Abstract:

Purpose: Evidence regarding functional impairment in people with severe mental disorders (SMD) is sparse in low and middle-income countries. The aim of this study was to identify factors associated with functional impairment in people with enduring SMD in a rural African setting.

Methods: A cross-sectional study was conducted at the baseline of a health service intervention trial. A total of 324 participants were recruited from an existing community-ascertained cohort of people with SMD (n= 218), and attendees at the Butajira General Hospital psychiatric clinic (n= 106). Inclusion criteria defined people with SMD who had ongoing need for care: those who were on psychotropic medication, currently symptomatic or had a relapse in the preceding two years. The World Health Organization Disability Assessment Schedule (WHODAS-2.0) and the Butajira Functioning Scale (BFS), were used to assess functional impairment. Multivariable negative binomial regression models were fitted to investigate the association between demographic, socio-economic and clinical characteristics, and functional impairment.

Results: Increasing age, being unmarried, rural residence, poorer socio-economic status, symptom severity, continuous course of illness, medication side effects and internalized stigma were associated with functional impairment across self-reported and caregiver responses for both the WHODAS and the BFS. Diagnosis per se was not associated consistently with functional impairment.

Conclusion: To optimize functioning in people with chronic SMD in this setting, services need to target residual symptoms, poverty, medication side effects and internalized stigma. Testing the impact of community interventions to promote recovery will be useful. Advocacy for more tolerable treatment options is warranted.
Reviewer #1:
I think that the co-authors have provided an adequate reply to all my previous comments made over the first version of the manuscript, and I consider that this version of the manuscript is adequate for publication.
Thank you.

Reviewer #2:
Now the article is OK in my humble opinion.
Thank you.

Reviewer #4:
Thank you for the opportunity to review this manuscript again. I believe the authors have answered most of the questions and suggestions raised by reviewers.
We would like to thank the reviewer for the compliment.
The manuscript is acceptable for publication, however, I have several small suggested revisions:
1. P4 line 9 - "experienced" instead of "did experience"
   We would like to thank the reviewer for identifying this. We have now replaced “did experience” by “experienced” (see page 4 line 9).
2. P9 line 25-26 - to be consistent and informative the authors should mention the country of affiliation for the NiMH DSMB.
   We have now mentioned the country of affiliation for the NIMH DSMB and rewritten it as follows:
   “The United States of America’s National Institute of Mental Health Data Safety and Monitoring Board (DSMB) (see page 9 lines 25-26).”
3. P13 line 23-24 the direction of the association between khat use and WHO DAS & BFS scores should be noted.
   We would like to thank the reviewer for this useful suggestion. We have now indicated the direction of association between problematic khat use and WHODAS and BFS scores and rewritten the sentence as follows.
   “More specifically, in the univariate models, problematic khat use was associated with increasing patient-reported and caregiver-reported WHODAS scores and increasing caregiver-reported BFS scores. In the multivariable models, problematic khat use was associated only with increasing caregiver-reported BFS scores.”
4. Why is religion mentioned as significant in the results section of the manuscript (P12) but not in the discussion or conclusion sections of the manuscript?
   As the reviewer correctly indicated, we presented, in the results section, that “Christian religion was associated with lower functional impairment”. Nevertheless, we did not want to take this further and give...
space in the discussion section. We did this intentionally because this is not a finding relevant to the study context. In the study setting, although the majority of the participants were Muslims (76.2%), there is no difference between Christians and Muslims in terms of their occupation, education level and socio-economic conditions. So, we believed that religion is not a relevant contextual factor that would affect functional impairment of people with severe mental disorder.

5. The spacing for Reference 50 needs to be corrected.

Thank you for the meticulous review and identifying errors at this greater detail. We have now manually corrected the spacing for reference 50.
Functional impairment among people with severe and enduring mental
disorder in rural Ethiopia: A cross-sectional study

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Acknowledgments

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ABSTRACT

Purpose: Evidence regarding functional impairment in people with severe mental disorders (SMD) is sparse in low and middle-income countries. The aim of this study was to identify factors associated with functional impairment in people with enduring SMD in a rural African setting.

Methods: A cross-sectional study was conducted at the baseline of a health service intervention trial. A total of 324 participants were recruited from an existing community-ascertained cohort of people with SMD (n= 218), and attendees at the Butajira General Hospital psychiatric clinic (n= 106). Inclusion criteria defined people with SMD who had ongoing need for care: those who were on psychotropic medication, currently symptomatic or had a relapse in the preceding two years. The World Health Organization Disability Assessment schedule (WHODAS-2.0) and the Butajira Functioning Scale (BFS), were used to assess functional impairment. Multivariable negative binomial regression models were fitted to investigate the association between demographic, socio-economic and clinical characteristics, and functional impairment.

Results: Increasing age, being unmarried, rural residence, poorer socio-economic status, symptom severity, continuous course of illness, medication side effects and internalized stigma were associated with functional impairment across self-reported and caregiver responses for both the WHODAS and the BFS. Diagnosis per se was not associated consistently with functional impairment.

Conclusion: To optimize functioning in people with chronic SMD in this setting, services need to target residual symptoms, poverty, medication side effects and internalized stigma. Testing the impact of community interventions to promote recovery will be useful. Advocacy for more tolerable treatment options is warranted.

Key words: Severe mental disorder, disability, low and middle income countries, schizophrenia, bipolar disorder, major depressive disorder
Background

Severe mental disorders (SMD), including schizophrenia, bipolar disorder and major depressive disorder with psychotic features, can be highly disabling illnesses [1-3]. The functional impairment seen in these conditions includes the compromised ability to work, to engage in interpersonal relationships, to care for oneself, and to participate in community activities [4]. In large, representative cohorts of people with schizophrenia in Finland [5], impairment in social functioning was present in more than 80% of participants. In a comparative study of manic or hypomanic, euthymic and depressed patients and healthy controls, 30 to 50% of people with bipolar disorder experienced significant social disability [6]. Data from the World Health Survey indicates that major depressive disorder results in the greatest disability compared with other chronic physical diseases [7].

There are very few population-based studies on the functional outcome of SMD from low- and middle-income countries (LMICs). The level of functioning of a population-based study of people with schizophrenia, bipolar disorder and severe major depressive disorder in rural Ethiopia was significantly lower than the normative value for the general population [8-10]. In studies comparing the level of functional impairment in different diagnostic categories, a mixed picture emerges, with some finding greater impairment in people with schizophrenia [11,12] and other studies showing that symptom severity was more predictive of functional impairment than clinical diagnosis [13,14].

Several studies, mostly from high income countries, identified factors that are associated with functional impairment in people with SMD: socio-demographic characteristics (male sex, older age, single or divorced marital status, urban residence, and lower socio-economic status) [15-18], illness characteristics (severity of negative and positive symptoms, long duration of untreated psychoses, co-morbid substance abuse, medication side effects, psychotic symptoms in the previous episode, low pre-morbid functioning, the number of prior episodes, prior hospital admissions, and younger age of onset) [13,15,19-23], social characteristics (lack of social support and stigma) [24,25] and cognitive impairment [4,26,27]. The association of symptom severity, medication side effects, stigma, and cognitive impairment with functional impairment is consistent across studies [17].
There is generally a lack of evidence regarding factors that are associated with functional impairment among people with SMD in LMICs. This study aimed, therefore, to elucidate the association of demographic, economic, social and clinical factors with functional impairment of people with enduring SMD in a rural African setting in order to inform service planning and development. In view of findings of previous studies and our own qualitative explorations and observations, we hypothesized that diagnostic category, severity of symptoms, medication side effects and internalized stigma would be associated with functional impairment in people with SMD.

Methods

Study design

The cross-sectional baseline data of the TaSCS (Task Sharing the Care of Severe Mental Disorders) trial [28] was used in this analysis. The aim of the TaSCS trial is to determine the effectiveness and cost-effectiveness of task-sharing mental health care for people with SMD in primary health care, compared to psychiatric nurse-led mental health care [29].

Study setting and context

The study was conducted in the town of Butajira and surrounding districts, located around 130km south of Addis Ababa, the capital city of Ethiopia. The study area is found in the Gurage and Silti Zones of the Southern Nations, Nationalities and People’s Region (SNNPR) of Ethiopia. Although there are both urban and rural dwellers, the area is predominantly rural. The area has diverse climatic and topographic features. Farming is the main means of livelihood in rural areas, whereas small scale trading is common in the towns. While maize is the main subsistence grain in the lowland areas, khat and chili pepper are the main cash crops. The highlanders mainly live on “kocho” (bread made from false banana trees). The area is also diverse in terms of ethnic identity with predominance of the Gurage and Silti ethnic groups. The majority of the population is either Muslim or Orthodox Christian by religion. Mental health research has been ongoing in the Butajira area for over 15 years. It is the site for a large, population-based cohort study looking at the course and outcome of schizophrenia, bipolar disorder and major depressive disorder [30], known as the Butajira SMD study. The TaSCS trial was nested within the Butajira SMD study after the study had been running for around 12 years.
People in the Butajira area use both traditional and biomedical treatment methods for their mental health problems. At the time of this study, biomedical mental health care was limited to the out-patient psychiatric unit at Butajira General Hospital. This service was provided by two psychiatric nurses.

**Participants and recruitment**

The details of the characteristics of the sample and the recruitment procedure have been reported elsewhere [28]. Nevertheless, we briefly described the sample and the recruitment procedure as follows. Participants were recruited from the Butajira SMD cohort and from attendees at the Butajira General Hospital psychiatric out-patient clinic. Initially, our plan was to recruit the sample from the Butajira SMD cohort because it was community ascertained, but we did not have a big enough sample for the study. So, that is why we then decided to recruit also from the Butajira General Hospital psychiatric outpatient clinic. Inclusion criteria defined people with enduring SMD who had a need for ongoing care: those who were on psychotropic medication, currently symptomatic or had experienced relapse in the preceding two years. The sample size for the study was 324. A total of 218 participants were recruited from 507 people who were in the Butajira SMD cohort. Among those who were in the cohort, 40 refused, 32 were not contactable, 187 had no ongoing need for mental health care, 2 were restrained at home, 1 was mourning a loss, 4 had died, 2 were profoundly deaf, 1 was imprisoned, 2 had just given birth, 10 were too unwell to be transported to screening site, 7 lacked capacity to consent and actively refused and 1 caregiver was not willing to bring the patient for screening. Only three potentially eligible participants refused to participate. The remaining participants (n=106) were recruited from consecutive attendees at the psychiatric clinic at Butajira General Hospital who had been in contact with services for at least two years, were aged 25 to 65 years and who resided in the geographical catchment area of the Butajira SMD study. Twelve people who were screened and potentially eligible did not consent to participate. We considered the criteria about age and time since illness started to make the two sub-samples more similar. Also, most important is that both sub-samples were defined in relation to needing ongoing care.

For participants recruited from the Butajira SMD study, historical diagnosis of SMD at the time of recruitment for the cohort was made using Schedules for Assessment in Neuropsychiatry (SCAN) [31]. For recruits from the Butajira General Hospital psychiatric out-patient clinic, new
SCAN diagnoses were made by psychiatrists who had been trained by a psychiatrist who had training at an accredited SCAN training centre.

In addition to service users, we also included caregivers in our sample. Caregivers were defined as close family members (parents, sons/daughters, siblings or husband/wife) who were living with the person with SMD. After we finished recruiting the service users, we determined the caregiver of each service user using the above criteria.

Assessment of functional impairment

The 12 item version of the World Health Organization Disability Assessment Schedule (WHODAS-2.0) and the Butajira Functioning Scale (BFS) were used to assess functional impairment. The WHODAS is a generic, non-health condition specific, cross-cultural measure of activity limitations and social restrictions of a person in the past 30 days [32,33]. It is available in 12 and 36 item versions, can be self-administered or interviewer administered and responses can be provided by the person with the health condition, a caregiver or a clinician [34,35]. The psychometric properties of the WHODAS have been established in a number of studies [36-39]. The WHODAS has also been adapted and validated in different languages and cultures [33,35,40], including in the rural Ethiopian setting [41]. The BFS is a local functioning scale developed for people with SMD in a rural African context and piloted in the district where the current study was conducted. The BFS was developed following standard procedures, including a qualitative study [42], review of previous scales, free listing and pile sorting exercise, expert consensus, cognitive interviewing and pilot testing. The BFS has 33 shared items for men and women and 8 women-only items in three domains: self-care, work and social functioning [43]. The BFS is easy and fast to administer, with excellent internal consistency, construct and convergent validity and acceptable sensitivity to change over time. We used both the WHODAS and the BFS to assess functional impairment because we found in our previous validation studies [41,43] in that the two instruments complement with each other. Both the WHODAS and the BFS were administered to service users and caregivers.

Clinician-administered measures

The expanded version of the Brief Psychiatric Rating Scale (BPRS-E) was used to assess symptom severity. BPRS-E is a 24- item clinician administered symptom scale, which covers
four domains of symptoms of SMD (positive symptoms, negative symptoms, anxiety and depressive symptoms and manic excitement or disorganization) [44]. The BPRS-E has been used widely to detect clinical improvement in response to an intervention [45]. BPRS-E has been used previously in Ethiopia [43,46]. Psychiatric nurses who received training and ongoing supervision administered the BPRS-E. They were found to have good inter-rater reliability.

The Composite International Diagnostic Interview (CIDI) substance abuse module was used to assess khat use. The CIDI substance abuse module is a fully structured interview that ascertains the diagnosis of alcohol, tobacco and nine classes of psychoactive drugs. Excellent Kappa values for individual alcohol and drug symptoms have been reported for the CIDI substance abuse module [47]. Problematic khat use was operationalized in this study as endorsing any of the items of the CIDI relating to khat abuse or dependence. The Mini International Neuropsychiatric Interview (MINI) Suicidality Scale was used to assess self-harm and suicidal behaviors, including thought, intent and attempt. Each item is scored yes or no and weighted according to its estimated contribution to risk level. The MINI Suicidality Scale has been shown to be valid as a screen for the risk of suicidal behaviors [48]. Medication side effects were assessed using the Antipsychotic Side effects Checklist (ASC). The ASC was designed to assess a range of commonly encountered side-effects of antipsychotic medications. Clinical characteristics, including the course of psychosis and number of psychotic episodes were determined using the Life Chart Schedule (LCS) [49].

Lay-interviewer administered measures

Self-stigma was assessed using the Internalized Stigma of Mental Illness (ISMI) scale. The ISMI is a 29 item scale designed to measure the subjective experience of stigma, with five sub-scales (alienation, stereotype endorsement, perceived discrimination, social withdrawal, and stigma resistance) [50]. The ISMI has high internal consistency and test-retest reliability, and with good evidence in its convergent and construct validity [51]. The ISMI scale has been used across a wide range of languages and cultures [50]. The ISMI was used in a previous facility-based study in Ethiopia and found to have good construct validity and internal consistency [52]. An eight item, structured self-reported medication adherence measure, the Morisky Medication Adherence Scale [53], was employed to assess the extent to which patients were adherent to their respective medication. A structured self-report demographic, social and economic characteristics
questionnaire was used to collect data on sex, age, urban-rural residence, ethnic group, religion, marital status, educational status, ownership of household assets, food security and self-sufficiency and relative wealth of the participants. Experienced diploma holder data collectors were trained for two days to administer the lay-interviewer administered measures.

Data management and analysis

Data were double entered into an electronic Case Report Form using OpenClinica [54]. Data analysis took place using Stata Version 13. Frequencies and percentages were used to summarize categorical, socio-demographic and clinical characteristics, whereas mean and standard deviation were used for summarizing the continuous variables. Negative binomial regression models, for service user reported and caregiver reported scores of the WHODAS and the BFS, were fitted separately in order to see consistency of findings. Multivariable negative binomial regression models were fitted to assess the association of demographic, social, economic and clinical factors with functional impairment in people with SMD. We used negative binomial regression because WHODAS and BFS scores were not normally distributed and only non-negative integer values are possible. Crude and adjusted relative risks (RR) were used to estimate the strength of association between the independent and dependent variables. All statistical tests were set at $\alpha = 0.05$ for significance.

Ethical considerations

Ethical approval for the TaSCS trial was obtained from several international and local institutes: the Institutional Review Board of the College of Health Sciences, Addis Ababa University (Reference Number 030/12/Psy), the AHRI-ALERT Ethics Review Committee (Reference Number P037/13), the National Research Ethics Review Committee of Ethiopia (Reference Number 3.10/758/07), the Food, Medicine and Health Care Administration and Control Authority of Ethiopia (Reference Number 02/6/22/13), the University of Cape Town Human Research Ethics Committee (Reference Number 226/2011) and the United States of America’s National Institute of Mental Health Data Safety and Monitoring Board (DSMB). Written informed consent was obtained from most of the participants after the nature of the study and the information sought had been fully explained. The study included a few people (n= 10) with SMD who lacked capacity to consent to participate, were not actively refusing and had a guardian to
give permission. During the study period, participants were provided with free treatment for both their mental and physical health problems.

Results

Characteristics of the participants

A total of 324 people with SMD participated in the study. Socio-demographic characteristics are presented in Table 1. Of the total sample, 47.1% (n=137) had schizophrenia, 35.5% (n=116) had bipolar disorder and 21.9% (n=71) had major depressive disorder. Nearly half of the participants had either a continuous (27.5%) or episodic (20.1%) course for psychotic symptoms. Three quarters of participants receiving medication reported one or more medication side effects; 13.6% of the participants reported suicidal ideation in the past one month; and 6.8% reported problematic khat use. See Table 1.

Factors associated with WHODAS-2.0 scores

The mean score of the service user responses of the WHODAS was 22.3 (SD= 9.0) and of the caregiver responses was 24.7 (SD= 10.6) out of the maximum score of 60. Results from both the univariate and multivariable negative binomial regression models of the service user and caregiver reported WHODAS scores are presented in Table 2. In the multivariable model of service user reported WHODAS scores, increasing age, rural residence, being unmarried, lower perceived relative wealth, major depressive disorder, continuous course for psychosis, increasing scores of BPRS-E, increasing scores of internalized stigma and reporting two or more medication side effects were significantly associated with greater functional impairment.

In the multivariable model of caregiver reported WHODAS scores, the same factors were found to be associated with functional impairment. However, major depressive disorder, continuous course for psychosis and lower perceived relative wealth were not significantly associated. Christian religion was significantly and negatively associated with functional impairment.

Factors associated with BFS scores

The mean score of the service user responses from the BFS was 65.7 (SD= 28.5) and of the caregiver responses 76.4 (SD= 33.8) out of the maximum score of 165. Results from the univariate and multivariable negative binomial regression models of service user and caregiver reported BFS scores are presented in Table 3. As with the WHODAS, we found increasing age,
being unmarried, lower perceived relative wealth, continuous course of psychosis, increasing
scores of BPRS-E, increasing scores of internalized stigma and two or more medication side
effects to be associated with greater functional impairment. However, while increasing scores of
MINI Suicidal Scale scores were found to be associated with greater functional impairment in
addition to the above factors, rural residence and major depressive disorder were not
significantly associated.

In the multivariable model of caregiver reported BFS scores, the same factors were significantly
associated with functional impairment. Nevertheless, Christian religion was significantly
associated with lower functional impairment and rural residence and problematic khat use were
significantly associated with greater functional impairment. Continuous course of psychosis,
increasing age and MINI Suicidal Scale scores were not associated with functional impairment.

**Discussion**

In this cross-sectional study of people with enduring SMD in a rural African setting, increasing
age, being unmarried, rural residence, perceived lower relative wealth, continuous course of
psychosis, higher symptom severity, internalized stigma and two or more medication side effects
were consistently and significantly associated with functional impairment. Service user reported
and caregiver reported scores on both the cross-cultural WHODAS and the contextually valid
BFS measures gave similar patterns of associations. The study identified symptom severity,
continuous course of psychosis, internalized stigma and medication side effects as important
factors associated with functional impairment in people with severe and enduring SMD. The
study confirmed that risk factors of functional impairment in people with SMD from high
income country settings are also found to be important in LMIC settings.

A negative association was found between the diagnostic category of bipolar disorder and
caregiver reported WHODAS scores and between both bipolar disorder and major depressive
disorder and service user reported BFS scores, when compared to schizophrenia. In the
multivariable models, however, a significant association was found only between major
depressive disorder and service user reported WHODAS scores. Our sample was selected on the
basis of needing ongoing mental health care, which might explain the similarity in level of
functional impairment across diagnostic groups. Nonetheless, our finding is in keeping with the
evidence base [11-13,22], which indicates that the severity of symptoms, medication side effects, stigma and cognitive impairment are more important than diagnosis to predict functional impairment [17].

Among the socio-demographic factors considered in this study, increasing age and rural residence were positively associated with greater functional impairment, whereas being married was associated with lower levels of functional impairment. This is consistent with previous Ethiopian studies [8-10] and studies from elsewhere in the world [17]. Activity limitations and restrictions in participation are likely to increase with increasing age of living with severe mental illness due to deterioration of independent living skills, restricted social relationships, and comorbid medical and mental health conditions [55]. These may arise from the illness itself, medication side effects and stigma and discrimination. With regards to marital status, married people are likely to have the necessary social support to be more functional; and in addition to this there is also a likely social obligation to engage in several social activities compared to unmarried people. There is also a possibility that this association is due to reverse causality, in that better functioning people are more likely to get married and stay married. Our finding that people from rural areas are likely to have more functional impairment than urban residents is contrary to the widely held assumptions [56]. One possible explanation is that the kinds of activities rural residents are expected to perform, such as farming, are more difficult than activities of urban residents who are engaged in petty trade, office work or other small scale businesses. Therefore, rural residents are more likely to report difficulties of accomplishing those activities. An alternative explanation could be our use of culturally validated measures of functioning which are able to detect functional impairment in this rural setting. Residual confounding by socio-economic status might also contribute to the observed association.

Contrary to our expectation, economic variables, including composite scores obtained from several asset indicators as well as indicators of food security and self-sufficiency were not found to be associated with functional impairment, both in the univariate and multivariable analyses. Previous cross-sectional studies found that lower socio-economic status was associated with greater functional impairment, particularly in the interpersonal domain [57] and higher socio-economic status was associated with functional recovery [58]. Low variability in the socioeconomic status in this rural low-income setting may have contributed. Furthermore, we
only used a one-item crude indicator of food insecurity; in a neighbouring district, using a validated scale to measure food insecurity, an association between disability and food insecurity was observed in people with SMD [59]. However, the consistent association between lower perceived relative wealth and functional impairment is in keeping with our previous qualitative study [42] which suggested that the impact of SMD on functioning may be moderated by economic status.

Of the clinical characteristics considered, symptom severity and medication side effects were positively associated with functional impairment consistently in all the models estimated. There is generally a lack of evidence on the impact of medication side effects on the day to day functioning of people with SMD. Only first-generation antipsychotic medications are available in the study site, with a reportedly high burden of sedative and movement-related side effects [60]. In our previous qualitative study [42], service user and caregiver participants emphasized medication side effects as important factors for the day-to-day functioning of people with SMD. Another qualitative study in the same setting [61] found that medication side effects might contribute to non-adherence due to a desire to preserve functioning over symptom control. However, medication adherence was not found to be associated with functional impairment in our study. This may be attributed to our sample; we included stabilized people with SMD who had been in mental health care for more than 15 years. The other reason may be because Butajira SMD study participants were followed-up by project outreach workers who provided support with medication adherence. Our reliance on a self-report measure of adherence may also have under-estimated non-adherence due to social desirability bias. Although this is not consistent across measures and respondents, problematic khat use was associated with greater functional impairment. More specifically, in the univariate models, problematic khat use was associated with increasing patient-reported and caregiver-reported WHODAS scores and increasing caregiver-reported BFS scores. In the multivariable models, problematic khat use was associated only with increasing caregiver-reported BFS scores. There is lack of evidence regarding the association between khat use and functional impairment in people with SMD. A previous qualitative study in the same setting as this study found that people with SMD use khat to try to improve functioning [62]. This may be a reflection of reverse causality or perhaps khat does not actually improve functioning.
The association between clinical or illness related characteristics and functional impairment that we found in this study is consistent with the literature. A recent prospective cohort study among people with severe mental illnesses in China found a strong association between symptom severity and levels of functioning [23]. Bottlender and colleagues [13] concluded that the severity of illness symptoms and not the diagnosis of a mental disorder is the most significant factor in determining the level of functional impairment. In a ten year prospective study [19], participants with more severe psychotic symptoms demonstrated significantly more impairment in occupational functioning, irrespective of diagnosis. Hence, our findings emphasize the importance of achieving symptom remission and dealing with medication side effects as crucial aspects of the recovery process.

This study indicated that there is consistency between the responses obtained from the WHODAS and BFS measures in the kinds of factors that are found to be associated with functional impairment. Consistent association was found between symptom severity, internalized stigma, medication side effects and poverty with scores of functional impairment obtained from the WHODAS or the BFS. This is expected since our validation study of the BFS found that the two instruments have strong convergent validity [43]. Minor differences between the BFS and WHODAS relate to the association with diagnosis, MINI Suicidality scores and Khat use. The MINI Suicidality score was associated with scores on the service user reported BFS scores. Problematic Khat use was associated with the caregiver reported BFS scores. These differences indicate that the BFS, as a contextual and disease specific measure, may be more sensitive than the WHODAS.

In order to optimize the functioning of people with SMD who have ongoing need for mental health care, it may be useful to deal with the factors that are found to be consistently associated with functional impairment. For instance, community level rehabilitation services may help to improve family life and reduce stigma [63]. Mental health care services need to be expanded and give attention to controlling residual symptoms and medication side effects. Improved access to care (providing care closer to home) may affect the adequacy of symptom control [28]. There is a need for advocacy services by mental health researchers and professionals and civic organizations such as mental health service user organizations for more choice of medication and service expansion.
**Strengths and limitations**

Strengths of the study include use of standardized clinician evaluations for assessment of the key clinical variables, rigorous data management and use of a community-based population for our study. In addition, functional impairment was measured using two instruments: a standard, cross-cultural and locally validated instrument and a locally developed scale which was found to be contextually relevant. Responses for the outcome variable were also obtained from both service users and caregivers. Our use of two functional impairment measures and responses from service users and caregivers bring consistency to the study findings. Most of the previous studies assess functional impairment with only one instrument and obtain responses only from service users. Nevertheless, the following limitations need to be taken into account while interpreting the findings of this study. Our study is cross-sectional, and therefore the direction of association cannot be determined. We were not able to measure cognitive impairment, which is found to be consistently and strongly associated with functional impairment in several previous studies [27]. Other potential confounders, such as lifestyle factors, were not measured and adjusted in the regression models. The medication side effect scale has not been validated in the rural Ethiopian context. We used two types of sample in this study: the Butajira SMD cohort and attendees at the Butajira General Hospital psychiatric out-patient clinic. The first is a community sample while the latter is a clinical sample which may not represent the general population. Those who come to the clinic for seeking treatment may be different from those who did not and this may bring about selection bias.

**Conclusions**

In order to optimize functioning in people with chronic SMD in this setting, services need to target residual symptoms, poverty, medication side effects and internalized stigma. Testing the impact of adjunctive community-based interventions to promote inclusion and recovery will be useful. Advocacy for less sedating medication options is also warranted. Further research is required, in rural low income country settings, to elucidate the prospective association of socio-demographic, socio-economic and clinical characteristics with functional impairment in people with SMD.

**Competing interests**

The authors declare that they have no competing interests.
Availability of data and materials

The data is part of an ongoing cross-country clinical trial study, African Focus on Intervention Research for Mental Health (AFFIRM). Due to the cross-country and ongoing nature of the study, we are not able to make the data publicly available at present. However, the data set used for the current study will be made available and can be accessed from the corresponding author on reasonable request, once the study is completed within two years from now.

Authors’ contributions

KH, CH, AA, GM and AF conceived and designed the study. KH trained the data collectors and CH followed up the data collection. KH did the data analysis. GM and CH supervised analysis of the data. KH wrote the first draft of the manuscript. All authors agree with the results and conclusions, contributed to the writing of the manuscript and approved the final manuscript to be submitted for possible publication.

References


