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Impact of integrated district level mental health care on clinical and social outcomes of people with severe mental illness in rural Ethiopia: an intervention cohort study

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4   **Impact of integrated district level mental health care on clinical and social outcomes of people with**

5   **severe mental illness in rural Ethiopia: an intervention cohort study**

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9   **Short title:** District mental health care for people with SMI in Ethiopia

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31

32   **Abstract**

33   Aim

34   There is limited evidence of the safety and impact of task-shared care for people with severe mental

35   illnesses (SMI; psychotic disorders and bipolar disorder) in low-income countries. The aim of this study

36   was to evaluate the safety and impact of a district level plan for task-shared mental health care on 6 and

37   12-month clinical and social outcomes of people with SMI in rural southern Ethiopia.

38   Methods

39   In the Programme for Improving Mental health carE (PRIME), we conducted an intervention cohort

40   study. Trained primary healthcare (PHC) workers assessed community referrals, diagnosed SMI and

41   initiated treatment, with independent research diagnostic assessments by psychiatric nurses. Primary

42   outcomes were symptom severity and disability. Secondary outcomes included discrimination and

43   restraint.

44   Results

45   Almost all (94.5%) PHC worker diagnoses of SMI were verified by psychiatric nurses. All prescribing was

46   within recommended dose limits.

47   A total of 245 (81.7%) people with SMI were re-assessed at 12 months. Minimally adequate treatment

48   was received by 29.8%.

49   All clinical and social outcomes improved significantly. The impact on disability (standardised mean

50   difference 0.50; 95% confidence interval (CI) 0.35, 0.65) was greater than impact on symptom severity

51   (standardised mean difference 0.28; 95%CI 0.13, 0.44). Being restrained in the previous 12 months

52   reduced from 25.3% to 10.6%, and discrimination scores reduced significantly.

53   Conclusions

54   An integrated district level mental health care plan employing task-sharing safely addressed the large

55   treatment gap for people with SMI in a rural, low-income country setting. Randomised controlled trials

56   of differing models of task-shared care for people with SMI are warranted.

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Introduction

The treatment gap for people with severe mental illness (SMI) is over 90% in most low-income countries (Wang *et al.*, 2007). A 'full' task-sharing model whereby primary healthcare (PHC) workers are equipped to deliver all aspects of first-line mental health care, with limited specialist support, is recommended to increase access to care. Full task-sharing is at the heart of the World Health Organisation (WHO)'s mental health Gap Action Programme (mhGAP) (World Health Organization, 2008). However, many studies of task-shared care for SMI have employed a model whereby a mental health specialist makes the diagnosis of SMI, initiates treatment and provides ongoing review, combined with involvement of non-specialists in delivering psychosocial aspects of care (Chatterjee *et al.*, 2014). This 'partial' model of task-sharing cannot address the needs of most people with SMI in low-income countries due to the scarcity of mental health professionals. In the few examples of programmes employing a 'full' task-sharing approach (Gureje *et al.*, 2015, Ventevogel *et al.*, 2012), there is only limited evidence on whether care can be delivered safely and with sufficient quality to bring about improved outcomes for people with SMD (Jordans *et al.*, 2017, Jordans *et al.*, 2019). This lack of evidence may be fuelling reluctance to embrace the more ambitious task-sharing approach (Hanlon *et al.*, 2016b). To address this evidence gap, we present findings from the Programme for Improving Mental health carE (PRIME) (Fekadu *et al.*, 2016). We have shown that PRIME in Ethiopia achieved contact coverage of over 80% for people with SMI in the target population (Hailemariam *et al.*, 2018). The objective of the current study was to investigate the impact of implementing a district level mental health care plan on the 12-month clinical and social outcomes of people with SMI who engaged with primary mental health care in Ethiopia.

Methods

87   Study design

88   We conducted an intervention cohort study, with assessments conducted at the baseline of

89   implementation of the district mental health care plan (T0), and six (T1) and 12 months (T2) after initial

90   engagement of people with SMI in the new integrated service.

91   Setting

92   The PRIME study was carried out in Sodo district, in the Gurage Zone of the Southern Nations,

93   Nationalities and Peoples' Region of southern Ethiopia from December 2014 to July 2016. Sodo has an

94   estimated population of around 160,000 people (Hanlon *et al.*, 2014). More than 90% of inhabitants live

95   in rural areas and rely on subsistence farming and small-scale trading. At the time of the study, health

96   services in Sodo comprised 54 health posts, most of which were staffed by two community health

97   extension workers with one year of training in general health promotion and illness prevention, and

98   eight health centres, staffed by nurses, health officers and midwives, who provide basic curative and

99   obstetric care. There were no doctors or mental health specialists in the district. In the nearest town of

100   Butajira, located 30 to 50km from Sodo, there was a psychiatric nurse-led out-patient clinic. The nearest

101   in-patient mental health services were 100-120km away in the capital city, Addis Ababa.

102

103   Sample and recruitment procedures

104   As described previously (Baron *et al.*, 2018), people with possible SMI in the community were identified

105   by community key informants and health extension workers who had received half a day of training in

106   typical presentations of SMI (Shibre *et al.*, 2002). People with possible SMI were referred to the nearest

107   health centre and assessed by PHC workers who had been trained in mental health care for a total of 10

108   days: five days of classroom-based teaching using adapted mhGAP training materials and five days of

109 practical clinical training in the Butajira psychiatric clinic. The PHC workers assessed the referrals, made

110 a diagnosis of SMI and initiated treatment according to the evidence-based clinical guidelines in the

111 WHO mhGAP Intervention Guide (World Health Organization, 2016). Independent diagnostic review was

112 carried out with standardised, semi-structured clinical assessments by research psychiatric nurses using

113 the OPerational CRITeria for research (OPCRIT) (McGuffin P *et al.*, 1991). Diagnostic assessments were

114 conducted for all people with PHC worker-diagnosed SMI and wherever the PHC worker was uncertain

115 about the diagnosis. The research psychiatric nurses reviewed the initial treatment plan. Any changes

116 made by the psychiatric nurses were communicated back to the PHC workers.

117 Eligibility criteria

118 • Confirmatory research psychiatric nurse diagnosis of a psychotic disorder (including

119 schizophrenia, schizoaffective disorder and depression with psychotic features) or bipolar

120 disorder.

121 • Providing informed consent, or caregiver permission, to participate in the study if the person

122 with SMI lacked capacity to consent.

123 • Able to converse in Amharic, the official language of the region.

124 • Planning to reside in the district for at least 12 months.

125 • No cognitive or sensory impairment that interfered substantially with the clinical assessment.

126 • Not acutely physically unwell.

127 Sample size

128 The sample size for the PRIME SMI cohorts across countries was calculated to detect a 20% reduction in

129 severity of symptoms at 12 months, with 90% power, two-sided alpha of 0.05 and 20% attrition rate

130 (Baron *et al.*, 2018), leading to a target sample size of 150. However, in the Ethiopia district, all people

131   who received a confirmatory diagnosis of SMI were included to establish a completely ascertained

132   population cohort.

133

134   PRIME intervention for people with SMI

135   The integrated district mental health care plan for the Ethiopian setting has been described in detail

136   previously (Fekadu *et al.*, 2016), and involved interventions at the level of the health system, PHC facility

137   and community.

138   *Health system interventions*

139   The district health office staff were involved in participatory planning using Theory of Change

140   methodology (Hailemariam *et al.*, 2015). The district health office assigned a focal person for mental

141   health co-ordination. PRIME provided ongoing technical support with medication supply management

142   (including establishing a revolving drug fund and providing assistance with forecasting the amount of

143   psychotropic medication required), building capacity in supervision of mental healthcare (training high-

144   performing general health workers to supervise mental health care) and monitoring and evaluation

145   activities (e.g. aggregating data on facility contacts and feeding back at the advisory board meetings).

146   *PHC facility interventions*

147   All frontline PHC workers in Sodo district (n=128) were trained in mental healthcare. The PHC workers

148   received monthly supervision from a psychiatric nurse trained using the mhGAP supervisor training

149   manual. For rural health centres, supervision was conducted by telephone when weather conditions

150   precluded travel to the facility. PHC workers could also consult the psychiatric nurse for advice. People

151   with confirmed SMI were prescribed an antipsychotic and/or antidepressant medication and/or a

152   benzodiazepine, as indicated. There were no mood-stabiliser medications available, so people with

153   bipolar disorder received antipsychotic medication as per usual practice in this setting (Fekadu *et al.*,

154   2015). Almost all service users had to pay for medication.

155   In addition to prescription of medication, PHC workers were trained to provide psychoeducation,

156   activate social supports, address social stressors, monitor physical health, review response to treatment

157   and refer to specialist mental health care if needed. As prescriptions were usually for a maximum of one

158   month, follow-up appointments with the PHC workers were usually scheduled monthly.

159   *Community level interventions*

160   A multi-sectoral 'community advisory board' was established to support community awareness-raising

161   and mobilisation, to help with trouble-shooting during the implementation phase and to review project

162   activities and outcomes. A total of 96 community-based health extension workers were trained in case

163   detection, outreach to re-engage people who dropped out of care, identification of medication side

164   effects, community awareness-raising and supporting social reintegration and recovery of people with

165   SMI. In half of the sub-districts, people with schizophrenia who had enduring symptoms or disability

166   after six months received adjuvant community-based rehabilitation, delivered by trained lay workers

167   (n=75) or ongoing PRIME care (n=87), as part of a nested cluster randomised trial (the RISE trial) (Asher

168   *et al.*, 2016). Aside from the additional contacts from CBR workers in the intervention arm (weekly for

169   two to three months and two-weekly for the subsequent five to six months), there were no additional

170   trial-related contacts.

171

172   Measures

173   Primary outcomes

174 • Clinical symptom severity was measured using the Brief Psychiatric Rating Scale, expanded

175 version (BPRS-E) (Burlingame *et al.*, 2006). The BPRS-E is a 24-item, clinician-rated scale which

176 has been translated into Amharic and shown to have robust psychometric properties and

177 sensitivity to change in Ethiopia (Habtamu *et al.*, 2017).

178 • Disability was measured using the World Health Organisation Disability Assessment Schedule

179 (WHODAS), version 2.0, 36-item version (Üstün *et al.*, 2010). The WHODAS has been validated

180 for use in people with SMI in Ethiopia and is sensitive to change (Habtamu *et al.*, 2017). The

181 WHODAS was completed by a combination of responses from the person with SMI and the

182 caregiver responses to the proxy-WHODAS at the post-baseline assessments (19.8% of WHODAS

183 scores from caregivers at midline, 24.1% at endline). We used the polytomous summary score of

184 the WHODAS scaled from 0 to 100.

185 Secondary outcomes

186 • Experience of discrimination was measured using the 'unfair treatment' subscale of the

187 discrimination and stigma scale-12 (DISC-12) (Brohan E *et al.*, 2013). The original DISC-12 sub-

188 scale has 21 items. Four items lacked face validity or had a low frequency of endorsement, but

189 the remaining 17 items loaded onto a single factor using exploratory factor analysis and were

190 summed.

191 • Restraint was measured by self-report of whether the person had been 'restrained, chained or

192 confined' in the preceding 12 months.

193 • Alcohol use disorder was measured using the lay interviewer-administered Alcohol Use Disorder

194 Identification Test (AUDIT) (Babor TF *et al.*, 2001). This 10-item scale has been adapted for local

195 drinks in the Ethiopian setting. People scoring ≥8 are considered to have a probable alcohol use

196 disorder.

197   •   Depression was measured using a locally validated version of the Patient Health Questionnaire

198   (PHQ-9) (Kroenke and Spitzer, 2002). In the Ethiopian setting, a cut-off of 5 or more is indicative

199   of major depressive disorder (Hanlon *et al.*, 2015).

200   •   Suicide attempts in the past three months were assessed using the Mini International

201   Neuropsychiatric Interview (Sheehan *et al.*, 1997).

202 Potential effect modifiers

203 *Equity indicators*

204   •   Gender and residence (rural vs. urban).

205   •   Socio-economic status: a poverty index was constructed which loaded onto a unidimensional

206   scale using exploratory factor analysis: roof material made of straw (vs. corrugated iron),

207   unimproved water source, unimproved sanitation, no electricity, no separate room for kitchen,

208   no radio or television, no mobile phone.

209   •   Time to access the nearest health facility, estimated in minutes, whatever the means of travel.

210   This was dichotomised into less than 60 minutes vs. 60 minutes or longer.

211 *Baseline characteristic*

212   •   Diagnosis: clinician-assessed diagnosis using criteria of the Diagnostic and Statistical Manual of

213   the American Psychiatric Association, version IV) (American Psychiatric Association, 1994) from

214   OPCRIT (McGuffin P *et al.*, 1991).

215 *Process indicators*

216   •   Receipt of minimally adequate treatment used the definition proposed by Wang et al. (Wang *et*

217   *al.*, 2002): prescription of medication on at least one occasion combined with at least four

218   follow-up appointments with a health worker trained in mental health. We additionally required

219   that psychotropic medication should be prescribed at therapeutic levels (World Health

220   Organization, 2016). Data on the number of facility contacts and prescriptions were extracted

221   from the clinical records, cross-referenced with a facility registration book.

222   • Receipt of community support (measured at T1 and T2): support received with returning to

223   work, remembering to take medication, improving self-care, meeting people and social

224   engagement. Responses were summed and binarized: 0 to 2 types of community support vs. 3

225   to 5 types of community support.

226   • Receipt of in-patient care for mental health problems, contact with specialist mental health or

227   general health facilities and traditional or religious healers, and type of care received during

228   primary health care contacts were measured at T1 and T2.

229   Descriptive baseline characteristics

230   • Socio-demographic characteristics (age, educational level, marital status).

231   • Social support was assessed using the three-item Oslo Social Support Scale (OSS-3) (Dalgard OS

232   *et al.*, 2006), which asks about number of close supports, extent of concern from supports and

233   amount of practical support received. The OSS-3 total score was categorised as follows: 3 to 8

234   "poor support", 9 to 11 "intermediate support" and 12 to 14 "strong support".

235   • Duration of illness, type of illness onset (acute/sub-acute vs. gradual), psychiatric hospitalisation

236   in the past 12 months, presence of co-morbid medical condition and receipt of psychotropic

237   medication at baseline were obtained from the OPCRIT (McGuffin P *et al.*, 1991).

238   Data collection

239   The lay interviewers were individuals with an educational level of at least tenth grade who were

240   recruited from the local area and trained for 12 days on the study questionnaires and protocols,

241   including observed practice interviews. The trainers had master's level qualifications. Degree-level

242   supervisors monitored data quality in the field. The clinician assessments were conducted by research

243   psychiatric nurses who were trained for seven days by senior Ethiopian psychiatrists. The OPCRIT

244   diagnoses were double-checked by an Ethiopian psychiatrist by reviewing the OPCRIT responses and

245   clinical documentation and conducting verification interviews (n=2) where needed.

246   Data management and analysis

247   Data were double-entered using EpiData (Lauritsen and Bruus, 2003) and analysed using Stata version

248   13.1 (StataCorp LP, 2016). The data were summarised descriptively, with outcome data stratified by

249   equity indicators (gender, residence, distance from the health facility and poverty status). Comparison of

250   the characteristics of participants remaining in the cohort with those lost to follow-up at 12 months, as

251   well as by equity indicators, was conducted using Pearson chi-squared for categorical variables,

252   Student's t-test for comparing means in normally distributed variables and Kruskal Wallis equality-of-

253   populations rank test for non-normal continuous variables.

254   Mixed effects linear regression with random intercept was used to model the change in symptom

255   severity, disability and depressive symptoms over time. We tested for improvement in model fit using

256   likelihood ratio tests after adding random slopes. We also tested for any significant difference in the

257   mean change between T0 and T1 or between T1 and T2. Mixed effects ordinal regression was used to

258   model change in discrimination score over time. A prevalence ratio was calculated for change from T0 to

259   T2 in probable alcohol use disorder (AUDIT ≥ 8), suicide attempt in the preceding three months or

260   restraint in the preceding 12 months.

261   For the primary outcomes, we calculated standardised mean difference (Borenstein *et al.*, 2009) and

262   examined effect modification by the equity indicators, diagnosis (primary psychotic disorder vs. affective

263   disorder), process indicators (receipt of minimally adequate treatment and community support) and by

264   the community-based rehabilitation intervention group for the RISE trial. This was done by adding an

265 interaction term into the model and testing for improved model fit using a likelihood ratio test. Multiple

266 linear regression analysis was conducted to examine the association between baseline duration of

267 illness and type of illness onset with 12 month outcomes.

268 Ethical considerations

269 Ethical approval was obtained from the Institutional Review Board of the College of Health Sciences,

270 Addis Ababa University (No. 084/11/Psy). Informed consent was obtained where possible. If the person

271 lacked capacity and did not refuse, the accompanying caregiver was invited to give permission on the

272 person's behalf.

273

274 **Results**

275 Of the 294 people diagnosed by PHC workers as having SMI, 279 were confirmed to have SMI, giving a

276 positive predictive value for PHC worker diagnosis of 94.9%. A further 21 people referred by PHC

277 workers to psychiatric nurses for diagnostic review were also found to have SMI, giving a total of 300

278 participants. See Figure 1.

279
280
281 Figure 1: Flow diagram

282

283 Baseline characteristics

284 See Table 1. At baseline there was no significant difference in symptom severity score, disability,

285 discrimination or depressive symptoms by gender. The proportion with an alcohol use disorder (χ^2(1)

286 48.6750; p < 0.001) or who had been restrained (χ^2(1) 5.1154; p=0.024) was higher in men. Baseline

287 disability (t=2.1012; p=0.04) and restraint (χ^2(1) 3.9058; p=0.048) were significantly higher in those with

288   low socioeconomic status. Perceived negative discrimination at baseline was higher in urban residents

289   (χ^2(1) 3.986; p = 0.049) and people of low socioeconomic status (χ^2(1) 4.195; p = 0.04).

290   Cohort follow-up

291   A total of 247 (82.3%) people were assessed at T1 (mean 7.4 months; SD 1.49) and 245 (81.7%) at T2

292   (mean 12.3 months; SD 1.12). See Figure 1. There was no evidence of differential loss to follow-up based

293   on baseline characteristics (Supplementary File 1). During the follow-up period, 11 participants died.

294   Facility-based intervention

295   After review by psychiatric nurses, the medication initiated by PHC workers was unchanged or changed

296   within the same medication class for 184 (67.7%) participants. Psychiatric nurses increased the dose or

297   added another medication for 46 (16.9%), stopped or reduced the dose in 15 (5.9%), changed the class

298   of medication in 15 (5.5%) and stopped a prescription of depot antipsychotic medication in 5 (1.8%).

299   Participants attended a median of two PHC appointments during the follow-up period (IQR 2,4;

300   minimum 1 and maximum 12). Supplementary File 2. Minimally adequate treatment was received by 89

301   (29.8%). Supplementary File 3. There was no evidence of prescribing above recommended limits and

302   only one occurrence of antipsychotic polypharmacy. Admission for in-patient care was very low (1.4% at

303   T1 and 2.0% at T2) and less than 10% of participants had direct contact with a mental health specialist. A

304   high proportion reported receiving psychosocial support and explanation about medication

305   (Supplementary File 4).

306   Community-based interventions

307   Most people with SMI reported receiving support with medication adherence and to improve self-care.

308   More than half received support to get back to work, but less than a quarter were supported to get

309   involved in social activities and less than 10% had support with meeting people. Almost all support was

310   reported to come from the family. A small proportion reported contact with traditional or religious

311   healers: 13.0% at T1 and 11.6% at T2.

312
313   Impact on clinical and social outcomes

314   There was a significant improvement in all clinical (symptom severity score, depressive symptoms,

315   suicide attempts, alcohol use disorder) and social (functioning, discrimination, restraint). Tables 2 and 3.

316   The standardised mean difference for symptom severity was 0.18 (95% confidence interval (CI)) 0.02,

317   0.34) between T0 and T1 and 0.28 (95%CI 0.13, 0.44) from T0 to T2. For disability, the standardised

318   mean difference was larger at both time-points: T0 to T1: 0.27 (95%CI 0.13, 0.41), T0 to T2: 0.50 (95%CI

319   0.35, 0.65). The test for interaction between the RISE trial intervention group and the main outcomes

320   (symptom severity and functioning) at 12 months was non-significant.

321
322   For symptom severity and functioning, the magnitude of the change did not differ between T0 and T1

323   compared to T1 and T2. The reduction in depressive symptoms was significantly greater between T0 and

324   T1 than between T1 and T2 ($\chi^2(1)$ 4.26; p=0.039); similarly for change in perceived discrimination ($\chi^2(1)$

325   3.75; p=0.053).

326   There was no statistically significant effect modification by the equity indicators, diagnosis or process

327   indicators for the primary outcomes. At T1, higher receipt of community support had a borderline

328   statistical association with greater reduction in symptom severity (p=0.19) and disability (p=0.09).

329   Supplementary Files 5 and 6. There was no association between duration of illness or type of illness

330   onset and the mean improvement in the primary outcomes.

331
332   Discussion

333 In this community-ascertained intervention cohort of clinician-confirmed people with SMI, there was a

334 significant improvement in clinical and social outcomes after implementation of a district level mental

335 health care plan. PHC workers diagnosed SMI accurately, prescribed psychotropic medication safely and

336 were reported to have delivered psychoeducation and provided support to most people with SMI. The

337 findings from this study are generalizable to similar rural settings of low-income countries.

338 Although PHC workers prescribed safely (low polypharmacy and no doses above the recommended

339 therapeutic range), the psychiatric nurses did consider that it was necessary to change the initial

340 prescriptions of psychotropic medication in 30.1% of cases. This reinforces the need for task-shared care

341 to be supported by input by mental health specialists, either through regular supervision or through

342 timely review of newly diagnosed cases.

343 We are only aware of two previous studies, both from Nepal, where the impact of a 'full' task-sharing

344 model on clinical and social outcomes of people with SMI was evaluated (Jordans *et al.*, 2017, Jordans *et*

345 *al.*, 2019). Both studies found a significant reduction in symptom severity, disability and caregiver

346 burden but had sample sizes under 100 and included extensive community-based psychosocial

347 interventions (Jordans *et al.*, 2019). Our larger study, which included a more representative population

348 of people with SMI and a task-sharing intervention more closely based on mhGAP, provides more

349 definitive evidence of important clinical and social benefits from the recommended WHO mhGAP

350 approach.

351 In our study, the impact of the district mental health care plan care on psychotic symptoms was less

352 marked than the reductions seen in the social outcomes, with a reduction of 4.8 on the BPRSE being less

353 than that usually considered to be clinically significant (Hanlon *et al.*, 2016a). In previous intervention

354 studies for people with SMI in LMIC settings, a key factor for clinical improvement has been enhanced

355 adherence to antipsychotic medication (Chatterjee *et al.*, 2014), but only 30% of people with SMI in our

356   study received 'minimally adequate treatment' over the follow-up period. Our process data indicate that

357   engagement waxed and waned over time, rather than people dropping out of care altogether, and lends

358   support to the acceptability of care provided as well as providing explanation for the limited impact on

359   symptom improvement at cross-sectional assessment. In-depth interviews with study participants with

360   SMI who had disengaged from care indicated that most had experienced symptomatic improvement,

361   but that affordability of medication and side effects of medications was a barrier to continuous

362   engagement (Hailemariam *et al.*, 2018). This is supported by quantitative data from the same sample,

363   indicating high levels of poverty and out-of-pocket healthcare costs compared to the general population

364   (Hailemichael *et al.*, 2019). Mechanisms to reduce out-of-pocket healthcare costs for people with SMI

365   are needed to achieve improved access to mental health care (Hanlon, 2019).

366   Although disability is closely linked to symptom severity, our previous work in this community indicates

367   that stigma, discrimination and poverty also make important contributions (Habtamu *et al.*, 2018). The

368   borderline significant effect modification indicating greater improvements in disability in people with

369   higher receipt of community support may reflect the impact of reduced social exclusion. We observed a

370   significant decline in perceived negative discrimination in people with SMI. The PRIME mental health

371   care plan included a cascade model of training of community-based health extension workers to raise

372   community awareness and reduce stigma against mental health problems (Fekadu *et al.*, 2016);

373   however, the extent of implementation is not known. The growing community and family awareness of

374   the treatability of SMI, arising from the local availability of a treatment service and bearing witness to

375   the clinical improvement of people with SMI who were well-known to the community, might have also

376   reduced stigmatising attitudes, social exclusion and the need for people to be restrained (Hailemariam

377   *et al.*, 2018). Furthermore, the Community Advisory Board members were selected due to their level of

378   community influence and their endorsement of mental health care helped to reduce stigma and

379   misconceptions about mental illness in the study site. In a recent trial in Ghana, restraint was not

380   reduced by short-term provision of psychiatric care to people with SMI who were receiving faith healing

381   in prayer camps (Ofori-Atta *et al.*, 2018). In our study, the follow-up period was longer, which may have

382   allowed family members and the community to gain confidence in the beneficial effects of treatment

383   and the PRIME intervention incorporated community and system level interventions as well as task-

384   shared facility-based care.

385   Alternative approaches to expanding access to care for people with SMI in rural populations in LMICs

386   have been reported. One model is to utilise outreach clinics staffed by mental health specialists who

387   diagnose, prescribe and monitor clinical progress, combined with community-level interventions by non-

388   specialists to promote social inclusion and functional recovery (Chatterjee *et al.*, 2014, Chatterjee *et al.*,

389   2009, Srinivasa Murthy *et al.*, 2005). Another 'back-referral' model is for mental health specialists to

390   provide initial assessment and development of a care plan which is then implemented by non-specialist

391   health workers in the local area combined with task-shared psychosocial interventions (Xiang M *et al.*,

392   1994). Augmenting the PRIME model with more intensive and systematic community-based

393   rehabilitation delivered by non-specialists may help to address some of the gaps identified in our study

394   by strengthening engagement with PHC and supporting livelihoods (Asher *et al.*, 2016), although the

395   affordability and sustainability of such approaches needs evaluation. There are no published reports of

396   these task-sharing service models being successfully, safely and sustainably taken to scale and we have

397   no evidence regarding their relative impact on effective treatment coverage for people with SMI. In the

398   future, randomised controlled trials comparing task-shared models of care for people with SMI are

399   needed to inform policy decisions (Hanlon *et al.*, 2016a).

400   Limitations

401   PHC workers were informed of the research psychiatric nurse diagnosis and changes in treatment plan.

402   For diagnosis the concordance was high and so this is unlikely to have affected the outcome, but the

403   treatment plan reflected task-shared care with support from a mental health specialist.. We only

404   collected data on the positive and not the negative predictive value of the PHC worker diagnosis.

405   Calculating the negative predictive value would be an important focus for future studies. Due to ethical

406   concerns, there was no comparison group of people with SMI receiving 'usual care', which would have

407   amounted to no access to evidence-based care for most people. However, outcomes in people with

408   untreated schizophrenia (who formed the majority of our cohort) have been shown to be poor (Ran *et*

409   *al.*, 2001). Given the chronicity and severity of SMI at baseline, spontaneous improvement is unlikely.

410   This is supported by the lack of an association between baseline duration of illness or type of illness

411   onset and outcomes in our study.

412   Conclusions

413   An integrated district level mental health care plan employing a task-sharing approach safely addressed

414   the large treatment gap for people with SMI in a rural, low-income country setting, resulting in

415   improved clinical and social outcomes and reduced human rights abuses. Training and supporting PHC

416   workers to provide mental health care has great potential as a sustainable and feasible approach to the

417   care of people with SMI in resource-poor settings.

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Table 1: Baseline characteristics of the severe mental disorder cohort stratified by gender

Characteristics		Total N (%)	Male N (%)	Female N (%)
		300 (100.0)	172 (57.3)	128 (42.7)
Age (years)	Mean (Standard Deviation)	35.5 (13.45)	36.6 (12.86)	34.1 (14.1)
Educational level (n=299)	No formal education	157 (52.5)	79 (46.2)	78 (60.9)
	Primary education	112 (37.5)	75 (43.9)	37 (28.9)
	Secondary and above	30 (10.0)	17 (9.9)	13 (10.2)
Religious affiliation	Orthodox Christian	270 (90.0)	154 (89.5)	116 (90.6)
	Muslim	10 (3.3)	7 (4.1)	3 (2.3)
	Protestant Christian	19 (6.3)	10 (5.8)	9 (7.0)
	None	1 (0.3)	1 (0.6)	0 (0.0)
Ethnicity	Gurage	284 (94.7)	162 (94.2)	122 (95.3)
	Other	16 (5.3)	10 (5.8)	6 (4.7)
Marital status	Married	111 (37.0)	66 (38.4)	45 (35.2)
	Single	136 (45.3)	83 (48.3)	53 (41.1)
	Divorced or widowed	53 (17.7)	23 (13.4)	30 (23.4)
Household size (n=298)	1 to 2	34 (11.4)	19 (11.1)	15 (11.8)
	3 to 4	85 (28.5)	46 (26.9)	39 (30.7)
	5 to 6	92 (30.9)	47 (27.5)	45 (35.4)
	7 or more	87 (29.2)	59 (34.5)	28 (22.1)
Children in household (n=287)	None	138 (48.1)	89 (54.3)	49 (39.8)
	≤ 5 years	67 (23.3)	33 (20.1)	34 (27.6)
	5 to 15 years	58 (20.2)	35 (21.3)	23 (18.7)
	16 years and older	24 (8.4)	7 (4.3)	17 (13.8)
Socio-economic status (n=297)	Higher (poverty index ≤ 3)	177 (59.6)	100 (58.5)	77 (61.1)
	Lower (poverty index >3)	120 (40.4)	71 (41.5)	49 (38.9)
Residence (n=299)	Urban	60 (20.1)	36 (20.9)	24 (18.9)
	Rural	239 (79.9)	136 (79.1)	103 (81.1)
Social support (n=298)	Strong social support	56 (18.8)	31 (18.2)	25 (19.5)
	Intermediate support	151 (50.7)	83 (48.8)	68 (53.1)
	Poor support	91 (30.5)	56 (32.9)	35 (27.3)
Travel time to nearest health facility (n=299)	≤ 60 minutes	192 (64.2)	115 (67.3)	77 (60.2)
	61 to 120 minutes	60 (20.1)	32 (18.7)	28 (21.9)
	≥121 minutes	47 (15.7)	24 (14.0)	23 (18.0)
Diagnosis	Affective psychosis/bipolar disorder	44 (14.7)	21 (12.2)	23 (18.0)
	Schizophrenia & other psychoses	256 (85.3)	151 (87.8)	105 (82.0)
Duration of illness (years) (n=270)	Median (Interquartile range; IQR)	5 (2.8, 10)	5 (2.8, 10)	5.5 (2.8, 11)
Onset of illness (n=271)	Acute/sub-acute	100 (36.9)	55 (35.5)	45 (38.8)
	Gradual	171 (63.1)	100 (64.5)	71 (61.2)
Psychiatric admission	In past 12 months	11 (3.7)	5 (2.9)	6 (4.7)
Treatment at recruitment (n=261)	Prescribed medication at baseline	69 (26.4)	35 (23.5)	34 (30.4)
Co-morbid medical disorder (n=286)	Diagnosed medical condition	18 (6.3)	13 (8.1)	5 (4.0)

*Poverty index = roof material made of straw (vs. corrugated iron), unimproved water source, unimproved sanitation, no electricity, no separate room for kitchen, no radio or television, no mobile 'phone.

Table 2: Mixed effects modelling of primary outcomes stratified by equity indicators

Outcome		Baseline (T0) Mean (SD)	T0 to T1 mean difference (95% confidence intervals	T0 to T2 mean difference (95% confidence intervals
SMI symptoms (BPRS-E)		N=294	N=247	N=245
	Total sample	48.5 (15.6)	**-2.6 (-4.8,-0.4)**	**-4.8 (-7.0, -2.6)**
Gender	Male	47.9 (16.3)	-2.2 (-5.2, 0.9)	**-3.9 (-6.9, -0.8)**
	Female	49.4 (14.7)	**-3.2 (-6.3, -0.04)**	**-6.0 (-9.1, -2.8)**
Residence	Urban	47.4 (16.5)	-4.0 (-9.3, 1.2)	**-9.0 (-14.2, -3.8)**
	Rural	48.9 (15.4)	-2.3 (-4.7, 0.1)	**-4.1 (-6.5, -1.7)**
Health care access	<60 minutes	48.2 (16.2)	**-2.1 (-4.8, -0.7)**	**-5.5 (-8.3, -2.8)**
	≥ 60 minutes	49.3 (15.6)	**-3.9 (-7.5, -0.3)**	-3.4 (-7.0, 0.3)
Socio-economic status	Higher	49.2 (16.0)	**-3.5 (-6.6, -0.5)**	**-5.6 (-8.6, -2.5)**
	Lower	47.4 (15.1)	-0.8 (-3.9, 2.4)	**-3.1 (-6.2, -0.02)**
Disability (WHODAS 2.0)		N=296	N=246	N=245
	Total sample	52.2 (22.0)	**-6.2 (-9.3, -3.1)**	**-12.0 (-15.1, -8.9)**
Gender	Male	52.3 (21.5)	**-7.8 (-11.8, -3.8)**	**-10.1 (-14.2, -6.0)**
	Female	52.1 (22.7)	-4.2 (-9.0, 0.6)	**-14.3, (-19.1, -9.6)**
Residence	Urban	49.2 (22.3)	**-7.4 (-14.0, -0.7)**	**-14.1 (-20.6, -7.5)**
	Rural	53.1 (21.9)	**-6.2 (-9.7, -2.7)**	**-11.8 (-15.3, -8.2)**
Health care access	<60 minutes	50.4 (22.5)	**-4.8 (-8.7, -0.8)**	**-11.4 (-15.3, -7.4)**
	≥ 60 minutes	55.9 (20.7)	**-8.9 (-13.9, -3.8)**	**-13.4 (-18.5, -8.3)**
Socio-economic status	Higher	50.0 (21.8)	**-6.9 (-11.1, -2.7)**	**-11.4 (-15.6, -7.2)**
	Lower	55.3 (22.1)	**-4.7 (-9.3, -0.1)**	**-12.4 (-17.0, -7.9)**

427   **Table 3: Secondary clinical and social outcomes in people with SMI stratified by gender**

Outcome	Baseline (T0)	Follow-up (T2)	T0 to T2 change
	Mean (SD)	**Mean (SD)**	**Mean difference**
Depression symptoms (PHQ-9)	N=300	N=245	
Total sample	12.8 (5.43)	7.2 (4.80)	**-5.6 (-6.3, -4.8)**
Male	12.9 (5.64)	7.4 (4.84)	**-5.4 (-6.5, -4.4)**
Female	12.8 (5.15)	7.0 (4.75)	**-5.7 (-6.8, -4.6)**
	Median (IQR)	**Median (IQR)**	**Odds ratio**
Discrimination (DISC-12)	N=300	N=245	
Total sample	2 (0, 7)	0 (0, 3)	**0.4 (0.3, 0.5)**
Male	2 (0, 7)	0 (0, 4)	**0.5 (0.3, 0.8)**
Female	3 (0, 7)	0 (0, 2)	**0.2 (0.1, 0.4)**
	N (%)	**N (%)**	**Prevalence ratio**
Alcohol use disorder (AUDIT≥8)	N=300	N=245	
Total sample	87 (29.0)	40 (16.3)	**0.6 (0.5, 0.8)**
Male	77 (44.8)	34 (25.2)	**0.6 (0.4, 0.8)**
Female	10 (7.8)	6 (5.5)	0.7 (0.3, 1.4)
Suicide attempts past 3 months	N=300	N=245	
Total sample	42 (14.0)	12 (4.9)	**0.3 (0.2, 0.6)**
Male	20 (11.6)	8 (5.9)	0.5 (0.2, 1.0)
Female	22 (17.2)	4 (3.6)	**0.2 (0.1, 0.5)**
Restrained past 12 months	N=300	N=245	
Total sample	76 (25.3)	26 (10.6)	**0.4 (0.3, 0.6)**
Male	52 (30.2)	13 (9.6)	**0.3 (0.2, 0.5)**
Female	24 (18.8)	13 (11.8)	**0.6 (0.3, 1.0)**

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588 **Conflict of interest**

589 None.

590 **Ethical standards**

591 The authors assert that all procedures contributing to this work comply with the ethical standards of the

592 relevant national and institutional committees on human experimentation and with the Helsinki

593 Declaration of 1975, as revised in 2008.

594 **Availability of Data and Materials**

595 The datasets used and/or analysed during the current study are available from the corresponding author

596 on reasonable request. The PRIME datasets will be made publicly available during 2019 (via

597 www.prime.uct.ac.za).

598

599

600 **Supporting information captions**

601 **Supplementary file 1**

602 File format: WORD

603 Title: Characteristics of participants assessed at 12 months compared to those lost to follow-up

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604 Description: Table displaying baseline characteristic of people with SMI who were re-assessed at the 12-

605 month follow-up time-point compared to those who were lost to follow-up.

606 **Supplementary file 2**

607 File format: WORD (embedded tiff figure).

608 Title: Pattern of engagement with primary care mental health care

609 Description: Figure showing number of primary care contacts for mental health care for each 3 month

610 period of follow-up.

611 **Supplementary file 3**

612 File format: WORD

613 Title: Psychotropic medication prescribed to cohort participants

614 Description: Descriptive summary of % of people receiving different types of psychotropic medication.

615 **Supplementary file 4**

616 File format: WORD

617 Title: Receipt of community and facility level care over the follow-up period

618 Description: Types of care received by the participants over the 12 month follow-up period.

619 **Supplementary file 5**

620 File format: WORD

621 Title: Tests for effect modification of change in outcome variables between T0 and T1

622 Description: Table presenting statistical testing of effect modification between T0 and T1.

623 **Supplementary file 6**

624 File format: WORD

625 Title: Tests for effect modification of change in outcome variables between T0 and T2

626 Description: Table presenting statistical testing of effect modification between T0 and T2.
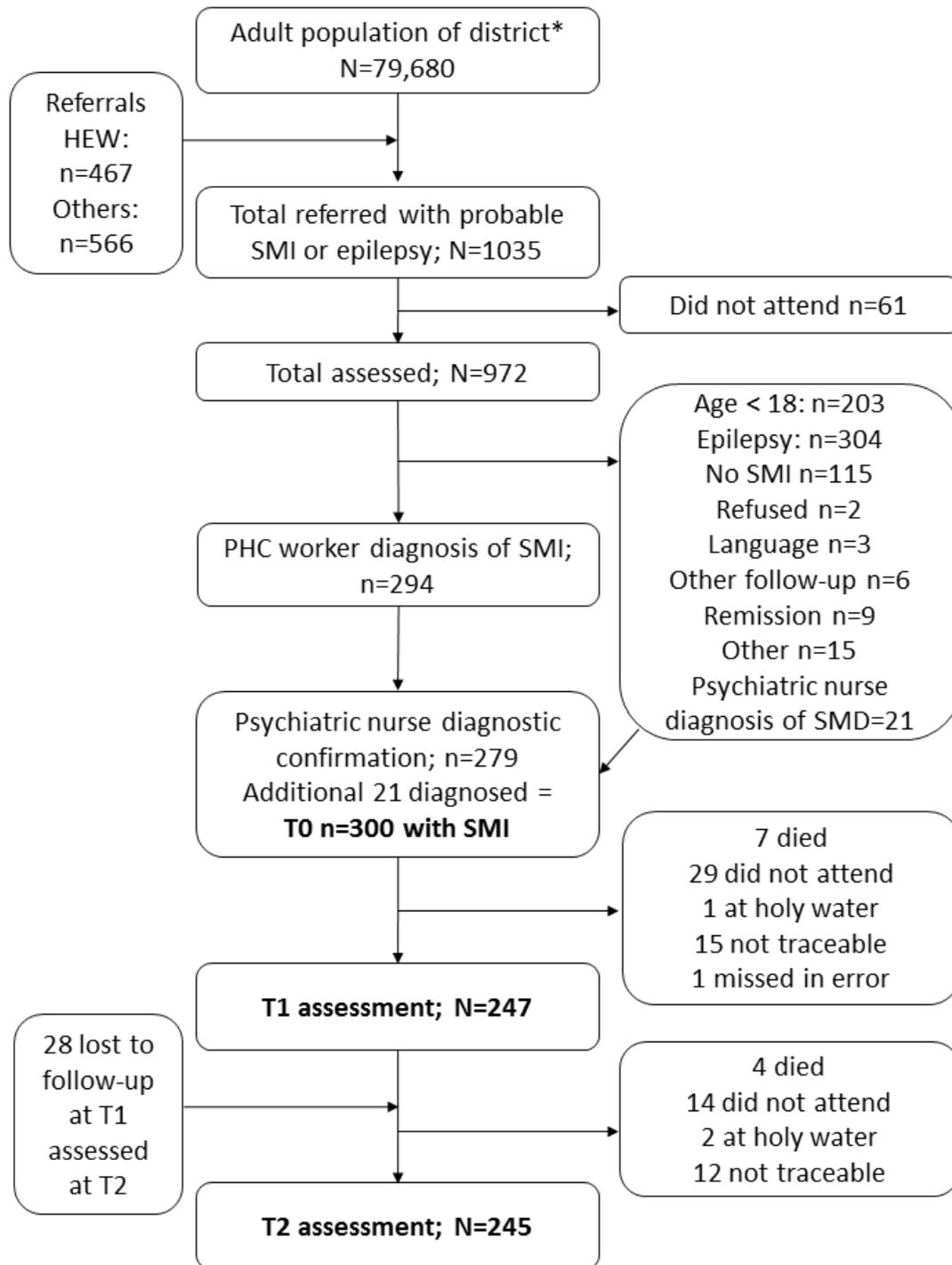
627 **Supplementary file 7**

628 File format: WORD

629 Title: STROBE checklist

630 Description: STROBE checklist for reporting of this study

631

632   Figure 1: flow chart of study participants