ያህል ይቸግርዎት ነበር	1	2	3	4	5
D3.4	ያለሰው ብቻዎትን ለተወሰኑ ቀናት መቆየት ሲኖርብዎት <u>**ብቻዎትን መቆየት**</u> ምን ያህል ይቸግርዎት ነበር?	1	2	3	4	5

4. <u>ከሰዎች ጋር መግባባት</u>

አሁን ከሰዎች ጋር መግባባትን በተመለከተ ያለበዎትን ችግር እጠይቅዎታለሁ፡፡ ያስታውሱ በጤና መታወክ ምክንያት የተፈጠሩ ችግሮችን ብቻ ነው የምጠይቅዎት፡፡ ይህም ማለት በሽታ ወይም ሕመም፤ ሌሎች ለአጭር ወይም ለረዥም ጊዜ የሚቆዩ የጤና ችግሮች፤ ጉዳቶች፤ የአዕምሮ ወይም የመንፈስ መታወክ እንዲሁም ከመጠጥና ከእፅ ጋር የተገናኙ ችግሮችን ይሆናል፡፡

	ባለፈው አንድ ወር ጊዜ ውስጥ	ምንም	አነስተኛ	መካከለኛ	ከፍተኛ	በጣም ከፍተኛ
D4.1	<u>**ከዚህ በፊት ከማያውቋቸው ሰዎች ጋር ለመጀመሪያ ጊዜ ለመግባባት**</u> ምን ያህል ይቸግርዎት ነበር?	1	2	3	4	5
D4.2	ከአንድ ሰው ጋር <u>**በጓደኝነት ለብዙ ጊዜ መቆየት**</u> ምን ያህል ይቸግርዎት ነበር?	1	2	3	4	5
D4.3	ከቤተሰቦችዎ፤ ከዘመዶችዎ እና ከቅርብ ጓደኞችዎ ጋር <u>**ተግባብቶ መኖር**</u> ምን ያህል ይቸግርዎት ነበር?	1	2	3	4	5
D4.4	<u>**አዲስ ጓደኝነት መጀመር**</u> ምን ያህል ይቸግርዎት ነበር?	1	2	3	4	5
D4.5	<u>**ከተቃራኒ ፆታ ጋር የፍቅር ግንኙነት ማድረግ**</u> ምን ያህል ይቸግርዎት ነበር?					

5. <u>የኑሮ እንቅስቃሴ</u>

5(1) <u>የቤት ውስጥ ስራዎች</u>

የሚከተሉት ጥያቄዎች እቤትዎ ውስጥ ስለሚያደርጉት እንቅስቃሴ እንዲሁም አብሮዎት የሚኖሩ ወይም ለርስዎ ቅርብ የሆኑ ሰዎችን ስለመንከባከብ ይሆናል፡፡ስራዎቹ ምግብ ማብሰል፤ ፅዳት፤ ሱቅ ወይም ገበያ መሄድ እንዲሁም ሌሎች ሰዎችን መንከባከብ እና ንብረትዎን መጠበቅ ናቸው፡፡

ካርድ ቁጥር አንድንና ካርድ ቁጥር ሁለትን አሳይ/አንብብ፡፡

	ባለፈው አንድ ወር ጊዜ ውስጥ	ምንም	አነስተኛ	መካከለኛ	ከፍተኛ	በጣም ከፍተኛ
D5.1	**<u>የቤትና የግቢ ውስጥ ስራዎችንና ሌሎች ኃላፊነቶችን</u>** **<u>መወጣት</u>** ምን ያህል ይቸግርዎት ነበር?	1	2	3	4	5
D5.2	በጣም አስፈላጊ የሚሏቸውን የቤትና የግቢ ውስጥ ስራዎች **<u>በጥሩ ሁኔታ</u>** መስራት ምን ያህል ይቸግርዎት ነበር?	1	2	3	4	5
D5.3	መስራት ያለብዎትን የቤትና የግቢ ውስጥ ስራዎች **<u>ሁሉንም</u>** ሰርቶ ለመጨረስ ምን ያህል ይቸግርዎት ነበር?	1	2	3	4	5
D5.4	የቤትና የግቢ ውስጥ ስራዎችን **<u>በሚፈልጉት ፍጥነት</u>** ለመስራት ምን ያህል ይቸግርዎት ነበር?	1	2	3	4	5

ከጥያቄ D5.1-D5.4 ውስጥ የቸግሩ ደረጃ ከምንም በላይ (ከ1 በላይ) ምላሽ የተሰጠበት ካለ የሚከተለውን ጠይቅ፡፡

D5.01	በባለፈው አንድ ወር ጊዜ ውስጥ በጤናዎ ችግር (በሕመምዎ) የተነሳ ለስንት ቀናት **<u>የቤት ውስጥ ስራዎችን</u>** መስራት ቀነሱ ወይም ሙሉ በሙሉ ሳይሰሩ ቀሩ?	የቀናት ብዛት ይመዝገብ ---------- ቀናት

መላሹ ሰራተኛ (በክፍያ፤ በነፃ፤ በግል የሚሰራ ከሆነ) ወይም ተማሪ ከሆነ ከD5.5-D5.10 ያለውን ሙላ፡፡ ካልሆነ ግን ወደ D6.1 እለፍ፡፡

5(2) <u>ስራ ወይም ትምህርት</u>

አሁን ደግሞ ስለስራዎ ወይም ስለትምህርትዎ ሁኔታ እጠይቅዎታለሁ፡፡

ካርድ ቁጥር አንድንና ካርድ ቁጥር ሁለትን አሳይ/አንብብ፡፡

	ባለፈው አንድ ወር ጊዜ ውስጥ	ምንም	አነስተኛ	መካከለኛ	ከፍተኛ	በጣም ከፍተኛ
D5.5	የእለት ተዕለት **<u>ስራዎትን ወይም ትምህርትዎትን</u>** ለማከናወን ምን ያህል ይቸግርዎት ነበር?	1	2	3	4	5
D5.6	በጣም አስፈላጊ የሚሉትን ስራ ወይም ትምህርት **<u>በጥሩ ሁኔታ</u>** መስራት ምን ያህል ይቸግርዎት ነበር?	1	2	3	4	5

D5.7	መስራት ያለብዎትን ስራ ወይም ትምህርት **<u>ሁሉንም ሰርቶ ለመጨረስ</u>** ምን ያህል ይቸግርዎት ነበር?	1	2	3	4	5
D5.8	ስራዎትን ወይም ትምህርትዎትን **<u>በሚፈልጉት ፍጥነት</u>** ለመስራት ምን ያህል ይቸግርዎት ነበር?	1	2	3	4	5
D5.9	በሕመምዎ ምክንያት ከሚጠበቅብዎ ወይም በፊት ይሰሩት ከነበረው ባነሰ መልኩ እንዲሰሩ ተገደዋል?				የለም	1
					አዎን	2
D5.10	በሕመምዎ ምክንያት ገቢዎ ቀንሷል?				የለም	1
					አዎን	2

ከጥያቄ D5.5-D5.8 ውስጥ የቸግሩ ደረጃ ከምንም በላይ (ከ በላይ) ምላሽ የተሰጠበት ካለ የሚከተለውን ጠይቅ፡፡

D5.02	በባለፈው አንድ ወር ጊዜ ውስጥ በጤናዎ ችግር (በሕመምዎ) የተነሳ **<u>ለግማሽ ቀን ወይም ከዚያ በላይ ስራ ሳይሰሩ የቀሩት</u>** ለምን ያል ቀናት ነበር?	የቀናት ብዛት ይመዝገብ ---------- ቀናት

6. ማሕበራዊ ተሳትፎ

አሁን በሚኖሩበት ማሕበረሰብ ውስጥ ስላለዎት ተሳትፎ እንዲሁም የጤና ችግርዎ (ሕመምዎ) በራስዎና በቤተሰብዎ ላይ ስላስከተለው ችግር አጠይቅዎታለሁ፡፡ አንዳንዶቹ ችግሮች ከአንድ ወር በላይ የቆዩ ሊሆኑ ይችላሉ፡፡ ሆኖም ግን የሚከተሉትን ጥያቄዎች ሲመልሱ እባክዎ ባለፈው አንድ ወር ጊዜ ውስጥ ስለነበረው ብቻ ያተኩሩ፡፡ እነዚህን ጥያቄዎች ሲመልሱ ስለጤናዎ ችግር (ስለሕመምዎ) እያሰቡ እንዲሆን በድጋሚ አሳስብዎታለሁ፡፡

ካርድ ቁጥር አንድንና ካርድ ቁጥር ሁለትን አሳይ/አንብብ፡፡

	ባለፈው አንድ ወር ጊዜ ውስጥ	ምንም	አነስተኛ	መካከለኛ	ከፍተኛ	በጣም ከፍተኛ
D6.1	**<u>በማሕበራዊ እንቅስቃሴ ውስጥ</u>** (ለምሳሌ፡ አመት በዓል፤ ድግስ፤ ለቅሶ፤ እድር፤ ሊቃ ወዘተ...) ልከ እንደሌላው ሰው መሳተፍ ምን ያህል ይቸግርዎት ነበር?	1	2	3	4	5
D6.2	እንደ አድሎና መገለል እና ሌሎችም በአካባቢዎ ባሉ **<u>መሰናክሎችና ምቹ ያልሆኑ ሁኔታዎች</u>** ምክንያት ምን ያህል ችግር ገጠመዎት?	1	2	3	4	5
D6.3	ሰዎች ለእርስዎ ባላቸው መጥፎ አመለካካትና ተገቢ ያልሆኑ ድርጊቶች የተነሳ **<u>በሰው ተከብረው</u>** ለመኖር ምን ያህል ተቸገሩ?	1	2	3	4	5

D6.4	ለሕመምዎ መፍትሄ ለማግኘት፤ ጠያቂ ለማነጋገር፤ ስለሕመምዎ ለሌሎች ለማስረዳት **ምን ያህል ጊዜ አጥፍተዋል**?	1	2	3	4	5
D6.5	በጤና ችግርዎ ወይም በሕመምዎ ምክንያት **ስሜትዎ ምን ያህል ተረብሿ**?	1	2	3	4	5
D6.6	የጤና ችግርዎ ወይም ሕመምዎ የእርስዎንና የቤተሰብዎን **ህብትና ንብረት ምን ያህል አራቆተ**?	1	2	3	4	5
D6.7	በእርስዎ የጤና ችግር ወይም በሕመምዎ ምክንያት **ቤተሰብዎ** ምን ያህል ተቸግሯል?	1	2	3	4	5
D6.8	**የሚያዝናናዎትን ወይም የሚያስደስትዎትን ነገር** ያለ ሌላ ሰው ድጋፍ ለማድረግ ምን ያህል ይከብድዎታል?	1	2	3	4	5

H1	በአጠቃላይ ባለፈው አንድ ወር ጊዜ ውስጥ እነዚህ ችግሮች **ለምን ያህል ቀናት ነበሩ**?	የቀናት ብዛት ይመዝገብ ---------- ቀናት
H2	በባለፈው አንድ ወር ጊዜ ውስጥ በማንኛውም የጤና ችግር ምክንያት የተለመደ ስራዎትን ወይም እንቅስቃሴዎትን **ሙሉ በሙሉ ማድረግ ያልቻሉት** ለምን ያህል ቀናት ነበር?	የቀናት ብዛት ይመዝገብ ---------- ቀናት
H3	በባለፈው አንድ ወር ጊዜ ውስጥ በማንኛውም የጤና ችግር ምክንያት (ሙሉ በሙሉ ምንም ስራ መስራት ያልቻሉበትን ሳይጨምር) የተለመደ ስራዎትን ወይም እንቅስቃሴዎትን **ለመቀነስ** የተገደዱባቸው ምን ያህል ቀናት ነበሩ?	የቀናት ብዛት ይመዝገብ ---------- ቀናት

ስለተጠያቂው ተጨማሪ አስተያየት

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ቃለ-መጠይቁ በዚህ ያበቃል። ለተሳትፎዎ በጣም አመሰግናለሁ።

ካርድ ቁጥር አንድ

የጤና ችግሮች

- በሽታ፤ ሕመም ወይም ሌላ የጤና ችግር
- ጉዳቶች
- የአዕምሮ ወይም የመንፈስ መታወክ
- ከመጠጥ (አልኮል) ጋር የተገናኙ ችግሮች
- ከእፅ ጋር የተያያዙ ችግሮች

አንድን ተግባር ለማከናወን መቸገር ማለት

- ስራውን ለማከናወን ተጨማሪ ጥረት ሲያስፈልግ
- ስራውን ለማከናወን አለመመቸት ወይም የሕመም ስሜት ሲፈጥር
- ስራውን ለማከናወን ብዙ ጊዜ ሲፈጅ
- ስራውን ለማከናወን ቀድሞ ከሚሰሩበት ሌላ መንገድ ለመጠቀም ሲገደዱ ማለት ነው።።

ካርድ ቁጥር ሁለት

5 -- በጣም ከፍተኛ

4 -- ከፍተኛ

3 -- መካከለኛ

2 -- አነስተኛ

1 -- ምንም

Appendix D1: Longitudinal Interval Follow-Up Evaluation-Range of Impaired Functioning Tool (LIFE-RIFT)

THE LIFE-RIFT

Work

(1 a) Employment: _____

Which of the following categories best characterizes the degree to which the patient's current (past week) work activities have been impaired as a result of psychopathology?

0 = Not applicable. Did not work during the past week, for reasons other than psychopathology.

1 = No impairment - high level. Worked as much as someone in his social situation would be expected to work, and worked at a high level.

2 = No impairment - satisfactory level. Worked as much as someone in his social situation would be expected to work, and worked at a satisfactory level.

3 = Mild impairment. Worked somewhat less than someone in his social situation would be expected to work and/or had mild difficulties in carrying out work activities.

4 = Moderate impairment. Has missed a lot of work and/or has had considerable difficulties in carrying out work activities.

5 = Severe impairment. Has missed a great deal of work when someone in his social situation would have been expected to work and/or has been virtually unable to carry out his work activities when he did work.

6 = No information.

*1 b) Household:*_____

Which of the following categories best characterizes the degree to which the patient's current (past week)
household work has been impaired as a result of psychopathology?

0 = Not applicable. Did not carry out household duties during the past week for reasons other than psychopathology.

1 = No impairment - high level. Has carried out housework most of the time that would be expected, and worked at a high level.

2 = No impairment - satisfactory level. Has carried out housework most of the time that would be expected, and worked at a satisfactory level.

3 = Mild impairment. Worked somewhat less than expected and/or had mild difficulties in carrying out housework.

4 = Moderate impairment. Has missed a lot of housework when expected and/or has had considerable difficulties in carrying out house work.

5 = Severe impairment. Has missed a great deal of housework when expected to work and/or has been virtually unable to carry out housework when he attempts it.

6 = No information.

(1 c) Student: _____

Which of the following categories best characterizes the degree to which the patient's current school work has been impaired as a result of psychopathology?

0 = Not applicable. Because not currently enrolled in a student program for reasons other than psychopathology.

1 = No impairment - high level. Worked as much as would be expected if not symptomatic and got high grades.

2 = No impairment - satisfactory level. Worked as much as would be expected if not symptomatic and got satisfactory grades.

3 = Mild impairment. Worked somewhat less and/or got grades somewhat below expected if not symptomatic.

4 = Moderate impairment. Missed a lot of school work and/or got grades consistently below expected.

5 = Severe impairment. Missed most of school work and/or dropped out of school or got grades far below those expected.

6 = No information.

(1) Work (maximum of 1 a, 1 band 1 c): _____

Interpersonal relations

Which of the following best characterizes the patient's level of interpersonal relationships with his family currently (past month)? [Provide separate ratings for spouse (2a), children (2b), neighbours (2c), families (2d), brothers and sisters (2e) and other relatives (2f).]

(2a) Interpersonal relations with spouse: _____

(2b) Interpersonal relations with children: _____

(2c) Interpersonal relations with neighbours: _____

(2d) Interpersonal relations with families: _____

(2e) Interpersonal relations with brothers and sisters: _____

(2f) Interpersonal relations with other relatives: _____

0 = Not applicable because does not have relatives in this category.

1 = Very good. Experiences very good relationships with this/these family member(s), with only transient friction which is rapidly resolved. Feels only very minor or occasional need to improve quality of relationship, which is usually close and satisfying.

2 = Good. Argues occasionally, but arguments usually resolve satisfactorily within a short time. May occasionally prefer not to be with them because of dissatisfaction with them or be actively working with them to improve relationship.

3 = Fair. Often argues with this (these) family member(s) and takes a long time to resolve arguments. May withdraw from this person (these people) due to dissatisfaction. Often thinks that relationship needs to be either more harmonious or closer emotionally even when no conflict is present. For those relatives not living with the subject, contacts with them by choice are less frequent than feasible or rarely enjoyed very much when made.

4 = Poor. Regularly argues with this (these) family member(s) and such arguments are rarely ever resolved satisfactorily. Regularly prefers to avoid contact with them and/or

feels great deficit in emotional closeness. For those family members out of the household, subject avoids seeing them as much as possible and derives no pleasure from contact when made.

5 = Very poor. Either constantly argues with this (these) family member(s) or withdraws from them most of the time. Separated or divorced from spouse or children moved out of household or almost always hostile to them when in contact.

6 = Variable. Different levels for various members of this group, and would warrant a rating of good or better (2, 1) with at least 1 member of this group. (Rate as 2.)

7 = Variable. Different levels for various members of this group, and would not warrant a rating of good or better (2, 1) with any member of this group. (Rate as 4.)

8 = No information.

(2g) Interpersonal relations with friends: _____

Which of the following best characterizes the patient's interpersonal relationships with friends currently (past month)?

1 = Very good. Had several special friends that he saw regularly and frequently and was close to.

2 = Good. Had at least two special friends that he saw from time to time and was fairly close to.

3 = Fair. Had only one special friend that he saw from time to time and was fairly close to; or contacts limited to several friends that he was not very close to emotionally.

4 = Poor. Had no special friends he saw from time to time and was fairly close to; or contacts limited to one or two friends that he was not very close to.

5 = Very poor. Had no special friends and practically no social contacts.

6 = No information.

(2) Interpersonal relations (maximum of 2a, 2b, 2c, 2d, 2e, 2f and 2g): _____

Satisfaction

(3) *Satisfaction:* _____

Which of the following best characterizes the patient's overall level of satisfaction (contentment, degree to which he feels fulfilled, gratification derived from activities) for the past week.

1 = Very good. Transient problems may occur, but generally satisfied with all aspects of his life. Occasional minor dissatisfaction in one area, but overall is quite content with himself, job, family, friends, activities, and finances.

2 = Good. Mild dissatisfaction persists, but only in one area or is intermittent in several areas. In balance, is generally content and able to enjoy life most of the time, but does think there should be some improvement in either occupational role, interpersonal relations, sexual activities, or finances.

3 = Fair. Moderate dissatisfaction in one or more areas, which is relatively persistent.

Either discontent with occupational role, interpersonal relations, sexual activities, or finances.

4 = Poor. Very dissatisfied in most areas and derives little pleasure from life. Rarely able to derive any satisfaction from activities or relationships.

5 = Very poor. Derives no satisfaction from anything. May feel no desire to carry out the smallest task or to be with other people.

6 = No information.

Recreation

(4) Recreation: _____

At what level has the patient been involved in and able to enjoy recreational activities and hobbies (reading, spectator or participant sports, gardening, music, sewing, attending parties or gatherings, church or community organizations) in the past week

1 = Very good. Has at least two activities which he enjoys fully and frequently.

2 = Good. Participates in several activities and does not always enjoy them fully; or participates in fewer activities or less frequently than optimal, but enjoys participation.

3 = Fair. Occasional participation in recreational activities or hobbies; or limited enjoyment when participation occurs.

4 = Poor. Some participation in recreational activities or hobbies and derives very little enjoyment from such activities.

5 = Very poor. No involvement in recreational activities or hobbies.

6 = No information.

THE LIFE-RIFT SUMMARY

(1) Work (maximum of 1a, 1 band 1c): _____

(2) Interpersonal relations (maximum of 2 a, 2 b, 2c, 2d, 2e, 2f and 2g):

_____

(3) Satisfaction: _____

(4) Recreation: _____

Total score (sum of 1, 2, 3 and 4): _____

Appendix D2: LIFE-RIFT (Amharic Version)

ነ. ስራን በተመለከተ

(ነ ሀ) ቅጥር

ከሚከተሉት ክፍፍሎች የታማሚው <u>የአሁን (ባለፈው ሳምንት)</u> የስራ እንቅስቃሴ በስነ-ልቦና/ስነ-አዕምሮ መታወክ [psychopathology] ምክንያት ምን ያህል እንደተዛባ የትኛው በደንብ ይገልጻል?

0= አይመለከተውም፡፡ ከስነ-ልቦና/ስነ-አዕምሮ መታወክ ጋር ባይያያዝም ባለፈው ሳምንት ስራ አልሰራውም፡፡

ነ= ጉድለት የለም— በከፍተኛ ደረጃ፡፡ በአካባቢው ማህበረሰብ ውስጥ ያለው ሰው እንዲሰራ የሚጠበቅበትን ያህል/እኩል ሰርቷል፤ እናም በከፍተኛ ደረጃ ሰርቷል፡፡

2= ጉድለት የለም፡፡ በአጥጋቢ መጠን፡፡ በአካባቢው ማህበረሰብ ውስጥ ያለው ሰው እንዲሰራ የሚጠበቅበትን ያህል/እኩል ሰርቷል፤ እናም በአጥጋቢ ደረጃ ሰርቷል፡፡

3= መለስተኛ ጉድለት፡፡ በአካባቢው ማህበረሰብ ውስጥ ያለው ሰው እንዲሰራ ከሚጠበቅበት ባነሰ መጠን ሰርቷል ወይም ነገሮችን በመለስተኛ ደረጃ መከወን አልቻለም ነበር፡፡

4= መካከለኛ ጉድለት፡፡ ብዙ ስራዎች አምልጠውታል ወይም ከፍ ያለ መስራት አለመቻል ነበረበት፡፡

5= የከፋ ጉድለት፡፡ በአካባቢው ማህበረሰብ ውስጥ ያለው ሰው ይሰራል ተብሎ የሚጠበቅበትን በጣም በርካታ ስራዎች አምልጠውታል እና/ወይም ስራዎችን ሲሰራ በቃ አልቻለም፡፡

6= መረጃ የለም፡፡

(ነ ለ) የቤት ውስጥ ስራ

ከሚከተሉት ክፍፍሎች የታማሚው <u>የአሁን (ባለፈው ሳምንት)</u> የቤት ውስጥ ስራ በስነ-ልቦና/ስነ-አዕምሮ መታወክ ምክንያት ምን ያህል እንደተዛባ ዬትኛው በደንብ ይገልጻል?

0= አይመለከተውም፡፡ በስነ-ልቦና መታወክ ጋር ባልተያያዘ ምክንያት ባለፈው ሳምንት የቤት ውስጥ ስራዎችን አላከናወናቸውም፡፡

ነ= ጉድለት የለም— በከፍተኛደረጃ፡፡ ብዙውን ጊዜ የሚጠበቅበትን የቤት ውስጥ ስራዎች አከናውኗል፤ እናም በከፍተኛ ደረጃ ሰርቷል፡፡

2= ጉድለት የለም— በበቂ ደረጃ፡፡ ብዙውን ጊዜ የሚጠበቅበትን የቤት ውስጥ ስራዎች አከናውኗል፤ እናም በበቂ ደረጃ ሰርቷል፡፡

3= መለስተኛ ጉድለት፡፡ ከሚጠበቅበት ያነሰ ሰራ እና/ወይም መለስተኛ የሆኑ የቤት ውስጥ ስራዎችን መስራት አለመቻል ይታዩበት ነበረ፡፡

4= መካከለኛ ጉድለት፡፡ ብዙ የሚጠበቁበት የቤት ውስጥ ስራዎች አምልጠውታል እና/ወይም ደረጃው ከፍ ያለ የቤት ውስጥ ስራዎችን መስራት አለመቻል ይታዩበት ነበር፡፡

5= የከፋ ጉድለት፡፡ እጅግ በርካታ እንድሰራ የሚጠበቁበት የቤት ውስጥ ስራዎች አምልጠውታል እና/ወይም የቤት ውስጥ ስራዎችን ለመስራት ሲሞክር በቃ ምንም መስራት አልቻለም፡፡

6= መረጃ የለም፡፡

(ነ ሐ) ተማሪ

ከሚከተሉት ክፍፍሎች የታማሚው <u>የአሁን (ባለፈው ሳምንት)</u> የትምህርት ቤት-ተኮር ተግባራት በስነ-ልቦና/ስነ-አዕምሮ መታወክ ምክንያት ምን ያህል እንደተዛቡ ዬትኛው በደንብ ይገልጻል?

0= አይመለከተውም፡፡ ከስነ-ልቦና/ስነ-አዕምሮ መታወክ ጋር ባልተያያዘ ምክንያት አሁን ተማሪ ሆኖ የተመዘገበበት መርሃ-ግብር የለም፡፡

ነ= ጉድለት የለም— በከፍተኛ ደረጃ፡፡ የህመም ምልክት ባይታይበት ራሱ የሚጠበቅበትን ያህል ሰርቶ ከፍተኛ ውጤት አስመዝግቧል፡፡

2= ጉድለት የለም— በበቂ ደረጃ፡፡ የህመም ምልክት ባይታይበት ራሱ የሚጠበቅበትን ያህል ሰርቶ አጥጋቢ ውጤት አስመዝግቧል፡፡

3= መለስተኛ ጉድለት፡፡ የህመም ምልክት ባይታይበት ራሱ እንደው አነስ ባለ ደረጃ ሰርቷል እና/ወይም ከሚጠበቅበት ውጤት በታች አስመዝግቧል፡፡

4= መካከለኛ ጉድለት፡፡ በርካታ ትምህርት ቤት-ተኮር ተግባራት አምልጠውታል እና/ወይም በተከታታይ ከሚጠበቅበት ውጤት በታች አስመዝግቧል፡፡

5= የከፋ ጉድለት፡፡ አብዛኛዎቹ ትምህርት ቤት-ተኮር ተግባራት አምልጠውታል እና/ወይም ትምህርቱን አቋርጧል ወይም በጣም ከሚጠበቅበት ውጤት በታች አስመዝግቧል፡፡

6= መረጃ የለም፡፡

ስራ (የነ ሀ፤ ነለ እና ነሐ ከፍተኛ) ፡----------

2. ከሰዎች ጋር ያለው ግንኙነቶች/ መስተጋብሮች

ከዚህ በታች ከተዘረዘሩት አማራጮች ውስጥ የትኛው ታማሚው አሁን (ባለፈው ወር) ከቤተሰቦቹ ጋር ያለው ግንኙነቶችን በትክክል ይገልጻል? [ለትዳር አጋሩ 2ሀ ፤ ለልጆቹ (2ለ) ፣ ለጎረቤቶቹ (2ሐ) ፣ ከወላጆቹ ጋር ያለው መስተጋብር (2መ) ፣ ከወንድማማቾቹ/ እህትማማቾቹ (2ሠ) እና ሌሎች ዘመዶቹ (2ረ) ራሱን የቻለ ግምገማ ስጥ፡፡]

0= አይመለከተውም፡፡ መላሹ እዚህ ክፍል ስር ዘመዶች ስለሌለው፡፡

1= በጣም ጥሩ፡፡ በጣም ጥሩ የሆነ መስተጋብር ከዚህ/ከነዚህ የቤተሰብ አባል/አባላት ጋር አለው፤ ወድያውኑ ከሚፈቱ ጊዜያዊ አለመግባባቶች በስተቀር፡፡ የመስተጋብሩን ጥራት ለማሻሻል በጣም መለስተኛ/አነስተኛ ፍላጎት ያሳያል፤ ይህም በአመዛኙ የጠበቀና አጥጋቢ ነው፡፡

2= ጥሩ፡፡ አንዳንዴ ከርከር ይገጥማል፤ ከርከሮቹ ግን በአጭር ጊዜ ውስጥ መፍትሄ ያገኛሉ፡፡ በእነሱ ስለማይረካ አንዳንዴም ከእነሱ ጋር አለመሆንን ልመርጥ ይችላል ወይም መስተጋብሩን ለማሻሻል አብሮ በደንብ መስራትን አንዳንዴም ላይመርጥ ይችላል፡፡

3= ደህና፡፡ በተደጋገሚ ከዚህ (ከነዚህ) የቤተሰብ አባል (አባላት) ጋር በመከራከር መፍትሄ ለማግኘት ረዥም ሰዓት ይወስዳል፡፡ባለመርካቱ ምክንያት ይህን ሰው/እነዚህን ሰዎች ሊተው ይችላል፡፡ ብዙውን ጊዜ መስተጋብር ግጭት በሌለበት ሁኔታ ራሱ ይበልጥ ሰላማዊ ወይም ጥብቅ ስሜት ያለው መሆን አለበት ብሎ ያስባል፡፡ ከእሱ ጋር የማይኖሩትን ዘመዶቹን ፈልጎ መገናኘት ከስንት አንዴ ያስደስተዋል እንጂ እምብዛም አይደለም፡፡

4= ደካማ፡፡ ብዙውን ጊዜ ከዚህ (ከነዚህ) የቤተሰብ አባል (አባላት) ጋር ይከራከራል፤ የዚህ ዓይነቱ ክርክር ደግም ከስንት አንዴ በበቂ ሁኔታ ይፈታል፡፡ ብዙውን ጊዜ ግንኙነቶችን መተው በመምረጥ በስሜት የመቅረብ ትልቅ ጎዶሎነት ይሰመዋል፡፡

5= በጣም ደካማ፡፡ ወይ ሁሌ ከዚህ (ከነዚህ) የቤተሰብ አባል (አባላት) ጋር ይከራከራል፤ ወይም ብዙውን ጊዜ ትቷቸው ይሄዳል፡፡ ከትዳር አጋሩ ተለያይቷል ወይም ተፋቷል፤ ወይም ልጆች ቤት ለቆ ወጥተዋል፤ ወይም ሁሌ ሲገናኙ የክፋት ስሜት ያንጸባርቅባቸዋል፡፡

6= ተለዋዋጭ፡፡ ለተለያዩ ለነዚህ ቡድን አባላት በተለያየ መጠን ሆኖ ቢያንስ ከአንድ ከነዚህ ቡድን አባል ጋር የተሻለ/ጥሩ ግምገማ (2 ፤ 1) ነው ተብሎ ዋጋ ይሰጠዋል (2ትን ሰጥተህ ገምግም) ፡፡

7= ተለዋዋጭ፡፡ ለተለያዩ ለነዚህ ቡድን አባላት በተለያየ መጠን ሆኖ ከማናቸውም ከነዚህ ቡድን አባል ጋር የተሻለ/ጥሩ ግምገማ (2 ፤ 1) ነው ተብሎ ዋጋ አያሰጥም (4ትን ሰጥተህ ገምግም) ፡፡

8= መረጃ የለም፡፡

(2ሀ) ከትዳር አጋሩ ጋር ያለው መስተጋብር: _____

(2ለ) ከልጆቹ ጋር ያለው መስተጋብር: _____

(2ሐ) ከጎረቤቶቹ ጋር ያለው መስተጋብር: _____

(2መ) ከወላጆቹ ጋር ያለው መስተጋብር: _____

(2ሠ) ከወንድማማቾቹ/እህትማማቾቹ ጋር ያለው መስተጋብር: _____

(2ረ) ከሌሎች ዘመዶቹ ጋር ያለው መስተጋብር: _____

(2 ሰ) ከጓደኞች ጋር ያለው ግንኙነቶች/መስተጋብሮች

ከሚከተሉት ክፍፍሎች የታማሚው አሁን (ባለፈው ወር) ከጓደኞቹ ጋር ያለው ግንኙነቶችን በትክክል ይገልጻል?

1= በጣም ጥሩ፡፡በየጊዜው የሚያገኛቸው በጣም የሚቀርባቸው በርካታ ቁምነገረኛ ጓደኞች ነበሩት፡፡

2= ጥሩ፡፡ ከቀን ወደ ቀን ሲያያቸው የነበሩ ቢያንስ ሁለት በመጠኑ የሚቀርባቸው ቁምነገረኛ ጓደኞች ነበሩት፡፡

3= ደህና፡፡ ከቀን ወደ ቀን ሲያየው የነበረና በመጠኑ የሚቀርበው አንድ ቁምነገረኛ ጓደኛ ብቻ ነበረው፤ ወይም ግንኙነቶቹ ብዙም በግለ-ስሜቱ የማይቀርባቸው ጓደኞች የተወሰነ ነበር፡፡

4= ደካማ፡፡ ከቀን ወደ ቀን ያየው በመጠኑ የሚቀርበው አንድም ቁምነገረኛ ጓደኛ አልነበረውም፤ ወይም ግንኙነቶቹ በጣም በግለ-ስሜቱ የማይቀርባቸው አንድ ወይም ሁለት ጓደኞች የተወሰነ ነበር፡፡

5= በጣም ደካማ፡፡ ቁምነገረኛ ጓደኞች አልነበረውም፤ ተጨባጭ የሆነ ማህበራዊ ግንኙነትም የለውም፡፡

6= መረጃ የለም፡፡

ከሰዎች ጋር ያለው ግንኙነቶች (የ 2ሀ፤2ለ፤2ሐ፣2መ፣ 2ሠ፣ 2ረ እና 2ሰ ከፍተኛ) ----------

3. እርካታ / ደስታ

ከሚከተሉት ዬትኛው የታማሚውን **የባለፈው ሳምንት** አጠቃላይ የእርካታ መጠን (በደስታ የመርካት ስሜት፤ የሙሉነት ስሜት፤ ከድርጊቶች የሚገኝ እርካታ) በትክክል ይገልጻል?

1= በጣም ጥሩ፡፡ ጊዜያዊ ችግሮች ይገጥሙ ይሆናል ባጠቃላይ ግን በሁሉም የህይወቱ ዘርፎች ረክቷል፡፡ አነስተኛ ወቅታዊ የሆነ አለመርካት በአንድ ዘርፍ ይኖራል፤ ግን ባጠቃላይ ከራሱ፤ ስራው፤ ቤተሰቡ፤ ጓደኞቹ፤ ተግባራቶቹና ገንዘብ ጋር በተያያዘ ፍጹም ደስተኛ ነው፡፡

2= ጥሩ፡፡ ቆይታ ያለው አነስተኛ የሆነ ያለመርካት ይኖራል፤ ግን በአንድ ዘርፍ ብቻ ወይም በብዙ ዘርፎች ቆይታ የሌለው ነው፡፡ ሲመዘን፤ ባጠቃላይ በደስታ ይረካል፤ በብዛት በሕይወቱ/ኑሮው ይረካል፤ ነገር ግን በሙያው፣ በሰዎች መስተጋብር፣ በወሲባዊ ድርጊቶቹ ወይም በገንዘብ የተወሰኑ መሻሻሎች መኖር እንዳለባቸው ያስባል፡፡

3= ደህና፡፡ አንጻራዊ ቆይታ ያለው በአንድ ወይም ከዚያ በላይ ዘርፎች መካከለኛ የሆነ ያለመርካት አለ፡፡ ወይ በሙያው፣ በሰዎች መስተጋብር፣ በወሲባዊ ድርጊቶቹ ወይም በገንዘብ ግን አለመደሰትና አለመርካት ይስተዋላል፡፡

4= ደካማ፡፡ በብዙ ዘርፎች በጣም አልረካም እናም ከኑሮው ትንሽ እርካታን ነው የሚያገኘው፡፡ ከስንት አንዴ ከተግባራትና መስተጋብሮች እርካታን ያገኛል፡፡

5= በጣም ደካማ፡፡ ከማንኛውም ነገር እርካታ አያገኝም፡፡ትንሿን ስራ ለመስራት ወይም ከሌላ ሰው ጋር ለመሆን የመፈለግ ስሜት ላያሳይ ይችላል፡፡

6= መረጃ የለም፡፡

4. መዝናናት

ታማሚው **ባለፈው ሳምንት** ምን ያህል በመዝናኛ ተግባራትና እርካታ-ሰጪ የትርፍ ጊዜ ተግባራት (ከሰው ጋ ሆኖ መጫወት ወይም ማውራት፣ መጠጥ ቤት/መሸታ ቤት፡ ጫት መቃም፡ ሙዚቃ፣ መስፋት፤፣ ሰዎች የተሰበሰቡበት ላይ መገኘት፣ ሰንበቴ፡ ማህበር፣ ከጎረቤት ጋ ቡና መጠጣት፡ ለሊቃ መሰብሰብ፣ እምነት ቦታ ወይም የህዝብ ማህበራትት ጋ መገኘት) መደሰት ቻለ?

1= በጣም ጥሩ፡፡ በየጊዜውና ሙሉ በሙሉ የሚደሰትባቸው ቢያንስ ሁለት ተግባራት አሉት፡፡

2= ጥሩ፡፡ በበርካታ ተግባራት ላይ ይሳተፋል ሁልጊዜ ግን ሙሉ በሙሉ የሚደሰትባቸው አይደሉም ወይም በጣት በሚቆጠሩ ተግባራት ወይም በመደበኛነት ሳያዘወትር በተሳትፎው ይደሰታል፡፡

3= ደህና፡፡ በመዝናኛ ተግባራትና እርካታ-ሰጪ የትርፍ ጊዜ ተግባራት ላይ በወቅታዊነት ተሳትፏል ወይም በተሳተፈ ጊዜም ውሱን ደስታን ያገኛል፡፡

4= ደካማ፡፡ በመዝናኛ ተግባራትና እርካታ-ሰጪ የትርፍ ጊዜ ተግባራት ላይ በጥቂቱ ተሳትፏል ወይም በተሳተፈ ጊዜም በጣም ጥቂት ደስታን ያገኛል፡፡

5= በጣም ደካማ፡፡ በመዝናኛ ተግባራትና እርካታ-ሰጪ የትርፍ ጊዜ ተግባራት ላይ አልተሳተፈም፡፡

6= መረጃ የለም፡፡

የ LIFE-RIFT ማጠቃለያ

(1) ስራ (የነ ሀ፤ ነለ እና ነሐ ከፍተኛ) ፡----------

(2) ከሰዎች ጋር ያለው ግንኙነቶች (የ 2ሀ፤2ለ፤2ሐ ፤2መ፤2ሠ፤2ረ እና 2ሰ ከፍተኛ) ----------

(3) እርካታ ፡----------

(4) መዝናናት ፡----------

Appendix E1. The Oslo 3-items social support scale)- English V.

Give a response which is correct about you			
1	How easy can you get practical help from neighbours if you should need it?	Very Difficult	1
		Difficult	2
		Possible though not easy	3
		Easy	4
		Very easy	5
2	How many people are so close to you that you can count on them if you have serious problems?	None	1
		1-2	2
		3-5	3
		5+	4
3	How much concern do people show in what you are doing?	No concern and interest	1
		Little concern and interest	2
		Uncertain	3
		Some concern and interest	4
		A lot of concern and interest	5

Appendix E2. The Oslo 3-items social support scale (Amharic V.)

ለእርሶ ሁኔታ ትክክለኛ የሆነውን መልስ ይስጡ			
1	ከጎረቤትዎቾ እርዳታ/ድጋፍ ቢያስፈልግዎ ማግኘት ምን ያህል ቀላል ነው?	በጣም አስቸጋሪ	1
		አስቸጋሪ	2
		ቀላልም ባይሆን የሚቻል	3
		ቀላል	4
		በጣም ቀላል	5
2	ከፍተኛ ችግር ቢያጋጥምዎ የቅርብ የሆኑ እና ይረዱኛል ብለው የሚተማመኑባቸው ምን ያህል ሰዎች ይኖራሉ?	ምንም	1
		1-2	2
		3-5	3
		5+	4
3	ሌሎች ሰዎች ስለ እርሶ ጉዳይ ምን ያህል ግድ ይላቸዋል ወይም ያስቡሎታል?	ምንም	1
		ትንሽ	2
		አላውቅም	3
		የተወሰነ	4
		በጣም	5

Appendix F. Medication treatment follow-up assessment form

HEALTH CENTER Name: _____

Category: Depression/Psychosis/Alcohol use disorders/Epilepsy : (underline the cohort in use)

Source of data: Patient Card/Treatment Sheet First Attendance Date: (EC) _____(GC) _____
Medication _____dose_____

Card No.	Patient Name	PRIME ID	Date of appointment	Date of attendance*	Medication (name & total daily dose)	Remark (e.g. date of missed appointment)
		PE				

*move from earliest to latest (begin with first date of attendance).

Compiled by: Name_____ Sig._____ Date_____

Appendix G. Disorder-specific mental health care plan-ethiopia

PSYCHOSES++

Level	Detection and diagnosis	Treatments*	Intervention/ Package**	Settings	Key Human Resources	Training and supervision	Roles
Health organisation	No direct role	No direct role	Educational and collaborative approaches	AHU, and higher level organisations	Bureau head, section heads, supervisors	Sensitisation workshops, involvement in major stepsof care plan development, six monthly meetings	Provide political support, support modification of the health information system to include key mental health indicators, provide supervision to the health facilities, negotiate with other political bodies (e.g., district administration).
General health care Facility (Clinical staff) Support and other staff	Clinical interview	Psychoeducation Antipsychotic medications Anticholinergic medications Community rehabilitation Monitoring	Conventional antipsychotics and psycho-educational intervention	Health centres	Nurses Health officers qualification between doctors and nurses)	Training: contextualised mhGAP-IG based 5-days training and 5-days on the job practical training (along with the other 3 conditions) Supervision: Standard supervision using existing structure; time-limited specialist supervision (psychiatric nurses)	Diagnosis, including excluding medical causes Prescribe medication Psychoeducation Referral Monitoring Education of service users Support lower level supervision Emergency management of agitated behaviour related to psychosis
	No direct role	Support Non-stigmatising environment	Create enabling environment Support health education	Health centres	Pharmacist Security and other support staff	Half a day sensitisation	Procurement of medication Support clinical staff Facilitate non-stigmatising care
Maternal health care	Clinical interview	Medication Psychoeducation Monitoring	Bio-medical Antipsychotics Anticholinergic	Health centres	Nurses Health officers qualification between doctors and nurses)	Training: contextualised mhGAP-IG based 5-days training and 5-days on the job	Assessment and diagnosis Psychoeducation Referral Prescribe medication

			Psychological Family and patient education			practical training (along with the other 3 conditions) <u>Supervision:</u> Standard supervision using existing structure; time-limited specialist supervision	Monitoring Education of general service users Support lower level supervision
Community1	Pro-active community case finding	Support psychosocial rehabilitation	Psycho-social rehab packages Detection and home-based care of SMD Psychosocial intervention package for SMD	Home visits and community meeting spaces	Health extension workers (community health workers - high school graduate with one-year training on health)	2 days training using HEAT material developed in Ethiopia in collaboration with OU, Weekly supervision by health centre nurse	Mental health assessments Detection and referral Psycho-education Livelihood counselling Family support Adherence management Establishing user self-help support groups
Community 2	Support community case finding	Support public awareness campaigns Support antistigma activities	Educational package	Community meeting spaces, workshops organised at the district for selected community members	Community health promoters Community volunteers Sub-district heads	Half a day training on mental health, disorders and care	Early case detection Encourage service utilisation Participate in public mental health literacy campaigns Support activities of the health extension worker
Community 3	Support community case finding	Support public awareness campaigns Support antistigma activities Support livelihood activities	Educational package	Community meeting spaces, workshops organised at the district for selected community members	*Idir* leaders, NGO representatives, traditional healers, religious leaders	Half a day training on mental health, disorders and care Supervision by health extension worker	Early case detection Encourage service utilisation Participate in public mental health literacy campaigns Support activities of the health extension worker

(note the material in the cells are intended to be illustrative examples). $^{++}$includes mania *these treatments are recommended by mhGAP. *Source: PRIME-Ethiopia MHCP, 2013 (unpublished). Annexed here with permission*

Appendix H-1: Participant information sheet (English version)

INFORMATION SHEET FOR PARTICIPANTS

IRB Reference Number: 026/15/Psy

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

Title of the project: "***FOOD INSECURITY, WORK IMPAIRMENT AND THE IMPACT OF INTEGRATED MENTAL HEALTH CARE AMONG PEOPLE WITH SEVERE MENTAL DISORDERS IN SOUTH ETHIOPIA, SODO DISTRICT***"

Principal Investigator: KEBEDE TIRFESSA LEMI (BA, MA)

Supervisor: **Dr. CHARLOTTE HANLON (PhD), Asso. Prof**

Coordinating office: Addis Ababa University, College of Health Sciences, School of Medicine, Department of Psychiatry.

We would like to invite you to participate in this original research project. You should only participate if you want to; choosing not to take part will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

This study is being funded by the UK Department for International Development and the study is being conducted by Addis Ababa University.

- **Aims of the research**

This study is looking at the impact of mental illness and mental health care on food insecurity, disability, and work productivity among persons with severe mental disorders.

- **Who are we recruiting?**

We are including persons with severe mental disorders, and their guardian or main caregivers to get information about household socioeconomic status and food security.

- **What will happen if you agree to take part?**

You will be invited to be interviewed by an interviewer while you are attending the health center. The interview will take place in a private place. You will be asked about different questions about your recent dietery experiences, working conditions and capacity to accomplish roles free of limitations. There will be no obligation or persuasion to talk about what you are not willing to talk about. The interview will take 1 to 1:30 hours. If you agree, I will tape-record the interview. You will be reimbursed for your time.

- **Risks of being in the study**

We don't expect that the interview will cause you any difficulties. On rare occasions, people might be upset by the questions that are being asked. If you are distressed by the questions then you do not have to answer the question or you can leave the interview at any time.

- **Possible benefits**

We hope that the information obtained will help to improve mental health services in Ethiopia and other similar countries.

Once the overall study is completed, we will let you know what we found, either by inviting you to a meeting, giving you a leaflet or publicising our findings in the district.

- **What we will do with your data**

If your voice is tape-recorded, we will make sure that the tapes do not include your name or identifying information. If notes are taken instead of tape-recording, these notes will not include your name or identifying information. The tapes and notes will be kept in a locked cupboard. Once the interview tapes have been written down, and the data has been analysed, the tapes will be cleared.

Nobody except the project co-ordinators and project data managers will know that the information belongs to you. We will keep the questionnaires in a locked cupboard.

After the end of this study, the information you tell us may be used by other researchers, but they will not be able to identify you in any way.

Main researchers:

- 1. Kebde Tirfessa Lemi and 2. Charlotte Hanlon, Dr. You can contact us at the Sodo project office on telephone number *********, from Monday to Friday during working hours.
  It is up to you to decide whether to take part or not. If you decide to take part you are still free to withdraw at any time and without giving a reason.

  If this study has harmed you in any way you can contact the Institutional Review Board, Addis Ababa University, using the details below for further advice and information:

- Institutional Review Board, School of Medicine, Addis Ababa University
  Telephone number: 0115-5538734

- You may withdraw your data from the project at any time up until it is transcribed for use in the final report.
- If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form.

Appendix H-2: Information sheet for participants (Amharic version)

ጥናት 5

Cohort study in primary care (የአዕምሮ ሕመም የሚያደርስዉን አሉታዊ ተጽዕኖ ለመገምገም የሚካሄድጥናት)

በዚህ ጥናት እንዲሳተፉ ተጋብዘዋል፡፡ ተሳትፎዎትም በእርሰዎ ፍላጎት ላይ ብቻ የተመሰረተ ይሆናል፡፡ በጥናቱ ላለመሳተፍ ከመረጡ/ከወሰኑ አለመሳተፈዎት በእርሰዎ ላይ ምንም የሚያስከትለው ችግር የለም፡፡ በጥናቱ ለመሳተፍ ከመወሰንዎ በፊት ጥናቱ ለምን እንደሚሰራና የእርስዎ ተሳትፎ ምን እንደሚያካትት መረዳቱ አስፈላጊ ነው፡፡ እባክዎ ከዚህ በታች የተሰጡ መረጃዎችን በጥንቃቄ ያዳምጡ/ያንብቡ፡፡ ግልጽ ያልሆነ ነገር ካለና የበለጠ መረጃ ከፈለጉ ሊጠይቁን ይችላሉ፡፡

ይህ ጥናት በአ.አ ዩኒቨርሲቲ ስር በሚገኘው በPRIME ፕሮጀክት የሚካሄድ ነው፡፡

የምርምሩ አላማ

ይህ ጥናት በአእምሮ ህመም የሚሰቃዩ፣ ከአልኮል ሱስ ጋራ የተያያዙ ችግሮች ወይም የሚጥል በሽታ ያለባቸው ሰዎችን በጤና ጣቢያ ደረጃ እንዴት የህክምና እርዳታ ሊያገኙ እንደሚችሉ፣ ህመማቸውን እንዴት እንደሚያዩት እና የሚያስፈልጋቸውን ህክምና እንዳያገኙ የሚያደርጋቸውን ምክንያቶችን የሚለይ እና **የአዕምሮ ሕመም በቤተሰብ ምጣኔ ሀብት ላይ የሚያደርሰዉን አሉታዊ ተጽዕኖ ለመገምገም** የሚካሄድ የማህበረሰብ የዳሰሳ ጥናት ነው፡፡

በጥናቱ እንዲሳተፉ የሚመረጡት እነ ማን ናቸው?

ከላይ በተጠቀሰው ርእስ ላይ መረጃ ሊሰጡን እንደሚችሉ የምናስባቸው ማናቸውም የማህበረሰብ አባላት ሁሉ ይካተታሉ፡፡

በጥናቱ ለመሳተፍ ቢስማሙ ምን ይደረጋል?

ከመረጃ ሰብሳቢዎቻችን አንዱ ጥያቄዎችን ያቀርብሎታል፡፡ ቃለ መጠይቁ ወደ ስልሳ ደቂቃ ገደማ ይወስዳል፡፡

በጥናቱ መሳተፍ ምን ጉዳት ይኖረዋል?

በቃለመጠይቁ መሳተፍ የሚያስከትለው ችግር የለም፡፡ቢሆንም አንዳንድ ሰዎች በሚነሱ ጥያቄዎች ሊረበሹ ይችሉ ይሆናል፡፡ እርስዎ በጥያቄዎቹ ደስተኛ ካልሆኑ መልስ ይሰጡ ዘንድ አይገደዱም፡፡ ቃለ መጠይቁም እዚሁ ላይ መቆም ይችላል፡፡፣

የሚገኘው መረጃ በኢትዮጵያም ሆነ በሌሎች ሀገሮች ያለውን የአእምሮ ጤና አገልግሎት እንደሚያሻሽለው ተስፋ እናደረጋለን፡፡ ጥናቱ ሲጠናቀቅ ግኝታችንን ለማወቅ ይችሉ ዘንድ በወረዳው ውስጥ ለህዝብ እንዲገለጽ እናደርጋለን፡፡

በሰጡን መረጃ ምን እናደርግበታለን?

ጥያቄዎቹ የእርስዎን ስም እንዲሁም ማንነት አያካትቱም፡፡ ስለዚህ ከፕሮጀክቱ አስተባባሪዎች ዶ/ር አባባው ፈቃዱ እና ዶ/ር ግርማይ መድህን እና የፕሮጀክቱ የመረጃ ሰራተኞች ውጪ ማንም ሌላ ሰው መረጃው የእርስዎ ስለመሆኑ የሚያውቀው አይኖርም ፡፡

የመረጃ ሰነዶቹን በሚቆለፉ መሳቢያ / መደርደርያ / እናስቀምጣለን፡፡ከጥናቱ ማለቅ በኋላ የሰጡን መረጃ ሌሎች ተመራማሪዎች ይጠቀሙበት ይሆናል፡፡ ግን በማንኛውም መንገድ መረጃ የሰጠውን ሰው መለየት እንዳይችሉ ይደረጋል፡፡

ዋና አጥኚዎች

ዶ/ር አበባው ፈቃዱ እና ዶ/ር ግርማይ መድህን፡፡ ሊያገኙን ከፈለጉ የቡታጅራ ፕሮጀክት ቢሮ ስልክ ቁጥር 046 115 15 95 በመጠቀም በስራ ቀኖች በሥራ ሰአት ሊደውሉልን ይችላሉ፡፡

በጥናቱ መሳተፍ የእርስዎ ውሳኔ ጉዳይ ይሆናል፡፡ በጥናቱ ለመሳተፍ ከወሰኑ በማንኛውም ሰአት ምክንያት መስጠት ሳይጠበቅብዎት በነጻነት ተሳትፎውን ማቋረጥ ይችላሉ፡፡

ይህ ጥናት በማንኛውም መንገድ ጉዳት ካደረሰብዎት የአዲስ አበባ ዩኒቨርሲቲ የህክምና ፋኩልቲ የስነምግባር (ኢቲክስ) ተቋማዊ የክለሳ ቦርድን ከዚህ በታች በተጠቀሰው አድራሻ ማነጋገር ይችላሉ፡፡

- ስልክ ቁጥር 0115-553 87 34

ማስታወሻ

- ✓ ወደ መጨረሻ ሪፖርትነት እስኪቀየር ድረስ በፈለጉት ሰአት መረጃዎን ከፕሮጀክቱ ሊያወጡ ይችላሉ፡፡
- ✓ በጥናቱ ለመሳተፍ ከወሰኑ ይህን የመረጃ ቅጽ ይሰጥዎትና ስምምነት ግን በፊርማ እንዲያረጋግጡ ይጠየቃሉ፡፡

Appendix I-1: Informed consent (English Version)

Please complete this form after you have read the Information Sheet and/or listened to an explanation about the research.

Title of Study: "***FOOD INSECURITY, WORK IMPAIRMENT AND THE IMPACT OF INTEGRATED MENTAL HEALTH CARE AMONG PEOPLE WITH SEVERE MENTAL DISORDERS IN SOUTH ETHIOPIA, SODO DISTRICT***"

Addis Ababa University Research Ethics Committee Ref: 026/15/Psy

Thank you for considering taking part in this research. The person organising the research must explain the project to you before you agree to take part. If you have any questions arising from the Information Sheet or explanation already given to you, please ask the researcher before you decide whether to join in. You will be given a copy of this Consent Form to keep and refer to at any time.

- I understand that this research undertaking is a post graduate degree partial fulfillment of research dissertation which is fully supported and coordinated by AAU Schools of Medicine and Public Health and the designate principal investigator is **Kebede Tirfessa Lemi**.
- I understand that if I decide at any time during the research that I no longer wish to participate, or for my child to participate, in this project, I can notify the researchers involved and withdraw from it immediately without giving any reason. Furthermore, I understand that I will be able to withdraw my data up until they are published.
- I consent to the processing of my personal information for the purposes explained to me. I understand that such information will be handled in accordance with the terms of the national data protection rules.
- If I am selected to be interviewed in more detail then I consent to that interview being audio-taped.
- The information you have submitted will be published as a report. Please note that confidentiality and anonymity will be maintained and it will not be possible to identify you from any publications.
- I agree that the research team may use anonymized data for future research.

Participant's Statement:

I _____

agree that the research project named above has been explained to me to my satisfaction and I agree to take part in the study. I have read both the notes written above and the Information Sheet about the project and understand what the research study involves.

Signed: _____

Date: _____

Witness Statement (in event that participant is not literate):

I _____

agree that the research project named above has been explained to _____ (participant) to her satisfaction and that she agrees to take part in the study. Both the notes written above and the Information Sheet about the project have been read to her, and she understands what the research study involves.

Signed: _____

Date: _____

Investigator's Statement:

I, _____

Confirm that I have carefully explained the nature, demands and any foreseeable risks (where applicable) of the proposed research to the participant.

Signed: _____

Date: _____

Appendix I-2: Informed consent (Amharic Version)

የፈቃደኝነት መጠየቅያ ቅጽ

የመረጃ ወረቀቱን ካነበቡ እና ወይም ስለምርምሩ የተሰጠውን መግለጫ ካዳመጡ/ካነበቡ በኋላ እባክዎን ይህን የፈቃደኝነት መጠየቅያ ቅጽ ይሙሉ፡፡

እባክዎ ከመረጃው ወረቀት ወይም ከተደረገልዎት ገለጻ የመነጨ ጥያቄ ካለዎት በምርምሩ ለመሳተፍ ከመወሰንዎ በፊት መጠይቁን የሚያካሂደውን ግለሰብ ይጠይቁ፤ በእጅዎ ይኖር ዘንድ እና በፈለጉ ጊዜ እንዲያመላክሩበት የዚህ የስምምነት ቅጽ ግልባጭ ይሰጥዎታል፡፡

- በማንኛውም ጊዜ በምርምሩ ላለመሳተፍ ከወሰንኩኝ፤ ለምርምሩ ለሚያካሂዱት ወይም ወኪሎቻቸው ማሳወቅ እንደምችልና ምንም ምክንያት ሳላቀርብ ከምርምሩ እራሴን ላገል እንደምችል ተረድቻለሁ፡፡ ከዚህም ባሻገር ጥናቱ እስኪታተም ድረስ የሰጠሁትን ቅጽ መረጃዎች ማውጣት እንደምችል ተረድቻለሁ፡፡ ☐
- የሰጠሁት የግል መረጃ ለተገለፀልኝ አላማ ጥቅም ላይ ይውል ዘንድ ተስማምቻለሁ፡፡ ☐
- በጥልቀት ቃለ መጠይቁን ለመስጠት ከተመረጥኩ ቃለ መጠይቁ በመቅረጸ ድምጽ ይቀዳ ዘንድ እስማማለሁ፡፡
- የሰጡን መረጃ እንደ ሪፖርት ይታተማል፡፡ የሚሰጡን መረጃ ሚስጥራዊነት እንደሚጠበቅና ከሚወጡትም ሪፖርቶች ማንነቶን ለማወቅ እንደማይቻል ልናረጋግጥ እንወዳለን፡፡ ☐
- የምርመራ ቡድኑ ቅድመ መረጃውን ለወደፊት ምርምር ሊጠቀም እንደሚችል እስማማለሁ፡፡ ☐

በተጨማሪ የፕራየም እና ኢምራልድ ተመራማሪዎች ለሌላ ተመሳሳይ ጥናት ማለትም የአዕምሮ ሕመም በቤተሰብ ምጣኔ ሀብት ላይ የሚያደርሰዉን አሉታዊ ተጽዕኖ ለመገምገም በሚደረግ ቃለመጠይቅ፡መረጃ ሰብሳቢዎች፤በመኖሪያ ቤታችን ተገኝተዉ ከቤተሰቡ ሃላፊ ጋር፡ ቃለመጠይቅ እንዲያደርጉ ፈቅጃለሁ፡፡ ☐

<u>ለመረጃ ሰብሳቢዉ፡</u>
የፈቃደኝነት ማረጋገጫ ከተገኘ (ከተሰጠ) በመኖሪያ ቤት መረጃ የሚሰጥ ሰዉ ሙሉ ስም፡እና የቀጠሮ ቀን ከዚህ ጋር ተያይዞ በሚገኘዉን ቅጽ ላይ በጥንቃቄ፡መ/ላ(መ/ይ)፡፡

የተሳታፊው መግለጫ_
እኔ ከላይ የተጠቀሰው የምርምር ፕሮጀክት በበቂ ሁኔታ ተብራርቶልኝ በጥናቱ ለመሳተፍ ተስማምቻለሁ፡፡ ከላይ የተጻፉትን ማሳሰቢያዎች እና ስለፕሮጀክቱ የሚገልጽ የመረጃ ወረቀት አንብቤ ጥናቱ የሚያካትተውን ተረድቻለሁ፡፡

ፊርማ _____
ቀን _____

የምስክር ቃል (ተሳታፊው ያልተማረ ከሆነ)
እኔ_____

ከላይ የተጠቀሰው የምርምር ፕሮጀክት በበቂ ሁኔታ ለ ተብራርቶላቸው በምርምሩ ለመሳተፍ ተስማምተዋል፡፡ ከላይ የተጻፉ ማሳሰቢያዎች እና ስለፕሮጀክቱ የሚገልጽ የመረጃ ወረቀት የተነበበላቸው ሲሆን ጥናቱ የሚያካትታቸውንም ጉዳዮች ተረድተዋል፡፡
ፊርማ _____
ቀን _____

Appendix J. Participant's Statement (Amharic version)

□ተሳታፊዎች ማረጋገጫ

እኔ _____ ከላይ ርዕሰ የተገለጸው የጥናቱ አላማ በምፈልገው መጠን ተገልጾልኝ በጥናቱ ለመሳተፍ ተስማምቻለሁ። ከላይ የተገለጸውን ስለ ጥናቱ የሚገልጽ ማብራሪያና የመረጃ ቅጽ እንዲሁም ጥናቱ ምን እንደሚያካትት ተረድቻለሁ።

ኝርማ _____ ቀን _____

Witness Statement (in event that participant is not literate): (Amharic version)

የምስክርነት ማረጋገጫ (ማንበብና መጻፍ ለማይችል ተሳታኝ)

እኔ _____ከላይ ርዕሱ የተገለጸው የጥናት አላማ ለ _____ (ተሳታፊ) በሚፈልጉት መጠን ተገልጾላቸዋል፤ በጥናቱ ለመሳተፍ ተስማምተዋል፤ ከላይ የተገለጸውን ስለ ጥናቱ የሚገልጽ ማብራሪያና የመረጃ ቅጽ ተነቦላቸዋል፤እንዲሁም ጥናቱ ምን እንደሚያካትት ተረድተዋል።

ኝርማ_____ ቀን _____

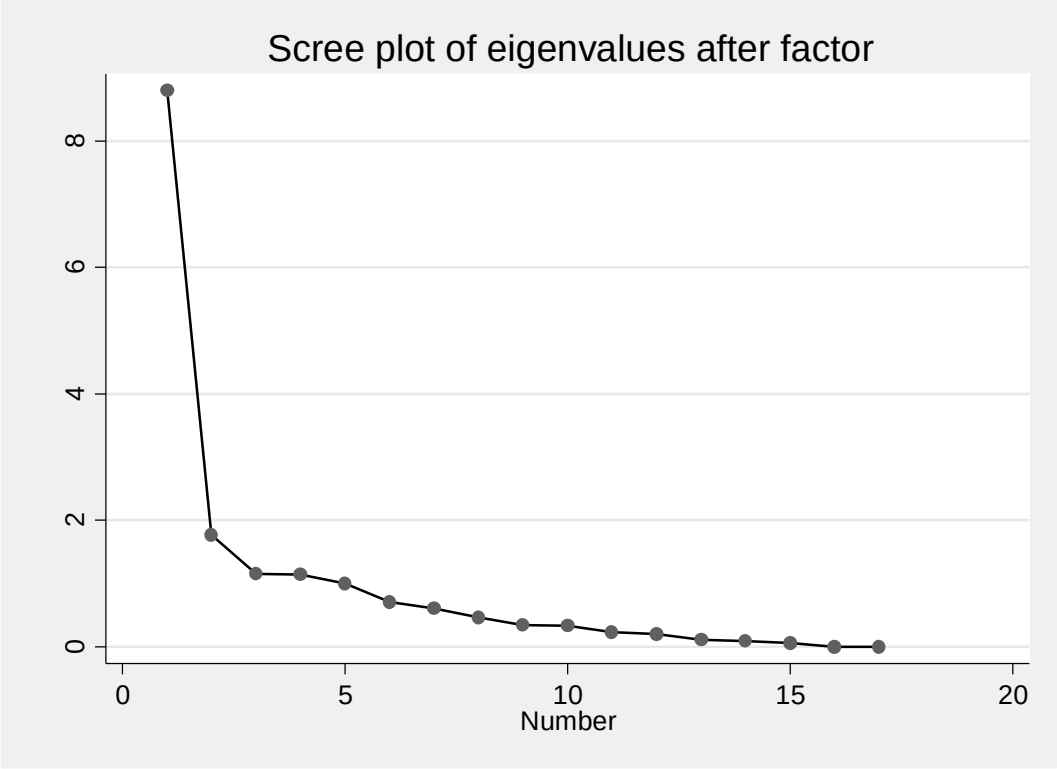
Investigator's Statement: (Amharic version)

□ተመራማሪዉ ማረፉ□□

እኔ _____ የጥናቱን ባህሪ ጥናቱ የሚፈልጋቸውንና ሊያስከትላቸው የሚችላቸውን ነገሮች ለተሳታፊዉ በጥንቃቄ የገለጽኩ መሆኔን አረጋግጣለሁ።።።

ኝርማ _____ ቀን _____

Appendix K-1: Scree-plot for Polychoric correlation factor analysis for DISC items



Appendix K-2. Factor loadings (pattern matrix) and unique variance

DISC items	Variable	Factor 1	Factor2	Uniqueness
making or keeping friends	difurmakin	0.7009		0.4059
inappropriately treated by neighbours	dnauinapro	0.7552		0.3860
dating and Intimate relationships	dlfuadatin	0.8018		0.3553
housing	dhrumhousi	0.7911		0.3321
education	decuteduca	0.6498		0.3775
marriage or divorce	dmrdmarria	0.6866		0.3689
inappropriately treated by family	dfbsrinapr	0.6931		0.3300
finding a job	dgwufindin	0.8454		0.2853
maintaining a job	dweumainta	0.8023		0.3376
public transportation	dprtupubli		0.6614	0.3137
religious practices	dudborelig		0.5706	0.5185
social life	dslptsocia	0.7527		0.2732
police	dplutpolic	0.6237		0.5986
personal safety	dpsrtperso	0.7662		0.4023
starting a family or having children	dfcpdstart	0.8428		0.2700
role as a parent	dfrtroleas	0.7034		0.5045
avoided or shunned by others	dmisaavoid	0.7466		0.4006

(blanks represent abs (loading) < 0.5)

Appendix L. Month of Assessment among Cases and Controls

Month of Assessment	**Group**	
	Cases N (%)	**Controls N (%)**
January	63 (21.6)	-
February	35 (12.0)	-
March	58 (19.9)	23 (8.1)
April	24 (8.2)	130 (45.8)
May	36 (12.3)	8 (2.8)
June	31 (10.6)	-
July	12 (4.1)	62 (21.8)
August	-	61 (21.5)
September	-	-
October	-	-
November	-	-
December	33 (11.3)	-
Total	**292 (100)**	**284 (100)**

Apppendix M. Sub-study-I: Published paper

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ORIGINAL ARTICLE

Food insecurity among people with severe mental disorder in a rural Ethiopian setting: a comparative, population-based study

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Aim. In low-income African countries, ensuring food security for all segments of the population is a high priority. Mental illness is associated consistently with poverty, but there is little evidence regarding the association with food insecurity. The aim of this study was to compare the levels of food insecurity in people with severe mental disorders (SMD) with the general population in a rural African setting with a high burden of food insecurity.

Method. Households of 292 community-ascertained people with a specialist-confirmed diagnosis of SMD (including schizophrenia and bipolar disorder) were compared with 284 households without a person with SMD in a rural district in south Ethiopia. At the time of the study, no mental health services were available within the district. Food insecurity was measured using a validated version of the Household Food Insecurity Access Scale. Disability was measured using the World Health Organisation Disability Assessment Schedule 2.0.

Result. Severe household food insecurity was reported by 32.5% of people with SMD and 15.9% of respondents from comparison households: adjusted odds ratio 2.82 (95% confidence interval 1.62 to 4.91). Higher annual income was associated independently with lower odds of severe food insecurity. When total disability scores were added into the model, the association between SMD and food insecurity became non-significant, indicating a possible mediating role of disability.

Conclusion. Efforts to alleviate food insecurity need to target people with SMD as a vulnerable group. Addressing the disabling effects of SMD would also be expected to reduce food insecurity. Access to mental health care integrated into primary care is being expanded in this district as part of the Programme for Improving Mental health carE (PRIME). The impact of treatment on disability and food insecurity will be evaluated.

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Key words: Disability, food insecurity, psychosis, severe mental disorder, sub-Saharan Africa.

Introduction

Secure access to adequate amounts of healthy and nutritious food is considered to be a foundational determinant of health (Muldoon *et al.* 2013). Food insecurity is conceptualised as limited or uncertain access to adequate food, and encompasses food availability, access and utilisation (Mengistu *et al.* 2009; United States Department of Agriculture, 2016). Ending hunger and achieving food security is one of the United Nation's Sustainable Developmental Goals (SDG) to be achieved by 2030 (United Nations, 2015). In Ethiopia, both chronic and transitory (seasonal) food insecurity are persistent problems for a large segment of the population (Mengistu *et al.* 2009). In 2012, there was an 82.3% prevalence of household-level food insecurity in a zone in southern Ethiopia (Regassa & Stoecker, 2011).

The associations between food insecurity and physical health problems are well documented, but the links between food insecurity and mental illness have

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been less well characterised (Collins, 2005). Ethnographic work has linked the experience of food insecurity with mood disorders, symptoms of anxiety and depression (Kempson *et al.* 2002), poor mental health in general (Xiong *et al.* 1994) and higher levels of stress, anxiety, irritability, social isolation and depression (Collins, 2005). In cross-sectional studies, a consistent association has also been found between depression and anxiety and food insecurity (Hadley & Patil, 2006; Sorsdahl *et al.* 2009; Cole & Tembo, 2011), including within Ethiopia (Hadley *et al.* 2008; Maes *et al.* 2010; Jebena *et al.* 2015). There have been few longitudinal studies to examine the direction of association, but it is hypothesised that depression or anxiety are more likely to be a consequence than a cause of poverty and associated food insecurity (Lund *et al.* 2010).

The risk of food insecurity has been much less well studied in people with severe mental disorders (SMD; including schizophrenia, schizoaffective disorder, bipolar disorder or severe depression/depression with psychotic features). In a study from the USA, 45.8% of people with SMD were classified as food insecure, of which 29.2% experienced very low food security (Goetz, 2008). Such studies are unlikely to be generalisable to low- and middle-income countries (LMICs), where the background burden of food insecurity is higher and the consequences of food security more dire.

In this study, we evaluated food insecurity in a population sample of people with SMD identified before introduction of integrated primary care-based mental health care in a rural Ethiopian district. The study aimed to compare food insecurity in households with a person with SMD compared with households from the general population.

Methods

Study design

A community-based, comparative cross-sectional study was conducted between December 2014 and August 2015.

Setting

The study was carried out in Sodo District, Gurage Zone, of the Southern Nations, Nationalities and Peoples' Region (SNNPR) of Ethiopia, which is located 100 km from the capital city, Addis Ababa. Sodo comprises 58 sub-districts (kebeles), with a total estimated population of around 165 000 (Lund *et al.* 2012). The district is mostly rural, with the majority of the population relying on subsistence farming. At the time of this study, there were no mental health services within the district. As part of the Programme for Improving Mental health carE (PRIME) (Lund *et al.* 2012), primary care workers were trained to detect and treat people with SMD, epilepsy, depression and alcohol use disorders. This study was nested within the PRIME project activities with people with SMD.

Sampling and recruitment

A summary of the study sampling and recruitment is found in Fig. 1. There were three sources of data: (1) person with probable SMD or their caregiver (PRIME project), (2) household of a person with SMD and (3) control household without a person with SMD. Data sources (2) and (3) were obtained from a household economic survey conducted by a linked project, Emerald (Emerging mental health systems in LMICs) (Semrau *et al.* 2015).

People with probable SMD were identified by community-based health extension workers, community leaders and project outreach workers who had received half a day of training on common presentations of SMD for the setting (Fekadu *et al.* 2016). This key informant method has been shown to be an effective means of community ascertainment of SMD for this setting (Shibre *et al.* 2002). People with suspected SMD were then referred to the nearest primary health care (PHC) centre and evaluated by primary care workers who had been trained in the World Health Organisation's mental health Gap Action Programme (mhGAP) base course (World Health Organisation, 2008; Dua *et al.* 2011). For those who received a PHC worker diagnosis of 'psychosis' or 'bipolar disorder', a confirmatory clinical interview was conducted by a psychiatric nurse using the semi-structured Operational Criteria for Research (OPCRIT) interview guide (McGuffin *et al.* 1991). Eligible people were then recruited into the study on the basis of the following criteria:

Eligibility criteria for people with SMD:

- Aged 18 years or older,
- Planning to stay resident in the district for the next 12 months,
- Provided informed consent (evaluated by trained psychiatric nurses) or, if lacked capacity to consent, did not refuse and guardian permission was obtained,
- Psychiatric nurse confirmed diagnosis using the OPCRIT, and
- Able to understand Amharic, the official language of Ethiopia and the working language of the study site.

Eligibility criteria for respondent from household of person with SMD:

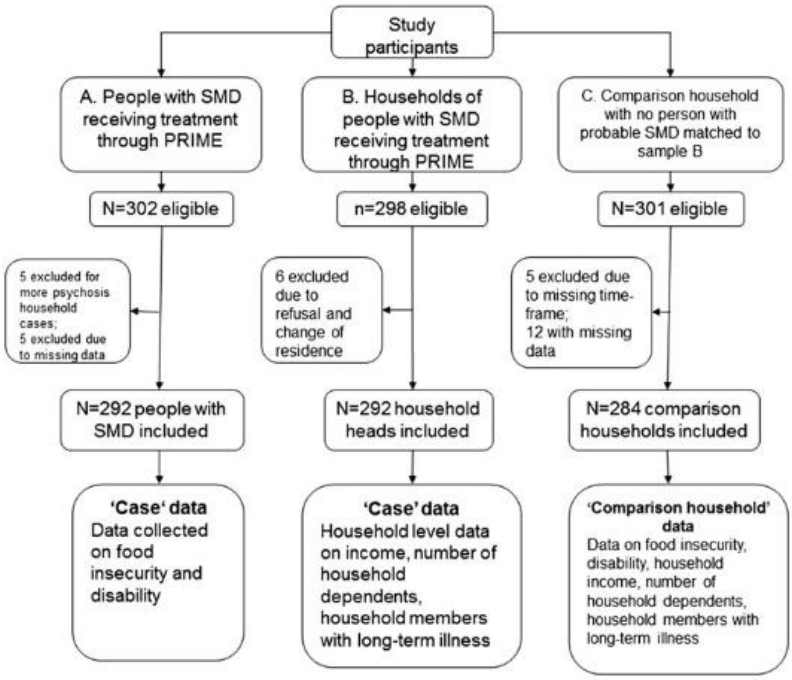

Fig. 1. Flow chart of participant recruitment.

- Having a person with SMD in a household; aged 18 years or above; provided informed consent; resided in the household for a minimum of 4 months; household head or the older person if two household members contributed equally to household decision-making;

Eligibility criteria for control households:

- No person/family member with suspected or confirmed SMD within the household; aged 18 years or above; providing informed consent.
- Matched to a household in which a person with SMD resided [on the basis of age (±5 years), sex, village (*gott*), household position (head *v.* not head) and household size, using a complete census of the district as a sampling frame (Fekadu *et al.* 2014)]. If more than one match was identified, the household was selected by lottery. If no respondent was identified for the first matched household after three home visits, or if they declined to participate, the next reserve was selected.

Sample size and power calculation

The sample size for this study was determined by the sample sizes for the PRIME and Emerald studies which were powered to detect change in symptoms and economic status in people with SMD and their households after introduction of mental health care. The PRIME study recruited 300 people with SMD. The Emerald study recruited 300 households of people with SMD and 300 households of controls. Details of the power that this sample size afforded us to detect differences in the prevalence of food insecurity are provided in Supplementary File 1.

Measures

Primary outcome: food insecurity

Food insecurity was measured using the Household Food Insecurity Access Scale (HFIAS) (Coates *et al.* 2007). The HFIAS was administered to people with SMD and the respondent for the control households. The HFIAS was developed to reflect three domains of the experience of inadequate household-level food access: (1) anxiety or uncertainty about food supply/access (item 1); (2) insufficient quality, which includes variety and preferences (items 2–4); and (3) insufficient quantity of food supply, the amount consumed and the physical consequences of insufficiency (items 5–9) (Swindale & Bilinsky, 2006). An Amharic version of the HFIAS-9 has been used in Ethiopia (Hadley *et al.*

2008; Maes *et al.* 2010; Jebena *et al.* 2015) and is reported to be valid in this setting (Gebreyesus *et al.* 2015). During piloting, there were acceptability concerns about items asking about missing meals. A contextualising lead-in statement was added, which led to improved acceptability. The HFIAS was administered by trained lay interviewers.

Primary exposure: SMD

The OPCRIT semi-structured interview was used to diagnose the presence of SMD (McGuffin *et al.* 1991). OPCRIT comprises a 90-item checklist of psychiatric symptoms, which is administered by a mental health professional and was used to generate psychiatric diagnoses according to the Diagnostic and Statistical Manual for mental disorders, version IV (McGuffin *et al.* 1991; Azevedo *et al.* 1999). OPCRIT allows the rater to make use of all available information sources, including clinical interviews with the person and their caregiver and case records and applies operational diagnostic criteria through a computer algorithm (Operational Criteria for Research, 2004). OPCRIT has been shown to have good inter-rater reliability, including among raters from different geographical and theoretical backgrounds (McGuffin *et al.* 1991; Williams *et al.* 1996). OPCRIT was administered by psychiatric nurses and only administered to people with suspected SMD.

Potential mediator: functional impairment

The World Health Organisation Disability Assessment Schedule 2.0 (WHODAS) was used to measure functional impairment (World Health Organisation, 1985). The WHODAS has been validated for use in people with SMD in rural Ethiopia (Habtamu *et al.* 2017). The WHODAS has both 36- and 12-item versions, with the 12-item version found to have equivalent psychometric properties to the longer version (Ustün *et al.* 2010). In the control households, the 12-item version of WHODAS was used. In the sample of people with SMD, the 12-item WHODAS was extracted from the longer 36-item version.

Potential confounders

Household measures. Structured lay interviewer-administered questions were used to assess household income, the number of household members with a long-term illness and the number of dependents (age 17 years or less) living in the household, employing items used in the WHO study on global ageing and adult health (World Health Organisation, 2013). Other potential confounders were age, sex, residence (urban or rural), household position (being a household head *v.* not being a household head) and educational level of the respondent. Month of assessment was also a potential confounder due to seasonal variation in food security.

Training of data collectors

The lay data collectors had completed at least tenth grade education and were recruited from the local area. The training was conducted for 12 days by project psychologists, public health and social work professionals and covered the following topics: basic interviewing skills, particular skills for interviewing people with SMD and their caregivers, ethical considerations and detailed training on the study instruments. The training included role play and observation of practice interviews.

Training of clinician assessors

The project psychiatric nurses were given intensive training by senior Ethiopian psychiatrists in the clinician-administered measures over a period of seven days. The training included observed interviews and feedback, although formal inter-rater reliability was not assessed formally.

Data management

Double data entry was carried out using EpiData software (Lauritsen & Bruus, 2003–2008). To maintain data quality, the field supervisor and principal investigator (PI) made unannounced visits to attend interviews at the site, with frequent and close supervision and cross-checks. Random quality checks of questionnaires were also made by the field supervisor and PI. Confidentiality was ensured. Hard copies of data were stored in a secure place, while the soft copies of data were saved on password-protected computers which could only be accessed by authorised members of the research team.

Statistical analysis

Data analysis was carried out using STATA software version 13.1 (StataCorp, 1985–2013). A conceptual model depicting hypothesised associations among the variables is presented in Fig. 2. The descriptive characteristics of cases (individual-level data from person with SMD combined with household reports) and controls were compared using Pearson χ^2 test for categorical variables, Kruskal–Wallis ($P<0.001$) for continuous non-normally distributed variables and two-sample *t*-test for continuous normally distributed variables.

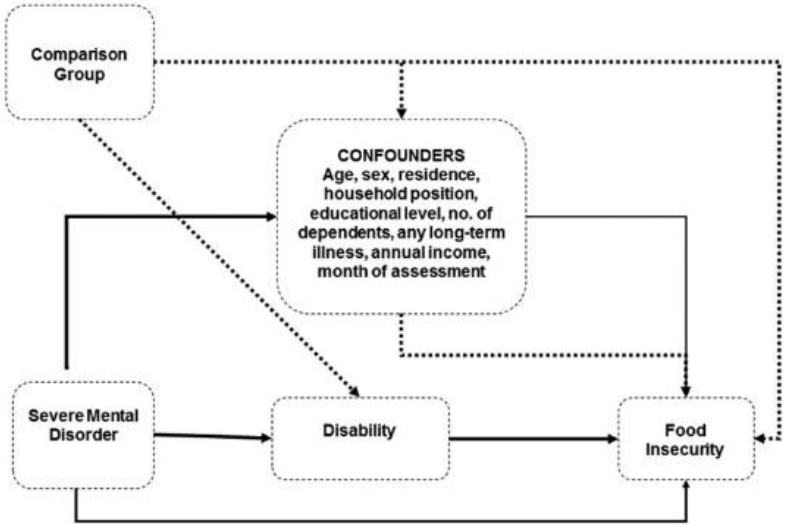

Fig. 2. Conceptual model for hypothesised associations between severe mental disorder, disability and food insecurity.

Multiple logistic regression was conducted to test the hypothesis that the presence of a household member with SMD was associated with food insecurity in that household. The HFIAS total score was dichotomised into severely food insecure *v.* combined categorised into severely food insecure *v.* combined categories of mild or moderate food insecurity or food secure (Swindale & Bilinsky, 2006). The rationale for this categorisation was that severe food insecurity was expected to be relatively common in the study setting and to represent a threshold which was likely to motivate intervention. We also repeated the analyses using a dichotomisation of no/mild food insecurity *v.* moderate/severe food insecurity as an exploratory secondary analysis. The potential confounders identified *a priori* (see above) were included into the model. In order to explore whether disability mediated the association between SMD and food insecurity, the total WHODAS score was added into the fully adjusted model with food insecurity as the dependent variable.

A further multivariable analysis was then conducted to examine factors associated with disability (total score on the WHODAS12-item version). On inspection, a histogram of WHODAS scores indicated excess zeroes. Variance in WHODAS scores was greater than the mean score (177.48 > 13.89), indicating overdispersion. The Vuong test *z*-value was significant, indicating that a zero-inflated negative binomial model was more appropriate than the standard negative binomial model. Coefficients are on a log scale and for ease of interpretation were exponentiated.

Results

Participant and household characteristics

Participant recruitment is summarised in Fig. 1. The characteristics of participants are summarised in characteristics of participants are summarised in Table 1. Respondents who had SMD were less likely to be the household head and to have dependents and more likely to be female, younger and have higher disability scores, formal education and lower annual income. The timing of assessments for case and comparison households differed significantly (see Supplementary File 2 for distribution). The assessment was conducted during the rainy season (June to August), a time of relative food insecurity, for 14.7% of case households and 43.3% of the comparison group. There was no significant difference in the location of the household (rural or urban) or presence of a household member with a long-term illness (excluding the person with SMD).

SMD and food insecurity

The percentage of respondents reporting severe household food insecurity was 32.5% for people with SMD and 15.9% for the control households. The median HFIAS score was higher for people with SMD (median 15, IQR 10) compared with control households (median 12, IQR 7) ($P < 0.001$).

In keeping with the hypothesis, SMD was associated with severe food insecurity (adjusted OR = 2.82; 95% CI 1.62, 4.91) after adjustment for potential

Table 1. *Characteristics of households with a person with severe mental disorder (SMD) and comparison households*

Characteristics	Person with severe mental disorder (SMD) *N* (%)	Comparison households with no person with SMD *N* (%)	*P*-value**
	Currently household head		
No	184 (63.0)	6 (2.1)	<0.001
Yes	108 (37.0)	277 (97.9)	
	Educational level		
Non-literate	116 (39.7)	99 (34.8)	<0.001
Able to read and write	37 (12.7)	88 (31.0)	
Formal education	139 (47.6)	97 (34.1)	
	Sex		
Female	126 (43.1)	77 (27.1)	<0.001
Male	166 (56.9)	207 (72.9)	
	Residence		
Urban	60 (20.6)	56 (19.7)	0.788
Rural	231 (79.4)	228 (80.3)	
	HFIAS		
Secure/mildly/moderately food insecure	195 (67.5)	239 (84.1)	<0.001
Severely food insecure	94 (32.5)	45 (15.9)	
	Mean (standard deviation)	Mean (standard deviation)	
Age (years)	35.6 (13.50)	49.7 (13.86)	<0.001
Month of assessment*	4.3 (3.28)	5.5 (1.84)	<0.001
	Median (25th, 75th centiles)	Median (25th, 75th centiles)	
No. of members with any Long-term illness	0 (0, 0)	0 (0, 0)	0.4701
No. of dependents	2 (1, 3)	2 (1, 4)	0.0001
Number of children	1 (0, 3)	4 (2, 6)	<0.001
Annual Income (ETB)	6000 (3000, 11 000)	9000 (5000, 15 000)	<0.001
WHODAS 2.0 total score	24 (14, 32)	2 (0, 7)	<0.001

*Months numbered starting from January. ETB: Ethiopian Birr; WHODAS: World Health Organisation Disability Assessment Schedule.
**P-value of Pearson χ^2 for categorical variables, Kruskal–Wallis for continuous non-normally distributed descriptive variables and two-sample *t*-test with equal variances for continuous normally distributed variables.

confounders (Table 2). Higher annual income was found to be associated independently with lower odds of food insecurity. There was no difference in the findings when the food insecurity score was categorised as no/mild food insecurity *v.* moderate/severe food insecurity (see Supplementary File 3).

Exploring mediation

After including total WHODAS 12.0 score in the multivariable model with food insecurity as the dependent variable, the association between SMD and food insecurity became non-significant, indicating the probable mediating role of disability in this relationship. Annual income remained associated significantly with food insecurity even after including disability within the model (Supplementary File 4).

Factors associated with disability

In the multivariable model, having SMD and increasing age were associated with increased disability, whereas formal education and current household head position were associated with lower disability (Table 3).

Discussion

In this community-based study conducted in rural Ethiopia, severe food insecurity and disability were increased significantly among people with SMD compared with general population controls, in support of our hypothesis.

The prevalence of severe food insecurity was more than twice as high in households with a member living with SMD compared with households from the general population, which is in keeping with the findings

Table 2. *Crude and adjusted model for association between severe mental disorder and severe food insecurity*

	Dependent variable: severe food insecurity	
Characteristics	Crude odds ratio (95% confidence interval)	Adjusted odds ratio (95% confidence interval) ($n = 556$)
Person with SMD	**2.56 (1.71, 3.83)**	**2.82 (1.62, 4.91)**
Male Sex	1.46 (0.98, 2.15)	1.12 (0.71, 1.78)
Age (in years)	0.99 (0.98, 1.01)	1.01 (0.99, 1.03)
Urban residence	0.88 (0.55, 1.42)	0.73 (0.43, 1.25)
Able to read and write	0.78 (0.47, 1.31)	1.01 (0.56, 1.81)
Formal education	0.69 (0.45, 1.07)	0.84 (0.49, 1.43)
Current household head	**0.67 (0.45, 0.99)**	1.06 (0.61, 1.85)
Annual income	**0.99 (0.99, 0.99)**	**0.99 (0.99, 0.99)**
Number of dependents	0.90 (0.81, 1.01)	1.07 (0.93, 1.22)
Any long-term illness	1.56 (0.98, 2.28)	1.34 (0.85,2.12)
Month of assessment	0.94 (0.87, 1.01)	0.98 (0.91, 1.06)

SMD: severe mental disorder.

Table 3. *Crude and adjusted models for factors associated with disability score*

Characteristics	WHODAS 12.0 crude multiplier value (95% CI)	WHODAS 12.0 adjusted multiplier value (95% CI) ($n = 559$)
Age (years)	**0.99 (0.98, 0.99)**	**1.01 (1.00, 1.01)**
Sex (male)	1.14 (0.96, 1.34)	1.08 (0.95, 1.23)
Residence (urban)	1.02 (0.83, 1.25)	1.04 (0.89, 1.21)
Education (formal)	0.93 (0.85, 1.02)	**0.91 (0.84, 0.98)**
Currently household head	*	**0.71 (0.61, 0.83)**
Number of dependents	**0.95 (0.91, 0.99)**	0.98 (0.94, 1.02)
Person with SMD	**3.30 (2.89, 3.77)**	**3.36 (2.83, 3.99)**
Annual income	**0.99 (0.99, 0.99)**	0.99 (0.99, 1.00)

SMD: severe mental disorder; WHODAS: World Health Organisation Disability Assessment Schedule.
*Fitting constant-only model; long iteration output.

from a small study from the USA (Goetz, 2008) and a facility-based case–control study from India (Trani *et al.* 2016). SMD was associated with household food insecurity independently of household annual income. In this subsistence farming community, food insecurity is related to the amount of food available due to household production and not just to income. In addition to the impact of disability of the person with SMD, the opportunity costs of other household members due to engagement in caregiving activities and direct reductions in productivity of caregivers are likely to contribute to an overall decrease in household productivity (Flyckt *et al.* 2011). In a qualitative study from the same area, respondents conceptualised disability in people with SMD as arising from a combination of direct effects of the illness, poverty and stigma (Habtamu *et al.* 2015). Stigma and discrimination extends beyond the individual person with SMD to affect the whole household (Shibre *et al.* 2001), which may lead to decreased co-operation with community members for key farming activities and resultant decrease in food production.

Ethiopia is reported to have well-established and strong programmes to address the food security needs of vulnerable groups (Combaz, 2013; Endalew *et al.* 2015). In the Productive Safety Net Programme, rural households facing chronic food insecurity are supported to resist financial shocks, create assets and become food self-sufficient by providing predictable transfers, as food, cash or a combination of both (Ministry of Agriculture & Rural Development, 2009; Endalew *et al.* 2015; World Food Program, 2016) conditional upon engagement in daily labouring activities. Households of people who are 'chronically sick, disabled or mentally challenged in such a way as to prevent them from undertaking work' are explicitly

excluded from this scheme but considered eligible for permanent direct support and the possibility of linkages to appropriate social services, where capacity exists at the district level (Ministry of Agriculture, 2014); however, the extent to which households with a person with SMD are able to access this support is unknown and likely to be low. As well as the prevailing low levels of awareness about mental health and illness, the stigma and social exclusion associated with SMD (Shibre *et al.* 2001) are likely to act as barriers to participation in interventions to address food insecurity.

The consequences of exposure to food insecurity in people with SMD in this setting may be profound. A previous study found that people with SMD in a rural Ethiopian district were more likely to be undernourished compared with community controls (Lijalem, 2002). Excess mortality in people with SMD in Ethiopia has been linked to undernutrition (Fekadu *et al.* 2015). Food insecurity is likely to also affect access to, and engagement with, care. In a qualitative study of people with SMD and their caregivers in a food-insecure area, justification for ongoing use of khat (chewing leaves containing the amphetamine-like substance cathinone) against medical advice was in part to curb one's appetite even though there was awareness that it could worsen the person's mental health (Teferra, 2011). Formative work indicated the need for interventions to address basic needs, including food security,

tions to address basic needs, including food security,

among people with SMD in Ethiopia to ensure equitable access to care (Hailemariam *et al.* 2016; Mall *et al.* 2017).

Our findings suggest that interventions to address food insecurity need to include both expanded access to mental health care (to reduce disability) and strategies to alleviate poverty, particularly for vulnerable individuals living with SMD. Through the PRIME project, and in keeping with the policy of the Federal Ministry of Health of Ethiopia, access to mental health care is being increased through integration into PHC in this district (Fekadu *et al.* 2016). Although there is an emphasis on community mobilisation in the PRIME Ethiopia plan, at the individual level the intervention is mostly centred on facility-based treatment and, specifically, on psychotropic medication combined with provision of information ('psychoeducation'). An evaluation of the BasicNeeds model of providing development interventions (e.g. income-generating activities and interventions to promote sustainable livelihoods) alongside mental health care (BasicNeeds, 2008; Raja *et al.* 2012) found improved economic status in people with SMD (Lund *et al.* 2013); however, the study design could not distinguish the effects of mental health care alone from any added value of development interventions. Within PRIME, planned follow-up assessments after 12 months of the new integrated service will help to answer the question of whether treatment alone is sufficient to address indicators of poverty in general, and food insecurity in particular. A community-based rehabilitation (CBR) intervention trial for people with schizophrenia is also underway in Ethiopia (Asher *et al.* 2016). The CBR model includes facility-based treatment, home-based sessions from community workers and community mobilisation. The goal of CBR is to promote restoration of functioning and recovery which is expected to translate into improved social inclusion, economic status and food security. The findings will show whether such an intensive intervention yields dividends over and above the PRIME service.

There were limitations of our study. Although the HFIAS is a household measure, the information for the 'case' group was provided by the person with SMD. It is possible that they reported higher food insecurity levels than other household members due to less access to household resources than other household members or that they experienced greater hunger due to appetite-stimulating effects of antipsychotic medication (Teferra *et al.* 2013); however, only a third (35.0%) of people with SMD were taking psychotropic medication at the time of assessment so this is unlikely to be the full explanation. Furthermore, the HFIAS is designed to capture household-level information regardless of the respondent. Respondents may have given affirmative responses in the expectation that

given affirmative responses in the expectation that

they would receive some kind of aid, although this would have applied to both case and comparison groups. Social desirability could also have led to minimisation of the true experience of food insecurity due to the sensitivity of the topic. There may have been inadequate adjustment for seasonal variation in food insecurity. Strengths of the study include the use of a culturally validated measure of food insecurity, use of standardised diagnostic assessment by mental health specialists to define SMD, the large sample size and the community-based ascertainment of cases which reduces the risk of selection bias.

Conclusions

People with SMD living in a rural Ethiopian district experienced higher levels of severe food insecurity than the general population. The inclusion and prioritisation of people with SMD in food security programmes and development opportunities, including income-generating opportunities and schemes should be ensured. This requires awareness-raising and tackling the stigma, which undermines inclusion of people with SMD. Increasing access to holistic mental health care is also expected to reduce food insecurity through a reduction in the disability associated with mental illness.

Supplementary material

The supplementary material for this article can be found at https://doi.org/10.1017/S2045796017000701

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Conflict of Interest

None.

Ethical Considerations

Ethical approval was obtained from the College of Health Sciences Institutional Review Board, Addis Ababa University (Ref. 026/15/Psy). Written informed consent was obtained from literate participants. For non-literate respondents, verbal consent was accompanied by a finger print in the presence of a literate witness. All participants with SMD were offered mental health care through the PRIME project. For people with SMD who lacked capacity to consent and were not refusing participation, caregiver permission was obtained.

Availability of Data and Materials

The data are being used for a PhD student (KT) for his thesis and are not, therefore, available at the present time to the general public. The data may be requested from the corresponding author for verification of the analyses in this paper.

References

Asher L, De-Silva M, Hanlon C, Weiss HA, Birhane R, Medhin G, Ejigu DA, Patel V, Fekadu A (2016). Community-based Rehabilitation Intervention for people with Schizophrenia in Ethiopia (RISE): study protocol for a cluster randomised controlled trial. *Trials* **17**, 299.

Azevedo MH, Soares MJ, Coelho I, Dourado A, Valente J, Macedo A, Pato M, Pato C (1999). Using consensus OPCRIT diagnoses. An efficient procedure for best-estimate lifetime diagnoses. *British Journal of Psychiatry* **175**, 154–157.

BasicNeeds (2008). *Mental Health and Development: A Model in Practice*. Leamington Spa: BasicNeeds.

Coates J, Swindale A, Bilinsky P (2007). *Household Food Insecurity Access Scale (HFIAS) for Measurement of Food Access: Indicator Guide*. Food and Nutrition Technical Assistance (FANTA) project. United States Agency for International Development: Washington, DC.

Cole S, Tembo G (2011). The effect of food insecurity on mental health: panel evidence from rural Zambia. *Social Science and Medicine* **73**, 1071–1079.

Collins L (2005). The impact of food insecurity on women's mental health. *Journal of the Association for Research on Mothering* **11**, 251–262.

Combaz E (2013). Social inclusion in productive safety net programmes. Help Desk Research Report. GSDRC, Applied Knowledge Services.

Dua T, Barbui C, Clark N, Fleischmann A, Poznyak V, van-Ommeren M, Taghi Yasamy MT, Ayuso- Mateos JL, Birbeck GL, Drummond C, Freeman M, Giannakopoulos P, Levav I, Obot IS, Omigbodun O, Patel V, Phillips M, Prince M, Rahimi-Movaghar A, Rahman A, Sander JW, Saunders JB, Servili C, Rangaswamy T, Unützer J, Ventevogel P, Vijayakumar L, Thornicroft G, Saxena S (2011). Evidence-based guidelines for mental, neurological, and substance use disorders in low- and middle-income countries: summary of WHO recommendations. *PLoS Medicine* **8**, e1001122.

Endalew B, Muche M, Tadesse S (2015). Assessment of food security situation in Ethiopia. *World Journal of Dairy and Food Sciences* **10**, 37–43.

Fekadu A, Medhin G, Selamu M, Hailemariam M, Alem A, Breuer E, Lund C, Prince M, Hanlon C (2014). Population level mental distress in rural Ethiopia. *BMC Psychiatry* **14**, 194.

Fekadu A, Medhin G, Kebede D, Alem A, Cleare AJ, Prince M, Hanlon C, Shibre T (2015). Excess mortality in severe mental illness: 10-year population-based cohort study in rural Ethiopia. *British Journal of Psychiatry* **206**, 289–296.

Fekadu A, Hanlon C, Medhin G, Alem A, Selamu M, Welde-Giorgis T, Shibre T, Teferra S, Tegegn T, Breuer E, Patel V, Tomlinson M, Thornicroft G, Prince M, Lund C (2016). Development of a scalable mental healthcare plan for a rural district in Ethiopia. *British Journal of Psychiatry* **208**, s4–s12.

Flyckt L, Lothman A, Jorgenson L, Rylander A, Koering T (2011). Burden of informal caregiving to patients with psychosis: a descriptive and methodological study. *International Journal of Social Psychiatry* **59**, 137–146.

Gebreyesus SH, Lunde T, HaileMariam D, Woldehanna T, Lindtjørn B (2015). Is the adapted Household Food Insecurity Access Scale (HFIAS) developed internationally to measure food insecurity valid in urban and rural households of Ethiopia? *BMC Nutrition* **1**, 2.

Goetz JR (2008). Exploring food insecurity among individuals with serious mental illness: a qualitative study. *Ph.D. Thesis*, University of Kansas, Kansas, USA.

Habtamu K, Alem A, Hanlon C (2015). Conceptualizing and contextualizing functioning in people with severe mental disorders in rural Ethiopia: a qualitative study. *BMC Psychiatry* **15**, 34.

Habtamu K, Alem A, Medhin G, Fekadu A, Dewey M, Prince M, Hanlon C (2017). Validation of the World Health Organization Disability Assessment Schedule in people with severe mental disorders in rural Ethiopia. *Health and Quality of Life Outcomes* **15**, 64.

Hadley C, Patil C (2006). Food insecurity in rural Tanzania is associated with maternal anxiety and depression. *American Journal of Human Biology* **18**, 359–368.

Hadley C, Tegegn A, Tessema F, Cowan JA, Asefa M, Galea S (2008). Food insecurity, stressful life events and symptoms of anxiety and depression in east Africa: evidence from the Gilgel Gibe growth and development study. *Journal of Epidemiology and Community Health* **62**, 980–986.

Hailemariam M, Fekadu A, Selamu M, Medhin G, Prince M, Hanlon C (2016). Equitable access to integrated primary mental healthcare for people with severe mental disorders in Ethiopia: a formative study. *International Journal for Equity in Health* **15**, 121.

Jebena M, Taha M, Nakajima M, Lemieux A, Lemessa F, Hoffman R, Tesfaye M, Tefera Belachew T, Workineh N, Kebede E, Tariku Y, Segni H, Kolsteren P, al'Absi M (2015). Household food insecurity and mental distress among pregnant women in southwestern Ethiopia: a cross-sectional study design. *BMC Pregnancy and Childbirth* **15**, 250.

Kempson KM, Keenan DP, Sadani PS, Ridlen S, Rosato NS (2002). Food management practices used by people with limited resources to maintain food sufficiency as reported by nutrition educators. *Journal of the American Dietetic Association* **102**, 1795–1799.

Lauritsen JM, Bruus M (2003–2008). EpiData (version 3). A comprehensive tool for validated entry and documentation of data (*ed. T. E. Association*): Odense, Denmark.

Lijalem M (2002). Assessment of nutritional status of people with major mental disorders and their controls in Meskan and Marako District (Butajira), Ethiopia. *MSc Thesis*, Addis Ababa University, Addis Ababa, Ethiopia.

Lund C, Breen A, Flisher AJ, Kakuma R, Corrigall J, Joska JA, Swartz L, Patel V (2010). Poverty and common mental disorders in low and middle income countries: a systematic review. *Social Science and Medicine* **71**, 517–528.

Lund C, Tomlinson M, De-Silva M, Fekadu A, Shidhaye R, Jordans M, Petersen I, Bhana A, Kigozi F, Prince M, Thornicroft G, Hanlon C, Kakuma R, McDaid D, Saxena S, Chisholm D, Raja S, Kippen-Wood S, Honikman S, Fairall L, Patel V (2012). PRIME: a programme to reduce the treatment gap for mental disorders in five low- and middle-income countries. *PLoS Medicine* **9**, e1001359.

Lund C, Waruguru M, Kingori J, Kippen-Wood S, Breuer E, Mannarath S, Raja S (2013). Outcomes of the mental health and development model in rural Kenya: a 2-year prospective cohort intervention study. *International Health* **5**, 43–50.

Maes K, Hadley C, Tesfaye F, Shifferaw S (2010). Food insecurity and mental health: surprising trends among community health volunteers in Addis Ababa, Ethiopia during the 2008 food crisis. *Social Science and Medicine* **70**, 1450–1457.

Mall S, Hailemariam M, Selamu M, Fekadu A, Lund C, Patel V, Petersen I, Hanlon C (2017). 'Restoring the person's life': a qualitative study to inform development of care for people with severe mental disorders in rural Ethiopia. *Epidemiology and Psychiatric Sciences* **26**, 43–52.

McGuffin P, Farmer AE, Harvey I (1991). A polydiagnostic application of operational criteria in studies of psychotic illness: development and reliability of the OPCRIT system. *Archives of General Psychiatry* **48**, 764–770.

Mengistu E, Regassa N, Yusufe A (2009). The Levels, Determinants and Coping Mechanisms of Food Insecure Households in Southern Ethiopia: Case Study of Sidama, Wolaita and Guraghe Zones. DCG Report No. 55.

Ministry of Agriculture (2014). Productive Safety Net Programme, Phase IV Programme Implementation Manual. 1.0.

Ministry of Agriculture and Rural Development (2009). *Food Security Programme 2010–2014: Productive Safety Net*. Addis Ababa.

Muldoon K, Duff P, Fielden SJ, Anema A (2013). Food insufficiency is associated with psychiatric morbidity in a nationally representative study of mental illness among food insecure Canadians. *Social Psychiatry and Psychiatric Epidemiology* **48**, 795–803.

Operational Criteria for Research (2004). Opcrit for Windows (v4), Item Checklist. Retrieved 14th January 2014 from sgdp.iop.kcl.ac.uk/opcrit/checklist.pdf.

Raja S, Underhill C, Shrestha P, Sunder U, Mannarath S, Kippen-Wood S, Patel V (2012). Integrating mental health and development: a case study of the basic needs model in Nepal. *PLoS Medicine* **9**, e1001261.

Regassa N, Stoecker BJ (2011). Household food insecurity and hunger among households in Sidama district, Southern Ethiopia. *Public Health Nutrition* **15**, 1276–1283.

Semrau M, Evans-Lacko S, Alem A, Ayuso-Mateos JL, Chisholm D, Gureje O, Hanlon C, Jordans M, Thornicroft G (2015). Strengthening mental health systems in low- and middle-income countries: the Emerald programme. *BMC Medicine* **13**, 79.

Shibre T, Negash A, Kullgren G, Kebede D, Alem A, Fekadu A, Fekadu D, Medhin G, Jacobsson L (2001). Perception of stigma among family members of individuals with schizophrenia and major affective disorders in rural Ethiopia. *Social Psychiatry and Psychiatric Epidemiology* **36**, 299–303.

Shibre T, Kebede D, Alem A, Negash A, Kibreab S, Fekadu A, Fekadu D, Jacobsson J, Kullgren G (2002). An evaluation of two screening methods to identify cases with schizophrenia and affective disorders in a community survey in rural Ethiopia. *International Journal of Social Psychiatry* **48**, 200–208.

Sorsdahl K, Slopen N, Siefert K, Seedat S, Stein DJ, Williams DR (2009). Household food insufficiency and mental health in South Africa. *Journal of Epidemiology and Community Health* **65**, 426e–431e.

StataCorp (1985–2013). STATA/SE 13.1. statacorp, college station, Texas USA.

Swindale A, Bilinsky P (2006). Development of a universally applicable household food insecurity measurement tool: process, current status, and outstanding issues. *Journal of Nutrition* **136**, 1449S-1452S.

Teferra S (2011). Studies on psychotic disorders in rural Ethiopia. *Umeå University Medical Dissertations*. New Series No 1427.

Teferra S, Hanlon C, Beyero T, Jacobsson L, Shibre T (2013). Perspectives on reasons for non-adherence to medication in persons with schizophrenia in Ethiopia: a qualitative study of patients, caregivers and health workers. *BMC Psychiatry* **13**, 168.

Trani J-S, Venkataraman H, Mishra N, Groce NE, Jadhav S, Deshpande S (2016). Mental illness, poverty and stigma in India: a case–control study. *BMJ Open* **5**, e006355.

United Nations (2015). Sustainable Development Goals: 17 Goals to transform the world. Retrieved 23 October 2016 from http://www.un.org/sustainabledevelopment/hunger/.

United States Department of Agriculture Economic Research Service (2016). Definitions of Food Security. Retrieved 12 January 2017 from https://www.ers.usda.gov/topics/food-nutrition-assistance/food-security-in-the-us/definitions-of-food-security.aspx.

Ustün TB, Chatterji S, Kostanjsek N, Rehm J, Kennedy C, Epping-Jordan J, Saxena S, von-Korff M, Pull C (2010). Developing the World Health Organization Disability Assessment Schedule 2.0. *Bulletin of the World Health Organization* **88**, 815–823.

Williams J, Farmer AE, Ackenheil M, Kaufmann CA, McGuffin P (1996). A multicentre inter-rater reliability study using the OPCRIT computerized diagnostic system. *Psychological Medicine* **26**, 775–783.

World Food Program (2016). Productive safety net program (PSNP): Ethiopia. Retrieved 29 November 2016 from https://www.wfp.org/sites/default/files/PSNP%20Factsheet.pdf.

World Health Organisation (1985). *World Health Organisation Disability Assessment Schedule*. WHO: Geneva.

World Health Organisation (2008). *WHO mhGAP: Mental Health Gap Action Programme: Scaling Up Care for Mental, Neurological and Substance use Disorders*. WHO: Geneva.

World Health Organisation (2013). *WHO Study on Global Ageing and Adult Health (SAGE)*. WHO: Geneva.

Xiong W, Philips M, Hu X, Wang R, Dai Q, Kleinman J, Kleinman A (1994). Family-based intervention for schizophrenia patients in China: a randomized control trial. *British Journal of Psychiatry* **165**, 239–247.

Appendix N. Sub-study-II: Published paper

Social Psychiatry and Psychiatric Epidemiology
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ORIGINAL PAPER

Food insecurity and work impairment in people with severe mental disorders in a rural district of Ethiopia: a cross-sectional survey

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Abstract

Purpose In this study, we aimed to identify factors associated with severe food insecurity and work impairment in people with severe mental disorders (SMD) in a rural African setting, with a view to identifying potential areas for intervention.

Methods A community-based, cross-sectional survey was conducted in Sodo district, south central Ethiopia. Key informant-identified people with possible SMD were referred for assessment by trained primary care workers and received confirmatory psychiatric diagnoses from psychiatric nurses using a standardized clinical interview. Food insecurity was measured using a locally validated measure, the Household Food Insecurity Access Scale (HFIAS). Work impairment was assessed using the Longitudinal Interval Follow-up Evaluation-Range of Impaired Functioning Tool. Potential moderator variables were specified a priori.

Results A total of 282 people with SMD participated in the study. The proportion of participants reporting severe food insecurity was 32.5% ($n=94$), with 53.6% ($n=147$) of participants reporting severe work impairment. In the multivariable model, severe food insecurity was associated with poor social support, experience of negative discrimination, higher disability and lower household annual income, but not with symptom severity or work impairment. Work impairment was associated significantly with symptom severity and disability.

Conclusion Work impairment and food insecurity were associated with distinct explanatory factors: predominantly social factors associated with food insecurity and clinical factors associated with work productivity. Longitudinal and intervention studies are needed to evaluate the extent to which clinical interventions need to be augmented by social interventions to alleviate food insecurity in people with SMD.

Keywords Psychosis · Schizophrenia · Bipolar disorder · Food insecurity · Work · Stigma and discrimination

Background

In many low-income countries, food insecurity is a pressing concern and thus ensuring food security for all segments of the population is a high priority. In a recent global analysis of 149 countries, the prevalence of any food insecurity ranged from 18.3% in the East Asian region to 76.1% in sub-Saharan Africa [1]. In Ethiopia, both chronic and transitory (seasonal) food insecurity are persistent problems for a large segment of the population [2]. The risk factors for food insecurity are low income [3], household structure and size [4] and living with disability [5].

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Severe mental disorders (SMD: including schizophrenia, bipolar disorder and depression with psychotic features) are associated with functional impairment [6], low levels of engagement in the workforce [7] and poor socioeconomic status [8]. In a qualitative study of key informants, including people with SMD and their caregivers, in rural Ethiopia, work impairment was described as one of the most important consequences of the illness [9], affected by a combination of stigma and discrimination, socio-economic status, substance use and the severity of symptoms. The consequences of not working may be particularly severe in low-income country settings, where food insecurity is a widespread concern for the rural population [1]. In a facility-based, case-control study in India, people with SMD were reported to be more deprived in terms of food insecurity (15.1% higher) compared to their controls [10]. In our previous study, we found

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that households of people with SMD in a rural district were more likely to be severely food insecure compared to households without a person living with SMD [11].

The importance of mental health for achieving the United Nations Sustainable Development Goals has been emphasized [12], particularly in relation to goals 1 (no poverty) and 2 (no hunger) by 2030. However, the factors associated with work impairment and food insecurity in people with SMD in LMICs have not been investigated in representative populations. A conceptual model for how SMD may be linked to food insecurity is presented in Fig. 1. Alcohol use disorder is known to complicate SMD [13] and is hypothesized to have an association with both work impairment and food insecurity in this study. The stigma associated with mental illness is high in this setting [14], with key informants reporting that stigma deprives people with SMD of full social participation, interpersonal relationships, marital and family life and even from employment [9], potentially leading to food insecurity.

The programme for improving mental health care (PRIME) [15] is a multi-country implementation research programme to implement and scale-up district-level mental health care plans which integrate mental health into primary care. PRIME brings together researchers, non-governmental organisations (NGOs), Ministry of Health partners and a range of local stakeholders in Ethiopia, India, Nepal, South Africa and Uganda.

In the present study, we aimed to identify the factors associated independently with the outcomes of severe food insecurity and work impairment in the PRIME sample of people with SMD. We hypothesized that food insecurity and work impairment would be related to one another but have distinct patterns of co-variates, and that associations would be modified by the level of social support.

Methods

Study design and period

A cross-sectional, community-based study was conducted between December 2014 and July 2015.

Setting

The study was conducted in Sodo district, in the Gurage Zone of the Southern Nations, Nationalities and Peoples' region of Ethiopia. The district is situated about 100 km from the capital city, Addis Ababa, and 88% of the population dwell in rural areas [16]. The official language of the district is Amharic. In common with many other rural areas in Ethiopia, the population of Sodo district engages in subsistence, non-industrialised farming. The main livelihoods are from mixed agriculture (farming of cereals, root crops or vegetables, planting trees, *Enset* [Ensete ventricosum or 'false banana'] which is a staple food in south and central Ethiopia and animal husbandry). No mental health service was available in the district at the time of

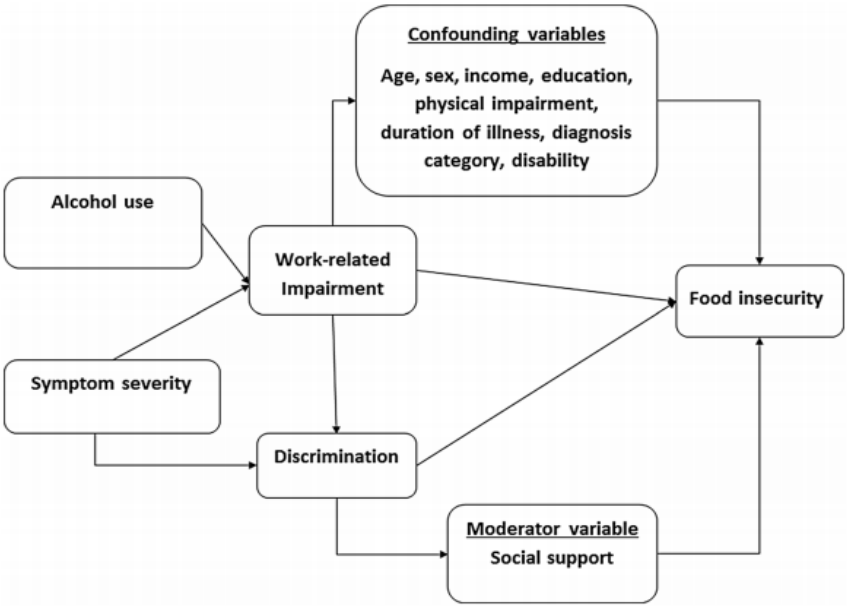

Fig. 1 A conceptual model for the relationship between severe mental disorder and food insecurity

the study. The data for this study were collected at the baseline of the PRIME intervention [11]. Sodo district was selected for the PRIME study on the basis of sharing characteristics of most districts in Ethiopia [17].

Participant recruitment

Community-based health extension workers, community leaders and project outreach workers were trained for half a day on familiar presentations of SMD and epilepsy in the local context [18]. They were then asked to identify and refer and people with possible SMD or epilepsy to the closest primary health care (PHC) facility. This approach to case ascertainment was found previously to be sensitive in a neighbouring district [19]. PHC staff had been trained in the World Health Organisation mental health Gap Action Program (mhGAP) and made an initial diagnostic assessment [20]. For people who received a PHC diagnosis of psychosis or bipolar disorder, an assessment by a psychiatric nurse was carried out using the OPerational CRITeria for research (OPCRIT) to confirm the diagnosis [21]. People with epilepsy that was not co-morbid with SMD were included in a different study. Senior psychiatrists from the PRIME project provided on-site supervision, reviewed the OPCRIT forms to identify any diagnostic uncertainty and carried out diagnostic re-assessment by reviewing the charts for all cases. The specific SMD diagnoses made using the diagnostic and statistical manual for mental disorders (DSM-V) [22] criteria were categorised into "primary psychotic disorder" (schizophrenia, schizoaffective disorder, schizophreniform disorder, brief psychotic disorder, acute psychosis) and "affective psychosis" (bipolar disorder and major depressive disorder with psychotic features).

People with confirmed SMD were then invited to participate in the study if they met the following eligibility criteria:

Inclusion criteria:

- Aged 18 years or older,
- Planning to stay resident in the district for the next 12 months,
- Provided informed consent (capacity to consent was evaluated by trained psychiatric nurses with a semi-structured assessment tool used previously in a similar rural Ethiopian setting [23]) or, if lacked capacity to consent, did not refuse and guardian permission was obtained.
- Psychiatric nurse confirmed diagnosis of schizophrenia or related psychotic disorder, bipolar disorder or depression with psychotic features using the OPCRIT, and
- Able to understand Amharic, the official language of Ethiopia and the working language of the study site.

Exclusion criteria:

- If additional SMD cases were identified from the same household, they were excluded from the cohort but provided with treatment.

Sample size

The sample size for this study was based on the sample size required by the PRIME study ($N = 300$) to detect functional improvement following the PRIME intervention [24].

Measures

Primary outcome: food insecurity

The household food insecurity access scale (HFIAS) was used to assess food insecurity [25]. The HFIAS questions relate to three different access domains of food insecurity: (1) anxiety and uncertainty about food supply, (2) insufficient quality (includes variety and preferences of the type of food), and (3) insufficient food intake and its physical consequences. Households are categorized as increasingly food insecure as they respond affirmatively to more severe conditions and/or experience those conditions more frequently. The HFIAS has been translated into Amharic [26], validated in a neighbouring district and used in several research studies in Ethiopia [27]. Recommended methodology was used to obtain the HFIAS categories of: food secure, mildly food insecure, moderately food insecure and severely food insecure. For data analysis, the HFIAS categories were collapsed to give two categories: (1) food secure/mildly food insecure/moderately food insecure and, (2) severely food insecure. This categorisation identified the most vulnerable group who would be the likely targets of future intervention and policy formulation.

Secondary outcome: work-related impairment

This was measured using the longitudinal interval follow-up evaluation-range of impaired functioning tool (LIFE-RIFT) [28]. The LIFE-RIFT is a clinician-administered tool utilizing information from the person, their caregiver and the clinician's judgment following comprehensive assessment. In this study the LIFE-RIFT was administered by psychiatric nurses. The LIFE-RIFT has been shown to be valid and reliable in high-income country settings [29] and to be acceptable, feasible and have convergent validity in the Ethiopian setting [personal communication, Fekadu, A., 2017].

The LIFE-RIFT comprises four major domains: work, interpersonal relations, satisfaction, and recreation [28]. The work domain covers employment, household and student sub-domains and assesses the degree to which a person's

current (past week) work activities have been impaired. Our analysis focused on the work domain alone.

Explanatory variables assessed by lay interviewers

Disability

The World Health Organisation Disability Assessment Schedule (WHODAS-2.0), 36-item version, which comprises six domains, was used to assess the degree of functional impairment [30]. The WHODAS 2.0 is based on the International Classification of Functioning, Disability and Health which can be applied to any health condition and is recommended by the DSM-V Disability Study Group as the best current measure of disability for research and routine clinical practice [31]. This measure has recently been validated for use in people with SMD in the neighboring district [32], which shares many agro-ecological features with the present study setting. The six domains of WHODAS are understanding and communicating, getting around, self-care, getting along with people, life activities (household or work/school) and participation in society. During analysis, the life activities domain was excluded to avoid potential overlap with the work impairment measures existing in the LIFE-RIFT measure. The simple WHODAS scoring method was used in this study.

Discrimination

Experience of negative discrimination was measured using the discrimination and stigma scale-12 (DISC-12) [33]. The DISC-12 is an interviewer-administered scale comprising four sections. Only the section on 'unfair treatment' was included in this study. The DISC-12 has been shown to be a reliable, valid, acceptable and feasible tool in high-income country settings [33], but has not been adapted previously for Ethiopia. There are five response options for DISC-12: "not at all", "a little", "moderately", "a lot" and "not applicable". Of the 21 items in section one, two items (unfair treatment in getting welfare benefits or disability pensions and unfair treatment in the level of privacy) were excluded due to lacking face validity or comprehensibility for the study area. We conducted exploratory factor analysis using pairwise polychoric correlation due to the missing data when the item was reported to be "not applicable". All items except item 14 (unfair treatment when getting help for physical health problems) and item 15 (unfair treatment from mental health professionals) loaded onto a single dimension. Items 14 and 15 had low frequency of endorsement (<5%) indicating that these are not salient indicators of discrimination in this setting. We, therefore, excluded items 14 and 15 and summed the remaining 17 items to give a total score indicating extent of experienced discrimination.

Socio-demographic characteristics, including age, sex and educational level, were obtained by self-report.

Alcohol use status was measured using the ten-item alcohol use disorder identification test (AUDIT) [34], which has been adapted and used in the Ethiopian setting [35].

Physical impairment was measured using the brief physical impairment checklist which was adapted by extracting items from the Washington Group General Disability Measure [36] and the Family and Wellbeing Index of physical impairment used in physical impairment and income study [37].

Annual household income and number of dependents was obtained from a household respondent and measured using items from the abbreviated version of the household survey instrument of the WHO study on global ageing and adult health which was conducted in six LMICs [38]. The measure consists of socio-economic, demographic, income and assets as its major components.

Explanatory variables assessed by clinicians

Symptom severity was assessed using the 24-item Brief Psychiatric Rating Scale-Expanded version, BPRS-E [39], which has been translated into Amharic and used in Ethiopia previously [40]. The BPRS-E is observer clinician-rated symptom scale. The clinical information on specific diagnosis and duration of illness was collected using the OPCRIT, as described above [21].

Potential moderator: social support

The level of social support was measured using the Oslo social support scale, OSS-3, which consists of three items covering the reported number of close friends and perceived concern and practical help received from others [41]. The OSS-3 was administered by trained lay interviewers. The OSS-3 has been used in previous community and facility-based studies in an Ethiopian setting and showed good utility [42]. OSS-3 total score was generated by summing up the scores as per the recommendations of the scale developers, followed by categorisation as follows: 3–8 "poor support", 9–11 "intermediate support" and 12–14 "strong support".

Training of lay interviewers

The lay interviewers were recruited from the study area, with a minimum educational level of tenth grade. Research assistants with masters level psychology, public health and social work qualifications trained the lay interviewers for 12 days. The training covered basic interviewing skills focusing on interviewing people with SMD and their caregivers, ethical considerations when interviewing people with mental health

problems, and in-depth training on the study measures. The training emphasized practice-oriented interview sessions.

Training of clinician assessors

Psychiatric nurses received 7 days of training from senior Ethiopian psychiatrists in the clinician-administered measures. The training included observed interviews and feedback, but formal inter-rater reliability was not undertaken.

Data management and quality assurance

Double data entry was carried out using EpiData software [43]. The first author and field supervisors provided close oversight of data collection by the lay interviewers. Psychiatrists supervised the clinical interviews. Random quality checks of questionnaires were carried out by the field supervisor and first author. The confidentiality of responses given by the respondents was ensured.

Data analysis

STATA software version 13.1 [44] was used for data analysis. The sociodemographic characteristics of study participants were summarized using descriptive statistical measures (frequencies, percentages, mean and median). Variables included in the multivariable model were those anticipated to have associations with the outcome variables on the basis of existing literature and our conceptual framework (Fig. 1). Multiple logistic regression was used to explore the factors associated with severe food insecurity and work-related impairment. Potential effect modification for the association between food insecurity and disability as well as between disability and work impairment by level of social support was explored using the Mantel–Haenszel test of homogeneity.

Ethical considerations

Ethical approval was obtained from Addis Ababa University, the College of Health Sciences, Institutional Review Board (Ref. 026/15/psy) and the Human Research Ethics Committee at the Faculty of Health Sciences, University of Cape Town (HREC REF: 412/2011). Written informed consent was obtained from the person with SMD or their caregiver, if the person with SMD lacked capacity to make the decision to participate. Non-literate participants gave finger-prints to signify their willingness to participate. Free primary care-based mental health treatment was provided via the PRIME project.

Results

Of the 1033 referred people with possible SMD or epilepsy, a total of 300 were confirmed to have SMD. See Fig. 2 for reasons for exclusion. Of the 300 people with SMD, a total of 282 eligible people with SMD were included in the study: 5 households had more than one household member with SMD and 13 cases had missing data relevant to the analyses in this paper.

Sample characteristics

Most participants were Orthodox Christians and Gurage by ethnicity (Table 1). Fewer than half of participants had attended formal education ($n = 134$; 47.5%). Most

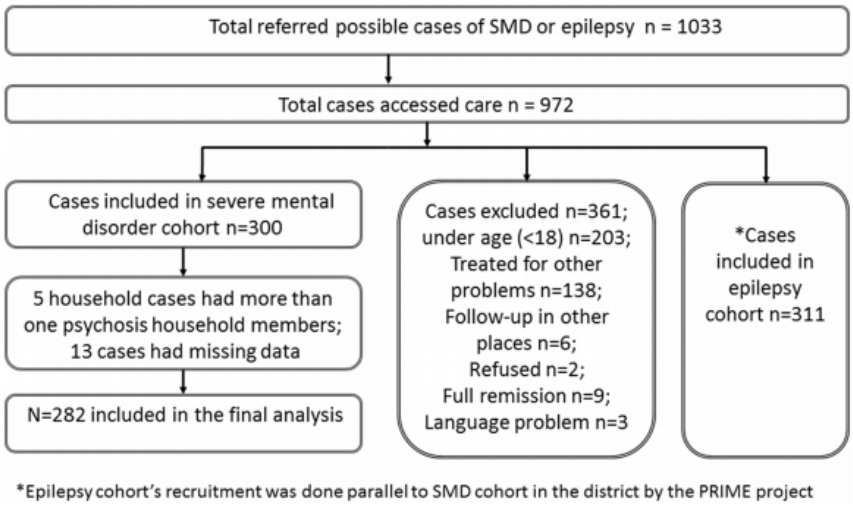

Fig. 2 Participant flow chart

Table 1 Sociodemographic and clinical characteristics of study participants

Characteristics	Frequency	Percent
Educational level		
Formal education	134	47.5
No-formal education	148	52.5
Sex		
Female	122	43.3
Male	160	56.7
Residence		
Urban	59	21.0
Rural	222	79.0
Occupation		
Unemployed	87	31.1
Agriculture	70	25.0
Housewife	57	20.4
Other	66	23.5
Marital status		
Single	124	44.0
Married	97	34.4
Divorced	40	14.2
Other	21	7.4
Ethnicity		
Gurage	268	95.0
Oromo	10	3.5
Other	4	1.5
Religion		
Orthodox Christian	254	90.1
Protestant	18	6.4
Muslim	9	3.2
Others	1	0.4
Oslo social support		
Intermediate/strong support	195	69.6
Poor support	85	30.4
AUDIT		
AUDIT score < 8	197	69.9
AUDIT score ≥ 8[c]	85	30.1
Diagnosis category		
Primary psychotic disorder	242	85.8
Affective psychosis	40	14.2
	Mean	Standard deviation
Age (years)	35.6	13.38
Month of assessment[a]	4.3	3.31
	Median	25th, 75th centiles
Number of children	3	2, 5
Annual income (ETB)[b]	6000	3000, 10 750
DISC total	2	0, 7
Physical impairment total	1	0, 3
BPRS-E total	48	35, 59
Duration of illness (years)	8	3, 20

WHODAS World Health Organization Disability Assessment Schedule, *LIFE-RIFT* longitudinal interval follow-up evaluation-range of impaired functioning tool, *DISC* discrimination and stigma scale, *BPRS-E* brief psychiatric rating scale-expanded version

[a]Months numbered as of January

[b]*ETB* Ethiopian Birr [USD ≈ 20.5 Birr (for 2015)], *AUDIT* alcohol use disorder identification test

[c]Includes hazardous use, harmful use and dependence

participants ($n = 242$; 85.8%) had a diagnosis of a primary psychotic disorder, with 40 (14.2%) having an affective disorder. The median BPRS-E score (symptom severity) was 48, [interquartile range (IQR) 35, 59]. The median duration of illness was 8 years (IQR 3, 20). During initial assessment, only 35.0% of participants reported taking antipsychotic medication.

Food insecurity and work impairment

One-third ($n = 94$; 32.5%) of households reported severe food insecurity, with a median HFIAS score of 15 (IQR 10). More than half (53.6%) of the participants had severe work impairment.

Multivariable analyses

1. Food insecurity

   In the fully adjusted model, severe food insecurity was associated with poor social support (adjusted odds ratio (aOR) 2.87; 95% CI 1.48, 5.55), negative experienced discrimination (aOR 1.08; 95% CI 1.03, 1.14), lower annual income (aOR 4.52; 95% CI 2.08, 9.81) and higher disability scores (aOR 1.02; 95% CI 1.00, 1.04), but not with symptom severity or work impairment (Table 2). Alcohol use disorder, symptom severity and physical impairment were associated with food insecurity in the crude analyses but not in the multivariable model. There was no evidence of effect modification by social support level in the association between severe food insecurity and disability (Mantel–Haenszel test of homogeneity: $p = 0.3947$).
2. Work-related impairment

   In the fully adjusted model (Table 3), work impairment was associated independently with symptom severity (adjusted OR 1.03; 95% CI 1.01, 1.06) and disability (adjusted OR 1.04; 95% CI 1.03, 1.06). Having no for-

Table 2 Factors associated with severe food insecurity in people with severe mental disorder

Characteristics	Crude odds ratio (95% confidence interval) $n=282$	Adjusted odds ratio[b] (95% confidence interval) $n=261$
Symptom severity (BPRS-E total score) [$n=279$]	**1.02 (1.00, 1.03)**	1.01 (0.98, 1.03)
Oslo social support scale [$n=277$]		
Intermediate/strong social support	Reference	Reference
Poor social support	**3.42 (1.99, 5.86)**	**2.87 (1.48, 5.55)**
Alcohol use disorder identification test [$n=279$]		
AUDIT < 8	Reference	Reference
AUDIT ≥ 8[a]	**2.00 (1.17, 3.41)**	1.12 (0.53, 2.38)
Physical impairment total [$n=279$]	**1.37 (1.15, 1.64)**	1.17 (0.93, 1.47)
Discrimination (DISC-12 total score) [$n=279$]	**1.13 (1.08, 1.18)**	**1.08 (1.03, 1.14)**
Work impairment [$n=271$]		
No/mild/moderate work impairment	Reference	Reference
Severe work impairment	1.30 (0.78, 2.17)	0.95 (0.46, 1.93)
Disability (WHODAS score)[c] [$n=279$]	**1.03 (1.02, 1.04)**	**1.02 (1.00, 1.04)** ±
Age (years)	1.00 (0.98, 1.02)	1.01 (0.98, 1.03)
Sex (male) [$n=279$]	0.90 (0.54, 1.49)	1.17 (0.59, 2.31)
Education [$n=279$]		
Formal education	Reference	Reference
No formal education	1.06 (0.64, 1.74)	0.63 (0.31, 1.25)
Annual household income (Birr)[d] [$n=269$]		
10,000 Birr or more/year	Reference	Reference
4000–9999 Birr/year	**2.05 (1.04, 4.05)**	1.74 (0.79, 3.78)
< 4000 Birr/year	**4.83 (2.47, 9.41)**	**4.52 (2.08, 9.81)**
Duration of illness (years) [$n=279$]	1.00 (0.98, 1.02)	1.00 (0.97, 1.03)
Diagnosis category [$n=279$]		
Affective psychosis	Reference	Reference
Primary psychotic disorder	1.57 (0.73, 3.36)	1.41 (0.56, 3.59)

BPRS-E brief psychiatric rating scale-expanded version

[a]Includes hazardous use, harmful use and dependence, *WHODAS* World Health Organization Disability Assessment Schedule

[b]Adjusted for all factors listed in the table

[c]Excluding work domain ±$p=0.021$

[d]1 USD ≈ 20.5 Birr (for 2015); values in bold are statistically significant

mal education was associated with work-related impairment in the crude, but not the adjusted, analyses. There was no evidence of effect modification by level of social support in the association between disability and work impairment level (Mantel–Haenszel test of homogeneity: $p=0.4593$).

Discussion

In this community-based sample of people with SMD from a rural Ethiopian district, work impairment and food insecurity were found to be associated with distinct, but overlapping, sets of explanatory factors: predominantly social factors associated with food insecurity and clinical factors associated with work productivity.

Food insecurity

In our previous study, we found that people with SMD reported more than double the level of severe food insecurity compared to the general population (32.5% vs. 15.9%) [11]. In this current study, food insecurity in people with SMD was associated with poor social support, lower income, negative discrimination and functional impairment, but was not associated directly with clinical symptom severity. In cultures valuing the needs of a group or community over an individual, such as that encountered in the rural Ethiopian setting, it is commonly assumed that high levels of social support will be provided to people with mental health or other health problems. However, about one-third (30.4%) of our sample reported poor social support. This level of social support was better than that

Table 3 Factors associated with work impairment in people with severe mental disorder

Characteristics	Crude odds ratio (95% confidence interval) $n=282$	Adjusted odds ratio[b] (95% confidence interval) $n=264$
Symptom severity (BPRS-E total score) [$n=274$]	**1.06 (1.04, 1.07)**	**1.03 (1.01, 1.06)**
Oslo social support scale [$n=273$]		
Poor social support	Reference	Reference
Intermediate/strong social support	0.87 (0.52, 1.46)	0.73 (0.38, 1.38)
Alcohol use disorder identification test [$n=274$]		
AUDIT ≥ 8[a]	Reference	Reference
AUDIT <8	0.84 (0.50, 1.41)	0.61 (0.30, 1.23)
Physical impairment total score [$n=274$]	1.13 (0.95, 1.34)	0.96 (0.77, 1.18)
Age (years) [$n=274$]	0.99 (0.97, 1.01)	0.98 (0.96, 1.02)
Sex (male) [$n=274$]	1.07 (0.66, 1.73)	0.66 (0.34, 1.25)
Education [$n=274$]		
Formal education	Reference	Reference
No formal education	**1.63 (1.01, 2.63)**	1.29 (0.69, 2.42)
Discrimination (DISC-12 total score) [$n=274$]	1.00 (0.97, 1.03)	0.98 (0.94, 1.02)
Disability (WHODAS score)[c]	**1.05 (1.03, 1.06)**	**1.04 (1.03, 1.06)**
Annual household income (Birr)[d] [$n=264$]		
10,000 Birr or more/year	Reference	Reference
4000-9999 Birr/year	1.11 (0.62, 2.00)	1.06 (0.53, 2.13)
<4000 Birr/year	0.99 (0.55, 1.78)	0.96 (0.47,1.97)
Duration of illness (total years) [$n=274$]	0.98 (0.97, 1.00)	1.00 (0.97, 1.03)
Diagnosis category [$n=274$]		
Affective psychosis	Reference	Reference
Primary psychotic disorder	1.26 (0.64, 2.48)	0.84 (0.37, 1.89)

[a]Includes hazardous use, harmful use and dependence

[b]Adjusted for all factors listed in the table

[c]Without work domain during computation

[d]1 USD $\approx$ 20.5 Birr (for 2015); values in bold are statistically significant

seen in the general population in the same district (poor support reported by 40.8%) [42], which may reflect some mobilization of community support for people with SMD, albeit inadequate to address food security needs. In our qualitative work with people with SMD from the same sample, the restrictions experienced in accessing social networks were highlighted [45]. Social connectedness relies upon the capacity of a person to reciprocate; SMD may directly (via disability) and indirectly (via worsened poverty) undermine the possibility of reciprocation. People who lack interpersonal supports may then be less able to avail themselves of social opportunities which are often tied to economic opportunities, including obtaining competitive jobs and satisfactory housing [46], accessing livelihoods or obtaining financial support.

Higher perceived negative discrimination was also associated with food insecurity. Stigma and discrimination work directly against recovery in people with SMD, leading to and reinforcing social exclusion at both an individual, household and community level [47]. Because of public misconceptions about SMDs, members of society may withhold opportunities [48] and societal prejudice can significantly exacerbate the impact that psychiatric symptoms have on social opportunities [46]. In this way, the social exclusion associated with discrimination against a person or household with SMD may lead to loss of economic opportunities and financial support, and subsequent impoverishment and food insecurity. The Ethiopian Federal Ministry of Health has included mental health in the training programme to upgrade community health extension workers, including interventions to increase community awareness about the treatability of mental health problems and to counter stigmatizing attitudes [49]. Our previous work has shown that stigmatizing attitudes in health extension workers in relation to child developmental disorders are reduced by this intervention [50]. The impact of this programme on households of a person with SMD has yet to be evaluated.

Low household income was also associated with severe food insecurity in the multivariable model. This indicates that intervention programs for people with SMD may need to

include income generation, livelihood and employment opportunities. This finding is in keeping with previous recommendations that people with SMD should be considered a vulnerable group and prioritized in community development efforts [8].

Work impairment

In this study, around half of the participants reported severe work impairment. This is noteworthy because, in the seminal World Health Organization (WHO)-led studies from the 1970s of people with SMD in LMICs, employment outcomes were found to be more favourable when compared to people with SMD in high-income country settings [51, 52]. In the follow-up WHO study, conducted in the 1980s and 1990s, the proportion of participants in LMICs diagnosed with "all psychoses" and reporting working (doing housework or paid work) was higher (79%) for most of the last 2 years compared with that of high-income settings (51%) [53]. The WHO studies have been critiqued for possible selection bias, not accounting for differential mortality and the measures used for work functioning [54]. In our study, use of the LIFE-RIFT measure may have enabled us to assess work impairment in a more comprehensive way, based on clinician judgement and drawing on all sources of information available (person with SMD, caregiver and clinical notes). Societal changes, including urbanization, may also be contributing to the higher levels of work impairment seen in our study [55].

Symptom severity and disability levels were associated strongly with work impairment, indicating that improved access to adequate mental health care may be able to support improved work functioning. However, in keeping with our proposed conceptual model, clinical symptom severity and work impairment may not determine household food insecurity, which may require interventions tackling discrimination, social isolation and potentially income security.

Strengths and limitations

Our study has a number of strengths: the population-based ascertainment of participants, as well as the use of trained clinician assessors, validated and standardized measures, and highly trained and experienced interviewers who were familiar with the sociocultural context.

In terms of limitations, we relied on self-report of physical impairment and did not measure physical ill-health in the study sample. Given the high burden of physical health problems in people with SMD [56], this could have led us to incorrectly attributing impact on work impairment and food insecurity to SMD. We also did not measure medication side effects which could adversely affect work capacity [57], although most participants were not taking psychotropic medication at the time of the study. It is possible that poverty, disability, discrimination and poor social support are all proxies for more severe and enduring illness which is then associated with food insecurity, but this is unlikely as we were able to adjust for symptom severity and duration of illness. Finally, due to the cross-sectional design, our study was also not able to draw any conclusions regarding temporal relationships or causality.

Conclusions

The complex relationships between social support, income, discrimination, illness-related disability, work impairment and food insecurity require further elucidation in a prospective study to identify the best targets for intervention. The findings from this study indicate that food insecurity in people with SMD is not just a consequence of illness severity. Although expanding access to care has the potential to improve clinical outcomes, reduce disability and improve the individual person's capacity to work, amelioration of household level food insecurity may need to additionally attend to social support, discrimination and access to livelihoods. This may require multi-sectoral working and engagement with community organisations and non-governmental organisations. The findings from this study are likely to be generalizable to other rural, food-insecure populations of sub-Saharan Africa.

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Authors' contributions KT, CL, AF and CH designed the study. KT and CH analyzed the data. KT drafted the manuscript and received critical feedbacks from (CL, KH, GM, YHM, AF and CH). All co-authors (CL, KH, GM, YHM, AF and CH) read and approved the final version of the manuscript and agreed on its submission for publication.

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Availability of data and materials The data are being used for a PhD student (KT) for his thesis and are not, therefore, available at the present time to the general public. The data may be requested from the corresponding author for verification of the analyses in this paper.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical statement This study was approved by the Institutional Review Board of Addis Ababa University (Ref. 026/15/psy) and the Human Research Ethics Committee at the Faculty of Health Sciences, University of Cape Town (HREC REF: 412/2011). Study participants were 18 years and older, and written informed consent was sought before data collection from the person with SMD or their caregiver, if the person with SMD lacked capacity to make the decision to participate. Non-literate participants

gave finger-prints to signify their willingness to participate. Free primary care-based mental health treatment was provided via the PRIME project.

References

1. Jones A (2017) Food insecurity and mental health status: a global analysis of 149 countries. Am J Prev Med 53(2):264–273
2. Mengistu E, Regassa N, Yusufe A (2009) The levels, determinants and coping mechanisms of food insecure households in Southern Ethiopia: case study of Sidama, Wolaita and Guraghe Zones Oslo: Drylands Coordination Group Report no. 55
3. Ashiabi G, O'Neal K (2008) A framework for understanding the association between food insecurity and children's developmental outcomes. Child Dev Perspect 2:71–77
4. Hailu A, Regassa N (2007) Correlates of household food security in densely populated areas of southern Ethiopia: does the household structure matter? Stud Home Community Sci 1(2):85–91
5. Brucker D, Mitra S, Chaitoo N, Mauro J (2015) More likely to be poor whatever the measure: working-age persons with disabilities in the United States. Soc Sci Q 96(1):273–296
6. Whiteford H, Ferrari A, Degenhardt L, Feigin V, Vos T (2015) The global burden of mental, neurological and substance use disorders: an analysis from the Global Burden of Disease Study 2010. PLoS One 10(2):e0116820
7. Mojtabai R, Stuart E, Hwang I, Susukida R, Eaton W, Sampson N et al (2015) Long-term effects of mental disorders on employment in the National Comorbidity Survey 10-year follow-up. Soc Psychiatry Psychiatr Epidemiol 50(11):1657–1668
8. World Health Organization (2010) Mental Health and Poverty Project Mental health and development: targeting people with mental health conditions as a vulnerable group. WHO, Geneva
9. Habtamu K, Alem A, Hanlon C (2015) Conceptualizing and contextualizing functioning in people with severe mental disorders in rural Ethiopia: a qualitative study. BMC Psychiatry 15:34
10. Trani J-S, Venkataraman H, Mishra N, Groce NE, Jadhav S, Deshpande S (2016) Mental illness, poverty and stigma in India: a case–control study. BMJ Open 5:e006355
11. Tirfessa K, Lund C, Medhin G, Hailemichael Y, Fekadu A, Hanlon C (2017) Food Insecurity among people with severe mental disorder in a rural Ethiopian setting: a comparative, population-based study. Epidemiol Psychiatr Sci, pp 1–11 **(Epub ahead of print)**
12. Patel V, Saxena S, Lund C, Thornicroft G, Baingana F, Bolton P et al (2018) The Lancet Commission on global mental health and sustainable development. Lancet 392:1553–1598
13. Drake R, Brunette M (1998) Complications of severe mental illness related to alcohol and drug use disorders. Recent Dev Alcohol 14:285–299
14. Shibre T, Negash A, Kullgren G, Kebede D, Alem A, Fekadu A, Fekadu D, Medhin G, Jacobsson L (2001) Perception of stigma among family members of individuals with schizophrenia and major affective disorders in rural Ethiopia. Soc Psychiatry Psychiatr Epidemiol 36:299–303
15. Lund C, Tomlinson M, De-Silva M, Fekadu A, Shidhaye R, Jordans M et al (2012) PRIME: a programme to reduce the treatment gap for mental disorders in five low- and middle-income countries. PLoS Med 9(12):e1001359
16. Federal Democratic Republic of Ethiopia (2008) Summary and statistical report of the 2007 population and housing census: population size by age and sex. Population Census Policy, Addis Ababa
17. Hanlon C, Luitel NP, Kathree T, Murhar V, Shrivasta S, Medhin G, Ssebunnya J, Fekadu A, Shidhaye R, Petersen I et al (2014) Challenges and opportunities for implementing integrated mental health care: a district level situation analysis from five low- and middle-income countries. PLoS One 9(2):e88437
18. Fekadu A, Hanlon C, Medhin G, Alem A, Selamu M, Welde-Giorgis T et al (2016) Development of a scalable mental healthcare plan for a rural district in Ethiopia. Br J Psychiatry 208:S4–S12
19. Shibre T, Kebede D, Alem A, Negash A, Kibreab S, Fekadu A et al (2002) An evaluation of two screening methods to identify cases with schizophrenia and affective disorders in a community survey in rural Ethiopia. Int J Soc Psychiatry 48(3):200–208
20. World Health Organization (2008) Mental health gap action programme (mhGAP): scaling up care for mental, neurological, and substance use disorders. WHO, Geneva
21. McGuffin P, Farmer AE, Harvey I (1991) A polydiagnostic application of operational criteria in studies of psychotic illness: development and reliability of the OPCRIT system. Arch Gen Psychiatry 48:764–770
22. American Psychiatric Association (2013) Diagnostic and statistical manual of mental disorders (DSM-V), 5th edn. American Psychiatric Publishing, Washington, DC
23. Hanlon C, Alem A, Medhin G, Shibre T, Ejigu DA, Negussie H, Dewey M, Wissow L, Prince M, Susser E et al (2016) Task sharing for the care of severe mental disorders in a low-income country (TaSCS): study protocol for a randomised, controlled, non-inferiority trial. Trials 17:76. https://doi.org/10.1186/s13063-13016-11191-x
24. Baron EC, Rathod SD, Hanlon C, Prince M, Fedaku A, Kigozi F, Jordans M, Luitel NP, Medhin G, Murhar V et al (2018) Impact of district mental health care plans on symptom severity and functioning of patients with priority mental health conditions: the programme for improving mental health care (PRIME) cohort protocol. BMC Psychiatry 18(1):61
25. Coates J (2004) Experience and expression of food insecurity across cultures: practical implications for valid measurement: Food and Nutrition Technical Assistance Project, Academy for Educational Development. Cooperative Agreement No. HRN-A-00–98–00046–00. Sponsored by the United States Agency for International Development. http://www.fantaproject.org/downloads/pdfs/Experience_Apr04.pdf. Cited 11 Aug 2005
26. Gebreyesus SH, Lunde T, Mariam DH, Woldehanna T, Lindtjørn B (2015) Is the adapted household food insecurity access scale (HFIAS) developed internationally to measure food insecurity valid in urban and rural households of Ethiopia? BMC Nutr 1:2. https://doi.org/10.1186/2055-0928-1181-1182
27. Jebena M, Taha M, Nakajima M, Lemieux A, Lemessa F, Hoffman R et al (2015) Household food insecurity and mental distress among pregnant women in southwestern Ethiopia: a cross-sectional study design. BMC Pregnancy Childbirth 15:250. https://doi.org/10.1186/s12884-12015-10699-12885
28. Leon AC, Solomon DA, Mueller TI, Turvey CL, Endicott J, Keller MB (1999) The range of impaired functioning tool (LIFE–RIFT): a brief measure of functional impairment. Psychol Med 29(04):869–878
29. Judd L, Akiskal H, Schettler P, Endicott J, Leon A, Solomon D, Coryell W, Maser J, Keller M (2005) Psychosocial disability in the course of bipolar I and II disorder. Arch Gen Psychiatry 62(12):1322–1330
30. World Health Organisation (1985) Disability assessment schedule. WHO, Geneva

31. Gold L (2014) DSM-5 and the assessment of functioning: the World Health Organization Disability Assessment Schedule 2.0 (WHODAS 2.0). J Am Acad Psychiatry Law 42:173–181
32. Habtamu K, Alem A, Medhin G, Fekadu A, Dewey M, Prince M, Hanlon C (2017) Validation of the World Health Organization Disability Assessment Schedule in people with severe mental disorders in rural Ethiopia. Health Qual Life Outcomes 15:64. https://doi.org/10.1186/s12888-12015-10418-12889
33. Brohan E, Clement S, Rose D, Sartorius N, Thornicroft G (2013) Development and psychometric evaluation of the Discrimination and Stigma Scale (DISC). Psychiatry Res 208:33–40
34. WHO (2001) WHO AUDIT: the alcohol usedisorders identification test:guidelines for use in primary care, 2nd edn. WHO, Geneva
35. Fekadu A, Hanlon C, Gebre-Eyesus E, Agedew M, Solomon H, Teferra S, Gebre-Eyesus T, Baheretibeb Y, Medhin G, Shibre T et al (2014) Burden of mental disorders and unmet needs among street homeless people in Addis Ababa, Ethiopia. BMC Med 12:138
36. Palmer M, Harley D (2012) Models and measurement in disability: an international review. Health Policy Plan 27(5):357–364
37. Mirowsky J, Hu PN (1996) physiacl impairment and the diminishing effects of income. Soc Forces 74(3):1073–1096
38. WHO (2013) WHO study on global ageing and adult health (SAGE). WHO, Geneva
39. Overall J, Gorham D (1962) The brief psychiatric rating scale. Psychol Rep 10:799–812
40. Youngmann R, Zilber N, Workneh F, Giel R (2008) Adapting the SRQ for Ethiopian populations: a culturally sensitive psychiatric screening instrument. Transcult Psychiatry 45(4):566–589
41. Brevik J, Dalgard O (1996) The health profile inventory. University of Oslo, Oslo
42. Fekadu A, Medhin G, Selamu M, Hailemariam M, Alem A, Breuer E et al (2014) Population level mental distress in rural Ethiopia. BMC Psychiatry 14:194 **(1471-1244X/1414/1194)**
43. Lauritsen JM, Bruus M (2003) Epidata (Version 3). A comprehensive tool for validated entry and documentation of data. The Epidata Association, Odense, Denmark
44. StataCorp LP (2016) Stata version 13.1. Texas, USA
45. Hailemariam M, Fekadu A, Selamu M, Medhin G, Prince M, Hanlon C (2016) Equitable access to integrated primary mental healthcare for people with severe mental disorders in Ethiopia: a formative study. Int J Equity Health 15:121
46. Corrigan PW, Penn D (1997) Disease and discrimination: two paradigms that describe severe mental illness. J Mental Health 6(4):355–366
47. Lapsley H, Nikora L, Black R (2002) "Kia Mauri Tau!": Narratives of Recovery from Disabling Mental Health Problems, Report of the University of Waikato Mental Health Narratives Project Mental Health Commission, Wellington
48. Stephens CL, Belisle KC (1993) The 'consumer as provider' movement. J Mental Health Adm 20:178–182
49. Open University. Health education and training programme (HEAT). http://www.open.ac.uk/africa/heat/. Accessed 16 Apr 2019
50. Tilahun D, Hanlon C, Fekadu A, Tekola B, Baheretibeb Y, Hoekstra R (2016) Stigma, explanatory models and unmet needs of caregivers of children with developmental disorders in a low-income African country: a cross-sectional facility based survey. BMC Health Serv Res 16:152
51. WHO (1973) Report of the International Pilot Study of Schizophrenia. Report. WHO, Geneva
52. WHO (1979) Schizophrenia: an international follow-up study. Wiley, Chichester
53. Hopper K, Wanderling J (2000) Revisiting the developed versus developing country distinction in course and outcome in schizophrenia: results from ISoS, the WHO collaborative followup project. Schizophr Bull 26(4):835–846
54. Cohen A, Patel V, Thara R, Gureje O (2008) Questioning an axiom: better prognosis for schizophrenia in the developing world? Schizophr Bull 34(2):229–244
55. United Nations (2018) Department of Economic and Social Affairs World Urbanisation Prospects 2018. In.: https://population.un.org/wup/Country-Profiles/. Accessed 28 March 2019
56. Cuc M, Bobes J, Cetkovich-Bakmas M, Cohen D, Asai Itsuo, Detraux J, Gautam S, Möller H-J, Ndetei D, Newcomer J et al (2011) Physical illness in patients with severe mental disorders: I Prevalence, impact of medications and disparities in health care. World Psychiatry 10(1):52–77
57. Khalema NE, Shankar J (2014) Perspectives on employment integration, mental illness and disability, and workplace health. Adv Public Health. https://doi.org/10.1155/2014/258614

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Appendix O. Sub-study-III: Submitted manuscript

Tropical Medicine & International Health

Impact of integrated mental healthcare on food insecurity of households of people with severe mental illness in a rural African district: a community-based, controlled before-after study

--Manuscript Draft--

Manuscript Number:	
Full Title:	Impact of integrated mental healthcare on food insecurity of households of people with severe mental illness in a rural African district: a community-based, controlled before-after study
Article Type:	Original Research Paper
Keywords:	Poverty; mental illness; schizophrenia; bipolar disorder; sub-Saharan Africa; task-sharing
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Abstract:	Objectives The objectives of the study were to (1) Evaluate the impact of integrated mental healthcare upon food insecurity (FI) in households of people with SMI in a rural Ethiopian district, and (2) investigate mediation by improved work impairment and discrimination. Methods A community-based, controlled before-after study was conducted. People with probable SMI were identified in the community, diagnosed by primary healthcare workers, with diagnostic confirmation from a psychiatric nurse. Households of a person with SMI were matched to control households. District wide integration of mental healthcare was implemented. Change in FI status over 12 months follow-up was measured using the Household Food Insecurity Access Scale. Multivariable models were used to assess improvement in FI. Direct and indirect mediators of change in FI status were modelled using path analysis.

	Results A total of 239 (81.8%) people with SMI and 273 (96.5%) control households were assessed after 12 months. Improvement in food insecurity status was observed in 43.5% of households of a person with SMI compared to 30.2% of control households (adjusted risk ratio 1.68: 95%CI 1.24, 2.26). Reduction in symptom severity was indirectly associated with improved FI status via an impact on reducing work impairment and discrimination ($p<0.001$). Conclusions Improving access to mental healthcare may reduce food insecurity in households of people with SMI. Optimising engagement in care and adding interventions to improve work functioning and tackle discrimination may further reduce food insecurity.

Impact of integrated mental healthcare on food insecurity of households of people with severe mental illness in a rural African district: a community-based, controlled before-after study

Short title: Impact of mental health care on food insecurity for people with severe mental illness

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Abstract

Objectives

The objectives of the study were to (1) Evaluate the impact of integrated mental healthcare upon food insecurity (FI) in households of people with SMI in a rural Ethiopian district, and (2) investigate mediation by improved work impairment and discrimination.

Methods

A community-based, controlled before-after study was conducted. People with probable SMI were identified in the community, diagnosed by primary healthcare workers, with diagnostic confirmation from a psychiatric nurse. Households of a person with SMI were matched to control households. District wide integration of mental healthcare was implemented. Change in FI status over 12 months follow-up was measured using the Household Food Insecurity Access Scale. Multivariable models were used to assess improvement in FI. Direct and indirect mediators of change in FI status were modelled using path analysis.

Results

A total of 239 (81.8%) people with SMI and 273 (96.5%) control households were assessed after 12 months. Improvement in food insecurity status was observed in 43.5% of households of a person with SMI compared to 30.2% of control households (adjusted risk ratio 1.68: 95%CI 1.24, 2.26). Reduction in symptom severity was indirectly associated with improved FI status via an impact on reducing work impairment and discrimination ($p<0.001$).

Conclusions

Improving access to mental healthcare may reduce food insecurity in households of people with SMI. Optimising engagement in care and adding interventions to improve work functioning and tackle discrimination may further reduce food insecurity.

Key words

Food security; poverty; mental illness; schizophrenia; bipolar disorder; sub-Saharan Africa; task-sharing; community mental health care

Declaration of interest

None

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Background

Severe mental illnesses (SMI; including psychotic disorders and bipolar disorder) are associated with recurrent or enduring work impairment (1), lower employment levels (2) and increased risk of poverty (3). For people with SMI living in low- and middle-income countries (LMICs), the situation can be particularly stark due to limited access to disability payments or other forms of social welfare (3). Indeed, we found previously that one-third of households of a person with SMI in a rural Ethiopian community were affected by severe food insecurity, an extreme manifestation of poverty (4). This level of food insecurity was significantly higher than that seen in the general population.

Although poverty can predispose to SMI (social causation), it is the consequence of developing SMI that is understood to make the largest contribution to poverty (social drift) (3). Effective treatment for SMI may, therefore, be an important poverty reduction strategy. In our previous study, we found that food insecurity in households of people with SMI was associated with poor social support, experience of negative discrimination, higher disability and lower household annual income, but not with symptom severity (5). Similarly, in a community sample of people with SMI in a neighbouring district, disability was associated with internalized stigma in addition to symptom severity (6). Building on these findings, a participatory planning approach emphasized the need for an holistic and multi-faceted approach to care for people with SMI in order to support recovery (7). A task-sharing model of primary care-based mental healthcare was, therefore, combined with interventions at the community and organizational

levels (8). In this paper we present findings evaluating the household level impact of this fully integrated model of mental healthcare on food insecurity. We hypothesized that:

(1) district wide mental healthcare would result in reduced household food insecurity over a 12-month period of follow-up, after accounting for secular trends in food security levels in the general population,

(2) there would be a significantly greater change in food insecurity in people with SMI who attend 50% or more of their follow-up appointments, and that

(3) any effect of mental healthcare on household food insecurity status would be mediated by reduction in psychotic symptom severity, disability, work impairment and negative discrimination, and improved annual household income.

Methods

The study design was a community-based, before-after study with a general population control group to account for secular trends. Assessments were conducted at the time of initial engagement with the new mental healthcare service (baseline) and after 12 months. Data collection was carried out from December 2014 to September 2016.

Setting

The study was conducted in the predominantly rural district of Sodo, Gurage Zone of the Southern Nations Nationalities and Peoples' Region of Ethiopia, approximately 100 km south of the capital city, Addis Ababa. The district has an estimated population of 165,000 people (9).

123 Mixed agriculture is the dominant means of livelihood. At the baseline of the study, there were
124 no mental health services in the district.

125 **The mental healthcare programme**

126 The district mental healthcare programme was developed as part of an implementation
127 research project, the Programme for Improving Mental HealthcarE (PRIME) (8). At the health
128 administration level, the focus of interventions was to raise awareness about mental health. All
129 clinicians working in government-owned primary care health centres in the district (n=128),
130 including nurses, midwives and health officers, were trained for 10 days to provide frontline
131 care for people with SMI, depression, epilepsy and alcohol use disorders using a contextualized
132 version of the World Health Organization's mental health Gap Action Programme (mhGAP)
133 intervention guide (8, 10). Face-to-face clinical supervision was provided at least monthly by
134 project psychiatric nurses, with consultations by phone as needed. Community-based health
135 extension workers (n=96) were trained for two days by psychiatrists and psychiatric nurses
136 about symptoms of mental illness, detection of medication side effects, community awareness-
137 raising and outreach to engage people with SMI in ongoing care. The district intervention also
138 included general community mobilization and awareness-raising, but no formal interventions to
139 address food insecurity or livelihood needs.

140 **Participant recruitment and follow-up**

141 Recruitment procedures have been described in detail previously (4). In brief, community key
142 informants detected people with possible SMI and referred them to the nearest health centre

for assessment and initiation of treatment by the trained PHC worker. Any person diagnosed as having a psychotic disorder or bipolar disorder was assessed by research psychiatric nurses using a standardized clinical diagnostic interview, the Operational Criteria for Research (OPCRIT) (11). A series of research measures were then administered. Within four weeks, a home visit was carried out to obtain economic information from a knowledgeable household informant as part of the Emerging Mental health systems in LMICs project (Emerald) (12).

The household of the person with SMI was matched by age (+/-5 years), sex, household position (household head vs. not head), household size and area of residence (‘*gott*’), to a comparison household which did not include a person with SMI. The comparison households were identified using data from a complete census carried out by PRIME (13). If more than one match was identified, the respondent was selected by lottery. If no respondent was identified after three home visits, or if they declined to participate, the next reserve was selected.

Sample size

The sample size for this follow-up study was based on the primary outcomes of the PRIME (14) and Emerald (12) studies. See supplementary file 1.

Eligibility criteria

Inclusion criteria for people with SMI: aged 18 years or older, planning to stay resident in the district for the next 12 months, provided informed consent or, if lacked capacity to consent, did not refuse and guardian permission was obtained, confirmatory psychiatric nurse diagnosis using OPCRIT, and able to understand Amharic, the official language.

Inclusion criteria for household respondents (in households with and without a person with SMI): aged 18 years or above; provided informed consent; resided in the household for a minimum of four months; household head or the spouse or the most knowledgeable person about the household.

Measures

Primary outcome: Food insecurity status. The household food insecurity access scale (HFIAS) was used to assess the access dimension of food insecurity (15). The HFIAS has been translated into Amharic and validated in a neighbouring district (16). HFIAS allows categorization of households as food secure or having mild, moderate or severe food insecurity.

Potential confounding variables (lay interviewer-administered)

Information about socio-demographic characteristics (age, sex, residence (urban/rural), household position (head vs not head), educational level) were obtained from self-report. Household measures, including annual income, number of household members with long-term illness and number of dependents, were assessed using items from a household economic survey adapted from the WHO study on global ageing and adult health (17).

Potential predictors and mediators

<u>Lay interviewer-administered measures:</u>

Discrimination: Experience of negative discrimination was measured using the 'unfair treatment' sub-scale of the discrimination and stigma scale-12 (DISC-12) (18). Following

adaptation (4), 17 items were summed to give a total score indicating extent of experienced discrimination.

Physical impairment was measured using the brief physical impairment checklist on items from the Washington Group General Disability Measure and the Family and Wellbeing Index (19, 20).

Disability was measured using the World Health Organization Disability Assessment Schedule (WHODAS) 2.0 12-item version (21). This measure was validated for use in people with SMI in the neighboring district (22). The simple WHODAS scoring method was used in this study.

Psychiatric nurse-administered measures

The following measures were administered by psychiatric nurses:

Work impairment: Work-impairment was measured using the Longitudinal Interval Follow-up Evaluation-Range of Impaired Functioning Tool (LIFE-RIFT) (23). The LIFE-RIFT integrates information from the person with a mental health problem, the caregiver and the clinician's judgement following detailed interview. The validity and reliability of LIFE-RIFT has been established in high-income country settings (23). In this study, the work domain of LIFE-RIFT was used.

Symptom severity was assessed using the 24-item Brief Psychiatric Rating Scale-Expanded version, BPRS-E (24). The BPRS-E is an observer-rated symptom scale assessed by a clinician, and has been translated into Amharic and used in Ethiopia previously (25).

Potential effect modifier

Data on the PHC attendance for mental healthcare and medication prescribed were extracted from clinical records and cross-checked against facility registers.

Training of lay interviewers

Lay interviewers were recruited from the study locality, with an educational level ranging from tenth grade to Bachelor's degree. The training lasted for twelve days and was carried out by a team of trainers, including research assistants and PhD students.

Training of clinician assessors

The psychiatric nurse assessors were trained for seven days by senior Ethiopian psychiatrists.

Data management

Supervisors monitored data quality. Double data entry was carried out using Epidata (26).

Statistical analysis

Stata software version 13.1 (27) and AMOS version 21.0 (28) were used for data analysis. Descriptive characteristics of people with SMI and comparison households were compared using appropriate statistical tests (Pearson chi-squared test; Kruskal-Wallis and two-sample t-test. For all analyses complete case analysis was conducted.

Primary analysis

For the primary analysis examining change in categorical food insecurity status in households of persons with SMI and comparison households, a Poisson working model with sandwich estimators of the standard error was used to estimate the risk ratio (29). HFIAS was categorized

as 'improved' if the household moved to a more food secure category between baseline and 12 months (e.g. from severe to moderate food insecurity) and 'non-improved' if the household remained in the same category or moved to a less food secure category. As a secondary analysis, the mean difference in change in HFIAS score between households of people with SMI and comparison households was modelled using multiple linear regression.

Multiple linear regression was carried out to examine factors associated with change in mean HFIAS scores in households of people with SMI. An interaction term for clinic attendance (6 or more appointments vs. 5 or fewer) and disability score was included in the final multivariable model and likelihood ratio test used to investigate improvement in model fit.

A path model was used to investigate the direct and indirect pathways through which reduction in severity of SMI symptoms was associated with changes in food insecurity status. See supplementary file 2 for the hypothesized path model and supplementary file 3 for fit indices and further analysis detail. The statistical significance of the indirect effects of the variables in the model was computed applying the bootstrapping method, whereby observations with non-missing data were considered for analysis.

Ethics statement

Ethical approval was obtained from the Institutional Review Board of the College of Health Sciences, AAU (Ref. 026/15/Psy) and the Human Research Ethics Committee at the Faculty of Health Sciences, University of Cape Town (HREC Ref: 412/2011). Written informed consent was obtained where possible. For non-refusing people with SMI who lacked capacity to consent,

permission was obtained from the caregiver. Non-literate participants gave a finger-print, with formal recording from a literate witness that the information was explained according to the written materials.

Results

From the 292 households of a person with SMI assessed at baseline, a total of 239 (81.8%) individuals and 239 (81.8%) household respondents were re-assessed at 12 months. A total of 273 (96.1%) comparison households were re-assessed at follow-up. Reasons for loss to follow-up are shown in supplementary file 4.

There was no evidence of significant differences in baseline characteristics of age, sex, annual income, household position, severe food insecurity or marital status in those who were lost to follow-up (see supplementary file 5).

Sociodemographic and clinical characteristics

See table 1. Compared to respondents from households without a person with SMI, people with SMI were significantly younger, had fewer children, had higher annual income, were more likely to have attended formal education and be female, unemployed, unmarried and not the household head. In people with SMI at baseline, the median BPRSE score was 47 (IQR = 24) and 69 (29.4%) were taking psychotropic medication.

[Table 1 about here]

Change in food insecurity and potential mediator variables

Overall, 43.5% of households with a person with SMI experienced an improvement in food insecurity category compared to the comparison households (30.2%). The proportion of households of people with SMI categorized as severely food insecure declined from 29.9% (71/237) at baseline to 15.6% (37/237) at 12 months, compared to a reduction from 13.5% (37/273) at baseline to 9.5% (26/273) at 12 months in comparison households.

Households of people with SMI had a significantly greater reduction in mean food insecurity score from baseline to 12 months compared to households without a person with SMI. The difference in mean HFIAS change between the two groups was -2.2; 95%CI -3.28, -1.05).

The change in potential mediators of food insecurity change between baseline and 12 months was as follows: symptom severity (mean BPRSE change -5.2, 95%CI -7.82, -2.58), disability (mean WHODAS change -7.3, 95%CI -11.7, -2.78), annual income (mean change 6384.6 Birr; 95%CI 4782.53, 7986.63), discrimination (mean DISC change -2.35, 95%CI -3.26, -1.43), work impairment (mean LIFE-RIFT change -0.4, 95%CI -0.62, -0.17).

Multivariable analysis

Food insecurity: In the fully adjusted model, the odds of improvement in food insecurity category at 12 months in households of people with SMI were significantly higher than in comparison households: adjusted risk ratio 1.68; 95%CI 1.24, 2.26 (Table 2).

[Table 2 about here]

279

280 Similarly, change in mean food insecurity score at 12 months was higher in households of
281 people with SMI compared to households without a person with SMI: adjusted beta coefficient
282 (β) -3.36; 95%CI 4.90, -1.81. Supplementary file 6.

283 In people with SMI, improvement in food insecurity was associated with current household
284 head position (adjusted mean difference (AMD) -2.54; 95%CI -4.92, -0.16), disability score (AMD
285 -0.05; 95%CI -0.09, -0.01) and physical impairment (AMD -0.93; 95%CI -1.68, -0.17). See
286 Supplementary file 7. Only a quarter of participants (n= 60/239; 25.1%) attended for six or more
287 monthly appointments (i.e. 50% of the follow-up period). There was no evidence of effect
288 modification by attendance at follow-up appointments.

289 **Path Analysis**

290 Two of the associations in the hypothesized path diagram (disability to discrimination and
291 symptom severity to income) were removed as they were non-significant and affected the
292 model fit adversely. The standardised path coefficients obtained for the final path model are
293 presented in Fig 1.

294 [Fig 1 about here]

295

296 The model fit was acceptable for all indices: Comparative Fit Index = 0.99, Tucker Lewis Index =
297 0.99 and Root Mean Square Error of Approximation = 0.01, 90%CI 0.00, 0.09).

298 Change in psychotic symptom severity was positively associated with change in disability (mean
299 difference = 0.30, 95%CI 0.07, 0.53) and change in work impairment (mean difference = 0.03,
300 95%CI 0.02, 0.04); but not with change in food insecurity. Similarly, change in discrimination
301 (mean difference = 0.47, 95%CI 0.35, 0.59) and change in work impairment (mean difference =
302 0.85, 95%CI 0.26, 1.43) were positively associated with change in food insecurity. These
303 associations were positive in both the direct and total effects analysis (see table 3 and
304 supplementary file 8).

305 [Table 3 about here]

306 Symptom severity had a statistically significant total effect on discrimination (mean difference =
307 0.17, 95%CI 0.03, 0.32) but no statistically significant direct effect. However, change in
308 symptom severity was found to have a statistically significant indirect/mediated effect on
309 change in food insecurity status (mean difference = 0.15, 95%CI 0.07, 0.26; $p<0.01$), through
310 impacting on work impairment and discrimination (supplementary file 9).

311

312 **Discussion**

313 In this community-based, controlled before-after study conducted in a rural Ethiopian district
314 where an integrated mental healthcare plan was implemented, there was significantly greater
315 improvement in food insecurity status in households of people with SMI compared to the

316 secular trend in the general population. Change in severity of psychotic symptoms was directly
317 associated with change in disability and work impairment, whereas change in food insecurity
318 status was directly associated with work impairment and discrimination. There was an indirect
319 association between reduction in symptom severity and improved food security, operating via a
320 reduction in disability and work impairment. There was no effect modification by number of
321 appointments attended.

322 The mental healthcare programme was multi-faceted and the impact on food insecurity may
323 have resulted from several aspects of the programme working in concert. In previous studies,
324 antipsychotic medication has been shown to lead to improved occupational, educational and
325 work functioning (30), a beneficial impact on productivity levels (31) and work engagement
326 (32), as well as a reduction in symptom severity (33). In a follow-up study (2.5 years on average)
327 conducted with 271 people with schizophrenia in a neighbouring Ethiopian district who
328 accessed free psychotropic medication through psychiatric nurse-led out-patient care,
329 significant reduction in psychosis symptom scores was associated with improvements in
330 physical and social functioning in people with both recent-onset and long-standing illness (34).
331 In our study, there was a low level of attendance at the PHC facility. As psychotropic medication
332 is usually prescribed monthly in this setting, it means that most people with SMI were not
333 receiving medication for more than 50% of the follow-up period. The lack of effect modification
334 of the change in food insecurity by attendance at appointments is likely to be a consequence of
335 this low level of attendance: people with SMI tended to attend when they were unwell and not
336 for maintenance care (35).

There was a statistically significant total effect of reduced psychotic symptom severity on level of reported discrimination, with the direct effect close to significance and the indirect effect not statistically significant. In qualitative interviews with community stakeholders during development of the district mental healthcare plan, stigma and discrimination were predicted to reduce when the community witnessed people with SMI show improvement with treatment (35). Feedback from the community leaders engaged in the PRIME advisory board indicated that the recovery of people who had been well-known to be incapacitated by SMI had led to more positive attitudes and support for people with SMI. This accords with findings from high-income countries that social contact interventions, whereby people gain direct exposure to people with SMI and learn about the treatability of their condition can be effective in reducing stigma and discrimination (36). Reduction in perceived discrimination and work impairment were also independently and directly associated with improved food security. The PRIME integrated mental healthcare plan may have contributed to greater social inclusion through community-level activities to improve mental health awareness and reduce stigma through training of community-based health extension workers and engagement of key community stakeholders in the advisory board. In a subsistence farming community where there is interdependence between community members, a reduction in social exclusion may result in more livelihood opportunities and access to shared community resources, thereby leading to reduced food insecurity. In our study, there was no association between change in household income and food insecurity level. This indicates that food insecurity is not just related to the capacity of the household to purchase necessary food. Given that most participants were

359 subsistence farmers, the capacity of household members to work productively (free from ill-
360 health and the need to care for ill family members) and co-operatively (not socially excluded)
361 with other households may be the over-riding influences on food access.
362
363 Our study indicates that scale-up of mental healthcare can support economic inclusion of
364 people with SMI, with impact on a key Sustainable Development Goal to end hunger and
365 achieve food security by 2030. However, although there was significant improvement in food
366 insecurity in people with SMI, the 12-month level of severe food insecurity remained higher
367 than that of the general population (15.6% vs. 9.5%). Concerted effort needs to be made to
368 strengthen engagement of people with SMI in care and ensure the affordability of psychotropic
369 medications. Specific interventions to alleviate food insecurity, reduce discrimination and
370 increase livelihood opportunities may also be required alongside the provision of integrated
371 mental healthcare. Community-based rehabilitation could be one approach to combining these
372 specific interventions and is being trialed in the study district (37).
373
374 **Strengths and Limitations**
375 Recruitment of a community-based sample increased the generalizability of the findings. A
376 randomized design would have been preferable, but it was considered unethical to compare
377 the new mental healthcare service to 'treatment as usual' due to the low coverage of effective
378 care at baseline. Although there was no control group of people with SMI who did not receive
379 the new integrated primary mental healthcare service, in previous longitudinal studies of

people with SMI who are not receiving treatment, there was little evidence of spontaneous remission of symptoms (38). We accounted for secular trends which may occur due to variation in the food productivity of a district, e.g. due to seasonal variations in harvests, the impact of new farming or community development initiatives. The sample size and prospective design allowed us to model indirect and direct pathways to impact. Other strengths included the use of clinical assessments, validated and standardized measures.

Implications

Findings from this study indicate that provision of fully integrated mental healthcare in this rural Ethiopia district was associated with an improvement in food insecurity status for households with a member living with SMI, beyond that observed due to secular trends. Optimising engagement in care and providing additional interventions to improve work functioning and tackle discrimination may further reduce food insecurity in this vulnerable group.

References

1. Dean B, Gerner D, Gerner R. A systematic review evaluating health-related quality of life, work impairment, and healthcare costs and utilization in bipolar disorder. Curr Med Res Opin 2004;20(2):139-54.
2. Ramsay C, Stewart T, Compton M. Unemployment among patients with newly diagnosed first-episode psychosis: prevalence and clinical correlates in a US sample. Social Psychiatry and Psychiatric Epidemiology. 2012;45(7):797-803.
3. Lund C, De-Silva M, Plagerson S, Cooper S, Chilshom D, Das J, et al. Poverty and Mental Disorders: Breaking the cycle in low-income and middle-income countries. Lancet. 2011;378(9801):1502-14.
4. Tirfessa K, Lund C, Medhin G, Hailemichael Y, Fekadu A, Hanlon C. Food Insecurity among People with Severe Mental Disorder in a Rural Ethiopian Setting: a comparative, population-based study. Epidemiology and Psychiatric Sciences. 2017;Epub ahead of print:doi:10.1017/S2045796017000701.
5. Tirfessa K, Lund C, Habtamu K, Medhin G, Hailemichael Y, Fekadu A, et al. Food insecurity and work impairment in people with severe mental disorders in a rural Sodo district of Ethiopia. Social Psychiatry and Psychiatric Epidemiology. 2019:https://doi.org/10.1007/s00127-019-1709-7.
6. Habtamu K, Alem A, Medhin G, Fekadu A, Hanlon C. Functional impairment among people with severe and enduring mental disorder in rural Ethiopia: a cross-sectional study. Social Psychiatry and Psychiatric Epidemiology. 2018;doi: 10.1007/s00127-018-1546-6.
7. Mall S, Hailemariam M, Selamu M, Fekadu A, Lund C, Patel V, et al. Restoring the person's life": a qualitative study to inform development of care for people with severe mental disorders in rural Ethiopia. Epidemiology and Psychiatric Sciences. 2017;26(1):43-52.
8. Fekadu A, Hanlon C, Medhin G, Alem A, Selamu M, Welde-Giorgis T, et al. Development of a scalable mental healthcare plan for a rural district in Ethiopia. British Journal of Psychiatry. 2016;208(S4-S12).
9. Lund C, Tomlinson M, De-Silva M, Fekadu A, Shidhaye R, Jordans M, et al. PRIME: A programme to reduce the treatment gap for mental disorders in five low- and middle-income countries. PLoS Medicine. 2012;9(12):e1001359.
10. WHO. mhGAP Intervention Guide - Version 2.0 for mental, neurological and substance use disorders in non-specialized health settings. 2016.
11. McGuffin P, Farmer AE, Harvey I. A polydiagnostic application of operational criteria in studies of psychotic illness: development and reliability of the OPCRIT system Archives of General Psychiatry. 1991;48:764-70.
12. Semrau M, Evans-Lacko S, Alem A, Ayuso-Mateos JL, Chisholm D, Gureje O, et al. Strengthening mental health systems in low- and middle-income countries: the Emerald programme. BMC Medicine. 2015;13(79):https://doi.org/10.1186/s12916-015-0309-4.
13. Fekadu A, Medhin G, Selamu M, Hailemariam M, Alem A, Breuer E, et al. Population level mental distress in rural Ethiopia. BMC Psychiatry. 2014;14(194):1471-244X/14/194.
14. Baron E, Rathod S, Hanlon C, Prince M, Fedaku A, Kigozi F, et al. Impact of district mental health care plans on symptom severity and functioning of patients with priority mental health conditions: the Programme for Improving Mental Health Care (PRIME) cohort protocol. BMC PSychiatry 2018;18(61):doi.org/10.1186/s12888-018-1642-x.
15. Coates J, Swindale A, Blinsky P. Household Food Insecurity Access Scale (HFIAS) for Measurement of Household Food Access: Indicator Guide (v.3) Washington, DC; 2007.

16. Gebreyesus SH, Lunde T, H-Mariam D, Woldehanna T, Lindtjørn B. Is the adapted Household Food Insecurity Access Scale (HFIAS) developed internationally to measure food insecurity valid in urban and rural households of Ethiopia? BMC Nutrition. 2015;1(2):doi:10.1186/2055-0928-1-2.
17. WHO. WHO study on global ageing and adult health (SAGE). Geneva, WHO. http://wwwwhoint/healthinfo/systems/sage/en/indexhtml. 2013.
18. Brohan E, Clement S, Rose D, Sartorius N, Thornicroft G. Development and psychometric evaluation of the Discrimination and Stigma Scale (DISC). Psychiatry Research. 2013;208:33-40.
19. Mirowsky J, PN H. Physical impairment and the diminishing effects of income. Social Forces. 1996;74(3):1073-96.
20. Palmer M, Harley D. Models and measurement in disability: an international review. Health Policy and Planning. 2012;27(5):357-64.
21. WHO. World Health Organisation. Disability Assessment Schedule. Geneva; 1985.
22. Habtamu K, Alem A, Medhin G, Fekadu A, Dewey M, Prince M, et al. Validation of the World Health Organization Disability Assessment Schedule in people with severe mental disorders in rural Ethiopia. Health and Quality of Life Outcomes. 2017;15(64):DOI 10.1186/s12888-015-0418-9.
23. Leon AC, Solomon DA, Mueller TI, Turvey CL, Endicott J, Keller MB. The Range of Impaired Functioning Tool (LIFE–RIFT): a brief measure of functional impairment. Psychological Medicine. 1999;29(04):869-78.
24. Overall J, Gorham D. The Brief Psychiatric Rating Scale. Psychological Reports. 1962;10:799-812.
25. Zilber N, Youngmann R, Workneh F, Giel R. Development of a culturally-sensitive psychiatric screening instrument for Ethiopian populations. Nuffic, Haigud: Netherlands-Israel Development Research Project. 2004;NIRP Research for Policy Series 20(280424).
26. Lauritsen JM, Bruus M. EpiData (version 3). A comprehensive tool for validated entry and documentation of data. In: Association TE, editor. Odense, Denmark 2003-2008.
27. StataCorp. STATA/SE 13.1. statacorp, college station. 13.1 ed. Texas USA1985-2013.
28. IBM corporation. SPSS Amos 21, version 21.0. 2011.
29. Lumley T, Kronmal R, Ma S. Relative risk regression in medical research: Models, contrasts, estimators and algorithms. Washington: University of Washington; 2006.
30. Harrow M, Jobe T, Faull R, Yang J. A 20-Year multi-followup longitudinal study assessing whether antipsychotic medications contribute to work functioning in schizophrenia. Psychiatry Research. 2017;256:267-74.
31. Liu-Seifert H, Ascher-Svanum H, Osuntokun O, Jen K, Gomez J. Change in level of productivity in the treatment of schizophrenia with olanzapine or other antipsychotics BMC Psychiatry. 2011;11(87).
32. Wils R, Gotfredsen D, Hjorthøj C, Austin S, Albert N, Secher R, et al. Antipsychotic medication and remission of psychotic symptoms 10 years after a first-episode psychosis. Schizophrenia Research 2017;182:42-8.
33. Zhu Y, Krause M, Huhn M, Rothe P, Schneider-Thoma J, Chaimani A, et al. Antipsychotic drugs for the acute treatment of patients with a first episode of schizophrenia: a systematic review with pairwise and network meta-analyses. Lancet Psychiatry. 2017;4(9):694-705.
34. Kebede D, Alem A, Shibre T, Negash A, Deyessa N, Beyero T, et al. Short term symptomatic and functional outcome of schizophrenia in Butajira, Ethiopia. Schizophrenia Research. 2005;78:171-85.
35. Hailemariam M, Fekadu A, Prince M, Hanlon C. Engaging and staying engaged: a phenomenological study of barriers to equitable access to mental healthcare for people with severe mental disorders in a rural African setting. International Journal for Equity in Health. 2017;16(156):DOI 10.1186/s12939-017-0657-0.

484 36. Semrau M, Evans-Lacko S, Koschorke M, Ashenafi L, Thornicroft G. Stigma and discrimination
485 related to mental illness in low- and middle-income countries Epidemiology and Psychiatric Sciences
486 2015;24:382-94.
487 37. Asher L, De-Silva M, Hanlon C, Weiss HA, Birhane R, Medhin G, et al. Community-based
488 Rehabilitation Intervention for people with Schizophrenia in Ethiopia (RISE): study protocol for a cluster
489 randomised controlled trial. BMC Trials. 2016;17(299).
490 38. Thirthalli J, Venkatesh BK, Kishorekumar KV, Arunachala U, Venkatasubramanian G,
491 Subbakrishna DK, et al. Prospective comparison of course of disability in antipsychotic-treated and
492 untreated schizophrenia patients. Acta Psychiatrica Scandinavica. 2009;119(3):209-17.

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Table 1. Baseline sociodemographic and clinical characteristics of study participants who were re-assessed at 12 months

Characteristics	Person with severe mental illness (n=239)	Comparison household respondent (n=273)	P-value*
	N (%)	N (%)	
Educational Level			
Formal education	112 (46.9)	92 (33.7)	<0.002
Illiterate/no formal education	127 (53.1)	181 (66.3)	
Sex			
Female	108 (45.2)	73 (26.7)	<0.001
Male	131 (54.8)	200 (73.3)	
Residence			
Urban	44 (18.5)	53 (19.4)	0.790
Rural	194 (81.5)	220 (80.6)	
Household position			
Head	94 (39.3)	267 (98.2)	<0.001
Not head	145 (60.7)	5 (1.8)	
Occupation			
Unemployed	74 (31.1)	1 (0.4)	
Agriculture	58 (24.4)	174 (63.7)	<0.001
Housewife	49 (20.6)	35 (12.8)	
Other[v]	57 (23.9)	63 (23.1)	
Marital status			
Single	110 (46.0)	2 (0.7)	
Married	84 (35.2)	211 (77.6)	<0.001
Divorced	30 (12.6)	10 (3.7)	
Widowed	7 (2.9)	45 (16.5)	
Married but living apart	8 (3.4)	4 (1.5)	
	Mean (SD)	**Mean (SD)**	
Age (years)	35.4 (13.63)	49.6 (13.76)	<0.001
Month of assessment[‡]	4.3 (3.32)	5.5 (1.84)	<0.001
	Median (25^{th}, 75^{th} centiles)	**Median (25^{th}, 75^{th} centiles)**	
No. of members with long-term illness	0 (0, 0)	0 (0, 0)	0.748
Number of children	1 (0, 3)	4 (2, 6)	<0.001
Annual household income (ETB)	12,000 (8000, 18,000)	9000 (5000, 15,000)	<0.001
Number of dependents	2 (1, 4)	2 (1,4)	0.778
Physical impairment total score	1 (0, 3)	-	-
Disability score (WHODAS-12)	23 (14, 32)	2 (0, 7)	<0.001
Work impairment score (LIFE-RIFT)	5 (3, 5)	-	-
Psychosis symptom severity score: BPRS-E	47 (35, 59)	-	-
Discrimination total score (DISC)	2 (0, 7)	-	-

*P-values of Pearson Chi-squared for categorical variables, Kruskal-Wallis for continuous non-normally distributed descriptive variables and two-sample t-test with equal variances for continuous normally distributed variables. [‡] months numbered starting from January; HFIAS: Household Food Insecurity Access Scale; ETB: Ethiopian Birr; WHODAS: World Health Organization Disability Assessment Schedule; LIFE-RIFT: Longitudinal Interval Follow-up Evaluation-Range of Impaired Functioning Tool; BPRS-E: Brief Psychiatric Rating Scale-Expanded; DISC: Discrimination and Stigma Scale; SD: Standard Deviation; [v] Includes: Daily laborer, government employee, run own business, student, pensioned, private firm employee and others.

Table 2. Factors associated with improved food insecurity in people with severe mental illness and comparison households

Characteristics		Crude risk ratio (95% confidence Interval) N=509	Fully adjusted risk ratio (95% confidence Interval) N= 496
Sex	Male	Reference	Reference
	Female	1.04 (0.82, 1.32)	0.93 (0.72, 1.20)
Age	Number of years	1.00 (0.99, 1.01)	1.00 (0.99, 1.01)
Residence (n=508)	Urban	Reference	Reference
	Rural	1.29 (0.92, 1.80)	1.23 (0.87, 1.75)
Education	Formal	Reference	Reference
	No formal education	1.02 (0.80, 1.29)	0.99 (0.76, 1.30)
Current household position (n=508)	Not head	Reference	Reference
	Head of household	0.85 (0.67, 1.08)	1.10 (0.81, 1.48)
Season of assessment	Harvest season	Reference	Reference
	Pre-harvest season	1.01 (0.79, 1.28)	1.05 (0.82, 1.35)
Household members with any long-term illness (n=504)		1.27 (1.00, 1.61)	1.25 (0.98, 1.59)
Annual household income (n=498) (x 1000 Ethiopian Birr)		0.99 (0.99, 1.00)	0.99 (0.98, 1.01)
Number of household dependents (n=504)		0.98 (0.91, 1.05)	1.01 (0.93, 1.09)
Household SMI status	Comparison household	Reference	Reference
	Household of person with severe mental illness	**1.44 (1.14, 1.82)**	**1.68 (1.24, 2.26)**

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Table 3: Parameters for the hypothesised path model with unstandardized regression weights for direct effects

Pathway		Unstandardized regression weight		p-value
From	To	Mean difference (Estimate)	95% confidence interval	
Symptom severity	Disability	0.30	**0.07, 0.53**	**0.01**
Symptom severity	Work impairment	0.03	**0.02, 0.04**	**<0.01**
Symptom severity	Discrimination	0.04	-0.00, 0.08	0.05
Symptom severity	Food insecurity	-0.01	-0.05, 0.04	0.81
Symptom severity	Annual income	-69.45	-162.38, 23.48	0.14
Disability	Work impairment	0.00	-0.00, 0.01	0.41
Disability	Food insecurity	0.01	-0.02, 0.03	0.46
Disability	Discrimination	0.01	-0.01, 0.04	0.39
Discrimination	Annual income	-16.62	-261.86, 228.62	0.89
Discrimination	Work impairment	-0.007	-0.03, 0.02	0.63
Discrimination	Food insecurity	0.47	**0.35, 0.59**	**<0.01**
Work impairment	Annual income	-425.48	-1315.56, 1064.59	0.84
Work impairment	Food insecurity	0.85	**0.26, 1.43**	**0.01**
Annual income	Food insecurity	0.00	0.00, 0.00	0.95

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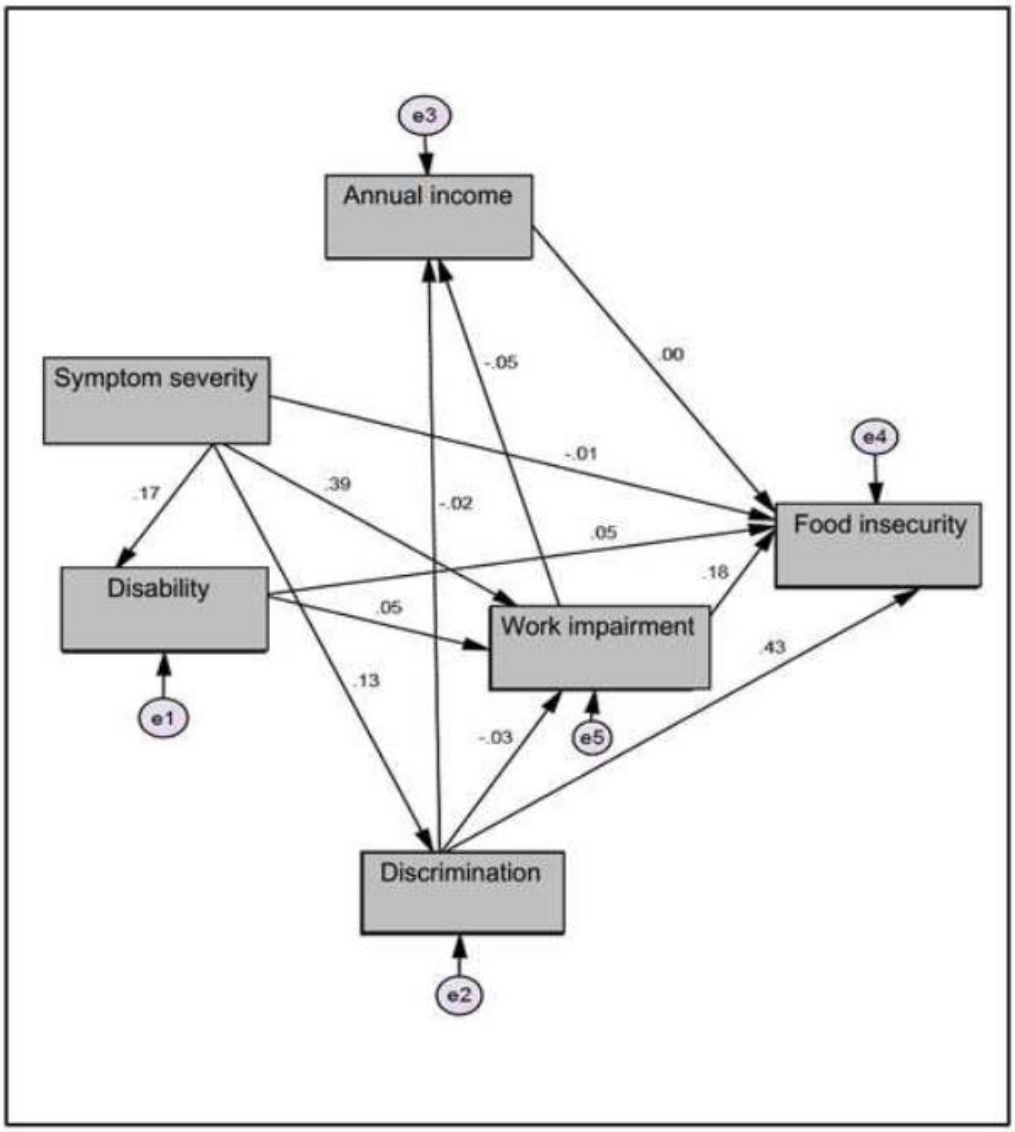


Supplementary file 1. Sample size estimations for differing assumptions

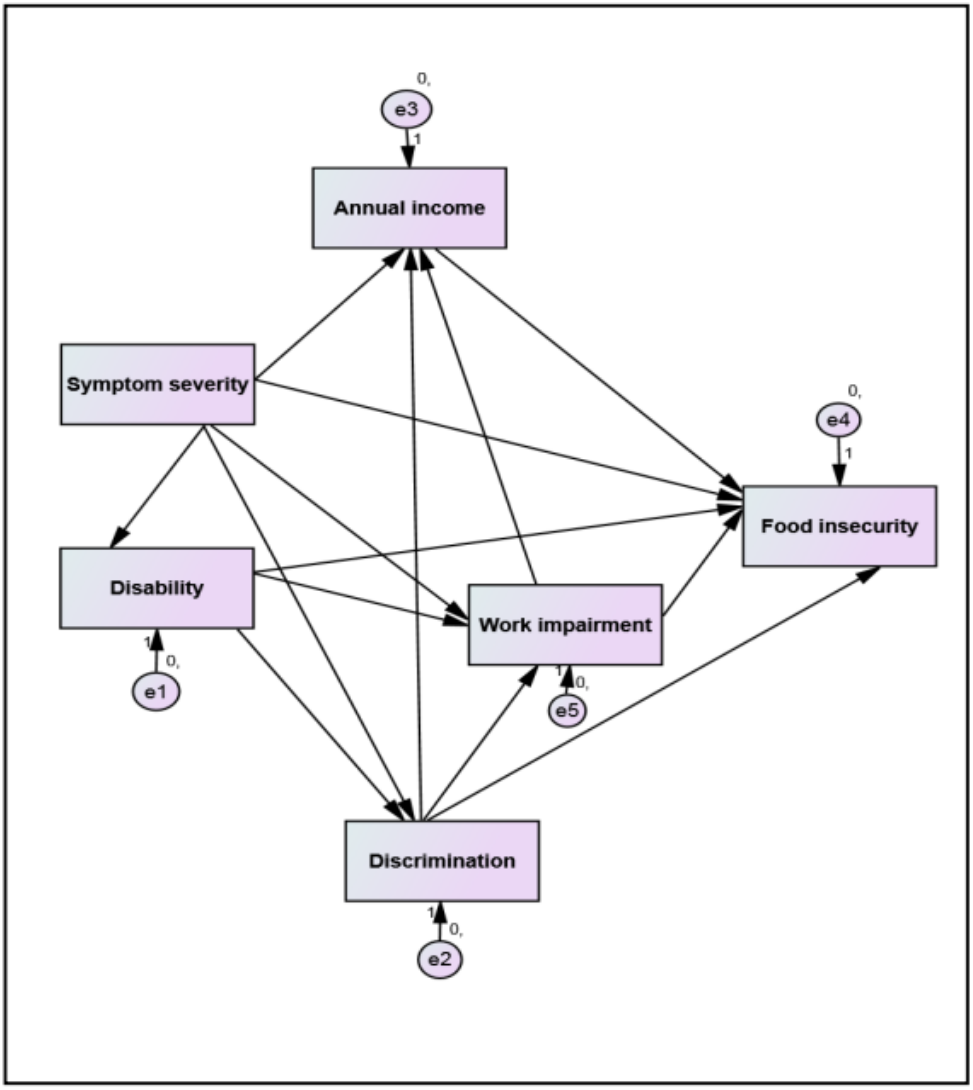
Baseline prevalence of food insecurity in general population	Estimated prevalence of food insecurity in people with SMI	Sample size of people with SMI	Sample size of general population
20%	30%	313	313
	32%	225	225
	34%	171	171
30%	40%	376	376
	42%	267	267
	44%	200	200
40%	50%	408	408
	52%	287	287
	54%	213	213

* This sample size considers the 10% estimates for the non-response rate.

SMI: severe mental illness

Note: Numbers highlighted above indicate possible sample size estimates.

Supplementary file 2. Hypothesized path diagram



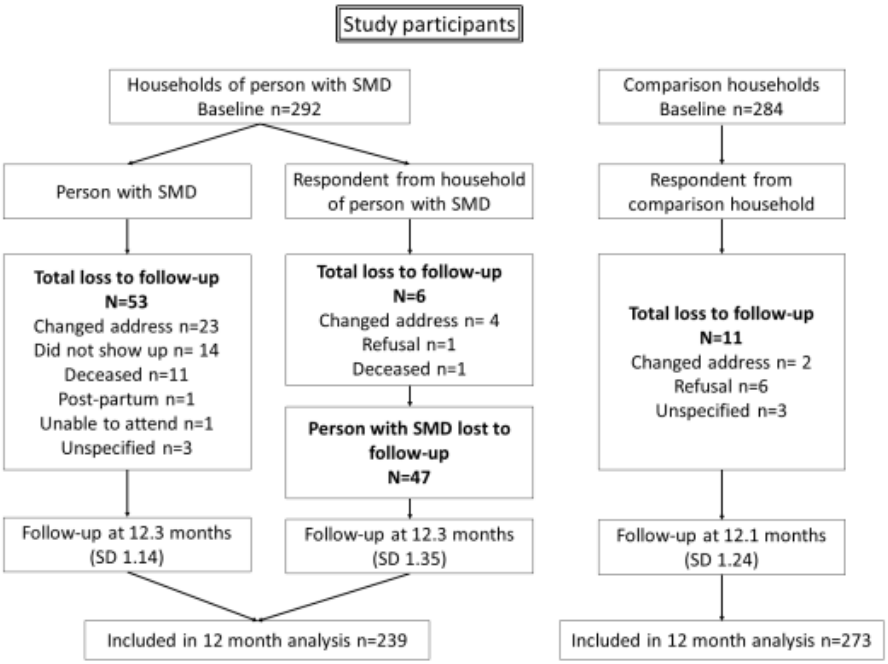
Difference in scores between baseline and 12 months were considered for all modelled variables
e1, e2, e3, e4 and e5 are error terms for the observed endogenous variables

Supplementary file 3: further detail of Path Analyses

Acceptable fit for path models is assessed in relation to the following indices: (1) a value of 0.08 or less for Root Mean Square Error of Approximation (RMSEA) and not greater than 0.1 (40), (2) Comparative Fit Index (CFI) is truncated to fall in the range from 0 to 1 although CFI values close to 1 indicate a very good fit (41), (3) Tucker Lewis Index (TLI) between 0 and 1 (42).

SMI symptom severity (total score on the BPRSE) was treated as an observed exogenous variable, whereas other variables were treated as observed endogenous variables and error terms as unobserved exogenous variables.

Supplementary file 4: Flow chart of loss to follow-up



Supplementary file 5. Association between baseline characteristics and loss to follow-up

Baseline characteristics	Category of participants	
	SMD	Comparison
	p-value*	p-value*
Age	0.68	0.32
Sex	0.14	0.48
Food insecurity severity	0.72	0.53
Annual income	0.38	0.68
Household position	0.08	0.10
Employment	0.83	**0.00**
Marital status	0.15	0.08

*Chi-square was used for categorical variables and t-test was used for continuous variables

Supplementary file 6: Multivariable analysis of factors associated with change in mean Household Food Insecurity Access Scale

Characteristics		Unadjusted Mean difference (95% Confidence interval)	Fully adjusted mean difference (95% Confidence interval) N=489
Sex [n= 502]	Male	Reference	Reference
	Female	-0.54 (-1.72, 0.64)	0.24 (-1.04, 1.52)
Age [n= 502]	Number of years	0.01 (-0.02, 0.05)	-0.01 (-0.05, 0.04)
Residence [n= 501]	Urban	Reference	Reference
	Rural	-0.14 (-1.58, 1.29)	0.10 (-1.37, 1.57)
Education [n= 502]	Formal education	Reference	Reference
	Not formal	-0.52 (-1.66, 0.64)	-0.48 (-1.80, 0.82)
Current household position [n= 501]	Not head	Reference	Reference
	Head of household	0.65 (-0.61, 1.89)	-1.53 (-3.22, 0.15)
Season of assessment [n= 502]	Harvest season	Reference	Reference
	Pre-harvest season	0.06 (-1.11, 1.23)	-0.07 (-1.27, 1.13)
Household members with any long-term illness [total score] [n= 497]	Number	**-1.69 (-3.11, -0.28)**	**-1.71 (-3.15, -0.27)**
Annual household income [n= 491]	In Ethiopian Birr	0.00 (-0.00, 0.00)	0.00 (-9.81, 0.00)
Number of household dependents [n= 497]	Number	-0.03 (-0.36, 0.29)	-0.20 (-0.57, 0.16)
Participants or case status [n= 509]	Comparison household	Reference	Reference
	Household of Person with severe mental disorders	**1.78 (1.24, 2.56)**	**-3.36 (-4.90, -1.81)**

Supplementary file 7: Table of factors associated with change in food insecurity score in people with severe mental illness

Characteristics		Unadjusted mean difference (95% Confidence Interval) N=229	Fully adjusted mean difference (95% Confidence Interval) N=215
Sex	Male	Reference	Reference
	Female	-0.98 (-2.92, 0.96)	-0.06 (-2.11, 1.98)
Age	Years	-0.2 (-0.09, 0.05)	0.02 (-0.06, 0.12)
Residence [n= 228]	Urban	Reference	Reference
	Rural	0.01 (-2.47, 2.49)	0.64 (-1.96, 3.25)
Education	Formal	Reference	Reference
	No formal education	-1.89 (-3.82, 0.03)	-0.73 (-2.93, 1.47)
Current household position	Not head	Reference	Reference
	Head of household	-1.66 (-3.62, 0.30)	**-2.54 (-4.92, -0.16)**
Season of assessment	Harvest season	Reference	Reference
	Pre-harvest season	-1.24 (-3.44, 0.95)	-1.30 (-3.57, 0.97)
Household members with any long-term illness [n= 224]		**-2.23 (-4.41, -0.05)**	-1.83 (-4.03, 0.36)
Disability [whodas36 simple]		**-0.06 (-0.09, -0.03)**	**-0.05 (-0.09, -0.01)**
Annual household income [n= 221] (Ethiopian Birr)		0.00 (-0.00, 0.00)	-0.00 (-0.00, 0.00)
Number of household dependents [n= 224]		-0.13 (-0.68, 0.43)	-0.22 (-0.82, 0.39)
Physical impairment (total score)		**-1.38 (-2.03, -0.73)**	**-0.93 (-1.68, -0.17)**
Work impairment [n= 224] (total score)		-0.56 (-1.29, 0.17)	-0.15 (-1.01, 0.70)

Supplementary file 8: Path model standardised total (direct and indirect) effects in the bootstrapped model

Effect in the pathway		Estimate	95% BC confidence interval	p-value
Effect of variable	**Effect on variable**			
Symptom severity	Disability	0.22	0.11, 0.33	**<0.01**
Symptom severity	Work impairment	0.38	0.26, 0.49	**<0.01**
Symptom severity	Discrimination	0.17	0.03, 0.32	**0.01**
Symptom severity	Food insecurity	0.09	-0.07, 0.24	0.21
Symptom severity	Annual income	-0.02	-0.07, 0.03	0.47
Disability	Work impairment	0.05	-0.09, 0.17	0.51
Disability	Food insecurity	0.07	-0.06, 0.21	0.31
Disability	Annual income	-0.00	-0.02, 0.00	0.36
Discrimination	Annual income	-0.01	-0.15, 0.15	0.92
Discrimination	Work impairment	-0.02	-0.18, 0.12	0.77
Discrimination	Food insecurity	0.46	0.34, 0.58	**<0.01**
Work impairment	Annual income	-0.04	-0.16, 0.07	0.47
Work impairment	Food insecurity	0.16	0.03, 0.29	**0.02**
Annual income	Food insecurity	-0.01	-0.16, -0.01	0.84

The standardized total (direct and indirect) effect of other variables in the model cannot be tested for significance with p-value; hence their estimates and confidence intervals were not included in the above table

Supplementary file 9: Path model standardized indirect effects, using a bootstrapped model

Effect in the Pathway*		Mean difference (estimate)	95% BC** confidence interval (CI)	p-value ǂ
Effect of variable	**Effect on variable**			
Symptom severity	Work impairment	0.01	-0.03, 0.05	0.79
Symptom severity	Annual income	-0.02	-0.06, 0.05	0.85
Symptom severity	Food insecurity	0.15	0.07, 0.26	**<0.01**
Symptom severity	Discrimination	0.00	-0.03, 0.04	0.74
Disability	Work impairment	0.00	-0.02, 0.01	0.81
Disability	Food insecurity	0.01	-0.04, 0.09	0.58
Discrimination	Annual income	0.00	-0.01, 0.01	0.81
Discrimination	Food insecurity	-0.00	-0.03, 0.03	0.77
Work impairment	Food insecurity	0.00	-0.01, 0.01	0.83

*Twelve month baseline scores differences were considered for all modelled variables; **Bias-corrected two-tailed significance; ǂ The standardized indirect (mediated) effect of other variables in the model cannot be tested for significance with p-value; hence their estimates, CI and p-values was not included in the above table

LETTER OF DECLARATION

I, the undersigned, declare that this is my original work, has never been presented in this or any other university, and that all the resources and materials used for the dissertation, have been fully acknowledged.

Name: _____

Signature: _____

Date: _____

Place: _____

Date of submission: _____

This dissertation has been submitted for examination with my approval as a university supervisor.

Name: _____

Signature: _____

Date: _____