



## Feasibility and effectiveness of nurses and clinical officers in implementing the WHO mhGAP intervention guide: Pilot study in Makueni County, Kenya

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### ABSTRACT

**Objectives:** (1) To determine the feasibility and effectiveness of nurses and clinical officers in using the mental health Global Action Programme Intervention Guide (mhGAP-IG) as an intervention tool in reducing disability, improving quality of life in the clinical outcomes in patients with the mhGAP-IG priority mental disorders in a Kenyan rural setting. (2) To identify any gaps that can be contributed towards future research.

**Methods:** This study was conducted in 20 healthcare facilities across Makueni County in the South East of Kenya. This county had a population of approximately one million people, with no psychiatrist or clinical psychologist. We recruited 2306 participants from the healthcare facilities in the catchment areas that had previously been exposed to the community mental health awareness campaigns, while being subjected to screening for the mhGAP-IG disorders. We used the Mini-International Neuropsychiatric Interview for adults (MINI-Plus) for DSM-IV confirmatory diagnosis on those who screened positive on the mhGAP-IG. We measured disability using WHO-Disability Assessment Schedule II (DAS II), Quality of Life (QoL) using the WHO QoL-BREF, depression using Patient Health Questionnaire (PHQ-9), suicidality using The Beck Suicide Scale (BSS), psychosis using the Washington Early Recognition Center Affectivity and Psychosis (WERCAP), epilepsy using a seizure questionnaire and alcohol and substance abuse using The Alcohol, Smoking and Substance Involvement Screening Test (ASSIST). These measurements were at the baseline, followed by the training for the health professionals on using the WHO mhGAP-IG as an interventional tool. The measurements were repeated at 3 and 6 months post-intervention.

**Results:** Of the 2306 participants enrolled in the study, we followed 1718 at 3 months and 1371 at 6 months a follow-up rate of 74.5% and 59.4% respectively. All participants received psycho-education and most depending on condition also received medication. Overall, there was significant decline in disabilities, improvement in seizure control and improvement in clinical outcomes on the identified mental disorders.

**Conclusions:** Trained, supervised and supported nurses and clinical officers can produce good outcomes using the mhGAP-IG for mental health.

### 1. Introduction

The mental health Global Action Programme Intervention Guide (mhGAP-IG) was developed by the World Health Organization (WHO) as an evidence-based tool for use by trained, supervised and supported non-specialized health workers, including informal health workers in low- and middle-income countries (LMICs) with the aim to reduce the

treatment gap and the high burden of mental disorders in LMICs as compared to High Income Countries (HICs) [1–5]. In LMICs, there is a dearth of mental health specialists [6–8] despite similar mental health epidemiological patterns as found in HICs [9,10]. Hence the need to innovatively maximize available resources to increase mental health coverage, even in the absence of the highly specialized mental health skills found in the HICs [7,11].

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The original version of WHO mhGAP Intervention Guide (mhGAP-IG) (which was the version available during our study) focuses on priority mental health conditions: depression, schizophrenia and other psychotic disorders, suicide, epilepsy, dementia, disorders due to use of alcohol, disorders due to use of illicit drugs [1] but the new version 2.0 has some additional and updated categories [12]. The priority conditions in the original version were selected because they represent a large burden in terms of mortality, morbidity or disability, high economic costs and are associated with violations of human rights [1]. They are also associated with reduced quality of life and increased disability [13,14].

Our study focuses on clinical officers and nurses as health care providers who outnumber doctors; are allowed some leeway to prescribe and are found at primary healthcare facilities [15]. A clinical officer in Kenya is a high school graduate who undergoes four years of clinical skills and competence-oriented training in a mid-level College. At the end of successful training for these four years they would receive a diploma (not degree). Similarly, nurses are normally high school graduates who undergo a four year nursing skills and competence training at a mid-level college.

**Research Question:** Can nurses and clinical officers, who have been trained on the mhGAP-IG and are supported and supervised as they offer the mhGAP-IG, produce significant outcomes on disability, quality of life and clinical improvements?

## 2. Methods

### 2.1. Study site and settings

This study was conducted in Makueni County, one of the 47 counties in Kenya with a population of approximately one million [16]. At the time of the study, it had neither a psychiatrist nor a clinical psychologist. It had the following healthcare facilities: one referral hospital, six sub-county hospitals, 21 health centers, 113 dispensaries and 11 private clinics [17]. In consultation with the county officials and in order to achieve equitable representation of the facilities; five dispensaries, nine health centers, five sub-county hospitals and the county referral hospital were selected as study sites.

### 2.2. Study design

This was an uncontrolled, prospective, continuous recruitment design, intervention study. For the purposes of this study, we started recruitment when the trained nurses and clinical officers had gained six months hands-on experience in the application of the mhGAP-IG. They had to be under the supervision and the support of mental health workers, and the research staff from Africa Mental Health Research and Training Foundation (AMHRTF).

### 2.3. Participant's recruitment

We trained Community Health Workers (CHWs), Traditional Healers (THs), Faith Healers (FHs), families and clinicians who volunteered for this study, on how to create awareness of the symptoms of each of the priority mhGAP-IG, psychiatric disorders in their adult clientele, friends and families and to refer to the nearest healthcare facility those they suspected to have any of the priority disorders. Those who were referred to a healthcare facility underwent confirmatory diagnosis for their suspected disorders using the MINI Plus [18], which was administered by a trained research assistant (who operated independently of service providers) to generate or rule out DSM-IV/ICD 10 [19] diagnosis. The MINI Plus has good psychometric properties [18] and has been used extensively including in the LMICs [20,21]. Those confirmed positive on M.I.N.I. Plus were then referred for interventions by the trained nurses and clinical officers and constituted the participants for this study after informed consent was obtained.

### 2.4. Adaptation, translation, piloting and adoption of the mhGAP-IG

We followed the WHO mhGAP-IG recommendations [1] for adaptation, translation, piloting and adoption to the Kenyan context. This was done as follows: -(1) We constituted an adaptation team consisting of a psychiatrist, clinical psychologists, nurses, clinical officer and a linguist who went through each question to ensure the language was culturally and linguistically appropriate for the Kenyan context, while at the same time ensuring retention of the original meaning of each of the statements. (2) Back translation of the adapted version i.e. from English to local dialect (Kikamba) back to English. (3) Piloting of the adapted version was done on a few patients who were not involved in the main study, to ensure they understood the questions and (4) adoption. We have described the process in more details in another publication [22].

### 2.5. The intervention: training, supervision and support

The adopted mhGAP-IG manual provided the framework for five full-day residential training for 40 nurses and clinical officers, conducted by an AMHRTF team, led by a psychiatrist (DMN). The training covered two disorders per day and included PowerPoint presentations, clinical case discussions combined with small group activities, mock screenings and referral processes. Their field work was supervised and supported by the same team at AMHRTF through face to face reviews every two weeks and virtual supervision on demand. In other studies we had demonstrated the feasibility of this type of supervision and support [23]. The support included provision of independent research assistants (RAs) to administer the various instruments, and the availing of the psychotropic drugs needed for the various disorders.

Psychoeducation was holistic and focused on educating both patients and families on patients' current mental disorder diagnosis. It also involved psycho-educating patients and family caregivers on the prescribed psychotropic drugs and the following areas: any side effects, the need to adhere to prescribed doses, adherence with appointments which were monthly for 6 months follow-up, and the involvement of the caregivers in supervising medication adherence.

### 2.6. The consenting process

Following community based awareness campaigns on mental health symptoms for common adult mental disorders in mhGAP-IG, those community members who felt that they had some of the symptoms and were willing to be screened. These community members were asked to see their usual health providers for a screening, which used the mhGAP-IG. Those who screened positive and were willing to be confirmed, were referred to the nearest health facility for confirmatory diagnosis and management. Trained RAs based in the facilities sought informed written consent from the referred patients. The RAs obtained consent in a language that the patient understood. The written consents were either in English, Kiswahili or Kamba. This process took place in one of the private rooms that had been reserved for this study. The RAs read the consent forms to the patient, explained everything to the individuals and answered the questions that the individuals didn't understand. Only those who gave written informed were included in the study. Every patient was given a copy of the signed consent form while the other one was transferred to Nairobi for safe storage under lock and key.

### 2.7. Measures

We held a two day residential training for independent research assistants on how to administer the instruments that measured the outcomes of the interventions. They were not allowed to interpret any of the questions to the interviewees or show any emotional reaction to the responses, but were to only read the questions to the respondents up

to a maximum of 3 times, then record the answers provided on the self-administered instruments. Socio-demographic variables and profiles, including the wealth index, and the independently made DSM-IV/ICD 10 diagnoses were recorded. The wealth index used is based on the World Bank Recommendation for LMICs [24] and has been adopted by the Kenya Government for use locally. It is classified into five sections, quintiles 1–5; quintile 1 representing the lowest level of wealth and 5 the highest level.

In order to determine the effectiveness of the interventions, we used different instruments in order to make objective measures of the outcomes of the interventions. The WHO-Disability Assessment Schedule II (DAS II) [25–27] was used to capture disabilities. The WHO Quality of Life Brief Scale (WHOQoL-BREF) [28] was used to capture quality of life. It has good psychometric properties with internal consistency (Cronbach's  $\alpha$ ) of  $> 0.68$  for the four domains [29]. It has been used cross-culturally in previous studies conducted in Africa, including Kenya [30–33]. The clinical outcomes of different mental disorders conditions were monitored using various tools for severity of symptoms as follows:

- i. **Depression:** We used the self-administered patient health questionnaire (PHQ-9) [34] to track participants' overall depression severity.
- ii. **Suicidality:** The Beck Suicide Scale (BSS) [35,36] was used to track the levels of suicidality. It is a 21-item self-report scale designed to detect the participant's desire, attitudes, behaviors, and plans to commit suicide.
- iii. **Psychosis:** The Washington Early Recognition Center Affectivity and Psychosis (WERCAP) Screen was adapted from Prevention through Risk Identification, Management, and Education (PRIME) group at Yale University (the PRIME screen) [37] and validated in Kenya to estimate the severity of psychotic symptoms and "affectivity", a measure of mood dysregulation [38].
- iv. **Epilepsy:** We used a researcher-designed seizure questionnaire to assess occurrence and compliance to medication related to seizures among the epileptic patients. The questions comprised of the following questions: (a) Total number of days with any seizure for the last 28 days (b) The longest period in days between which a seizure occurred (c) Total number of seizures reported over the 28 days period (d) Total number of days the participant did not take his/her medication as prescribed (e) Total number of days the participant took his/her medication as prescribed. Responses to these questions were used to assess the changes over time.
- v. **Alcohol and substance use:** We focused on the most common substances abuse in Kenya i.e. alcohol, tobacco, cannabis and khat [39]. We used the WHO's Alcohol, Smoking, and Substance Involvement Screening Test (ASSIST) [40]. The survey takes about 5 min to complete and has been validated for use in LMICs [41]. Khat is a herb widely chewed in East Africa and the horn of Africa and contains the psychoactive cathinone [42,43]. The ASSIST does not mention Khat specifically, but we added it as a substance of abuse because we had found it prevalent in previous studies [44,45].

Dementia was one of the conditions screened for using the mhGAP-IG. The Mini Mental State Examination (MMSE), can be used to monitor outcomes overtime. However, the MMSE is interviewer rated and requires clinical skills for interpretation by the interviewer. The research assistants we worked with did not have any clinical skills. This is unlike the other instruments which do not require clinical skills for interpretation and can be self-administered or read aloud to the participants. All that is required is to simply record the responses of the interviewees. Therefore, unable to predict the reliability of MMSE, as used by non-clinicians, we decided not to include dementia outcomes as one of the measurables.

## 2.8. Statistical analysis

Descriptive analysis was done for the socio-demographic variables, wealth index, primary diagnosis (DSM-IV/ICD 10 Diagnosis) [46]. We computed means and Standard Deviation (SD) of the scores of different instruments over time and we estimated the percentage change over baseline. We used multilevel linear mixed models [47,48] to estimate the effect of intervention over time and possible predictors of the observed change. We used a two-level model with repeated observations at level-1 and patients at level-2. Random effects were allowed to covary and variances to differ using unstructured covariance matrix. All predictors were entered as main effects. Participants were treated as random factors assumed to represent a randomly selected sample. The effect of time as a linear term over primary outcomes was assessed and included in the analysis as a random effect. Restricted maximum estimation was used for model fitting. Scores of participants who were lost to follow-up were imputed using five randomly generated scores based on their baseline characteristics and sensitivity analysis was done using complete cases only. Our numbers were large enough to make statistical inferences. All the analysis were done using STATA version 14 [49].

## 3. Results

Our results are in two categories: feasibility and effectiveness. We were able to demonstrate, using several broad themes, the feasibility to apply the mhGAP-IG. We achieved  $> 50\%$  follow up rate at 6 months. We included a wide diversity of social-demographics characteristics. Of all the participants there were more females (66.4%) than males (33.6%) at baseline and females continued to outnumber males at 3 and 6 months follow; most were married and had primary level education; nearly two thirds were either self-employed or employed by somebody else; the 60+ constituted one third; all the wealth levels were equally reported (Table 1). All mhGAP-IG disorders were confirmed by the MINI-plus to yield the DSM-IV diagnoses as summarized in Table 1. Major depression was the commonest DSM-IV diagnosis, found in more than a third, followed by dementia and epilepsy. A quarter of the participants had more than one DSM-IV diagnosis.

Nurses and clinical officers were able to provide the two broad categories of intervention prescribed by the mhGAP-IG i.e. psychoeducation and biological intervention (i.e. use of medication). That there was a wide variety of psychotropic drugs available is an indication of support by policy makers in making them available.

Fig. 1 gives a graphic summary of the management options for each of the disorders and a breakdown of the different types of medications prescribed. Both psychoeducation and medication were used in all conditions with the highest combination found in epilepsy (90.4%), psychosis (89.0%), dementia (64.6%) and depression (64.9%). Psychoeducation alone was mainly for suicidality (60.7%); alcohol and substance abuse (61.7% and 67.7% respectively) whereas psychoeducation alone was least used for epilepsy (9.6%) and psychosis (11.0%). Amitriptyline was the commonest indication (43.1%), followed by anti-convulsants and/or mood stabilizers, anti-psychotic and anxiolytics. However, 35.3% of the patients received medications prescribed for physical conditions.

We were able to demonstrate the effectiveness of the interventions. This effectiveness was affected by different socio-demographic indicators. Fig. 2 summarize the outcome on disabilities, quality of life and seizure control (columns A, B, C respectively), while Table 2 summarizes the predictors of those outcomes. On disability the largest decrease was between baseline and six months. Post hoc tests demonstrated that there were significant differences in all pair wise comparisons. The estimated effect size using partial Eta of the change was 0.233 for complete cases only and 0.185 for imputed missing values. After controlling for all other factors in a linear mixed effect model, the effect of time was significant in which there was reduction in WHO-DAS II scores as time progressed (Table 2). Better outcomes were associated

**Table 1**  
Demographic characteristics of participants and follow-up rates.

Variable	Category	Baseline (N = 2306)	Three months (N = 1718)	Follow-up rate (%)	Six months (N = 1371)	Follow-up rate (%)
		n (%)	n (%)	74.5	n (%)	59.4
Gender	Female	1531 (66.4)	1161 (67.6)	75.8	923 (67.3)	60.3
	Male	775 (33.6)	557 (32.4)	71.9	448 (32.7)	57.8
Marital status	Married	1446 (62.7)	1109 (64.6)	76.7	910 (66.4)	62.9
	Single/never married	391 (17.0)	274 (15.9)	70.1	210 (15.3)	53.7
	Widowed/divorced/separated	469 (20.3)	335 (19.5)	71.4	251 (18.3)	53.5
Education level	No formal education	529 (22.9)	408 (23.7)	77.1	332 (24.2)	62.8
	Primary education	1361 (59.0)	1006 (58.6)	73.9	810 (59.1)	59.5
	Secondary education	350 (15.2)	256 (14.9)	73.1	191 (13.9)	54.6
	Tertiary/university education	65 (2.8)	48 (2.8)	73.8	37 (2.7)	56.9
	Missing	1 (0.0)			1 (0.1)	
Employment status	Self-Employed	872 (37.8)	708 (41.2)	81.2	599 (43.7)	68.7
	Employed	524 (22.7)	383 (22.3)	73.1	311 (22.7)	59.4
	Unemployed	906 (39.3)	624 (36.3)	68.9	459 (33.5)	50.7
	Missing	4 (0.2)	3 (0.2)		2 (0.1)	
Age category	20 and below	47 (2.0)	31 (1.8)	66.0	30 (2.2)	63.8
	21–30 years	329 (14.3)	237 (13.8)	72.0	181 (13.2)	55.0
	31–40 years	395 (17.1)	304 (17.7)	77.0	235 (17.1)	59.5
	41–50 years	359 (15.6)	266 (15.5)	74.1	221 (16.1)	61.6
	51–60 years	396 (17.2)	297 (17.3)	75.0	239 (17.4)	60.4
	60 and above	780 (33.8)	583 (33.9)	74.7	465 (33.9)	59.6
Socio-economic status	Quintile 1	400 (17.3)	292 (17.0)	73.0	257 (18.7)	64.3
	Quintile 2	386 (16.7)	302 (17.6)	78.2	207 (15.1)	53.6
	Quintile 3	483 (20.9)	352 (20.5)	72.9	284 (20.7)	58.8
	Quintile 4	447 (19.4)	315 (18.3)	70.5	259 (18.9)	57.9
	Quintile 5	590 (25.6)	457 (26.6)	77.5	364 (26.5)	61.7
Diagnosis	Major depression	885 (38.4)	696 (40.5)	78.6	591 (43.1)	66.8
	Suicide	26 (1.1)	13 (0.8)	50.0	12 (0.9)	46.2
	Mania/hypomania	19 (0.8)	15 (0.9)	78.9	10 (0.7)	52.6
	Alcohol dependence/abuse	103 (4.5)	71 (4.1)	68.9	65 (4.7)	63.1
	Substance abuse/dependence	40 (1.7)	30 (1.7)	75.0	24 (1.8)	60.0
	Psychosis	85 (3.7)	58 (3.4)	68.2	43 (3.1)	50.6
	Dementia	393 (17.0)	299 (17.4)	76.1	241 (17.6)	61.3
	Epilepsy	166 (7.2)	127 (7.4)	76.5	108 (7.9)	65.1
	Comorbid	589 (25.5)	409 (23.8)	69.4	277 (20.2)	47.0

with primary education and above, self-employed rather than unemployed. Participants who were young (20 and below) had better outcomes as compared to those aged 60 years and above. Participants with the lowest wealth index (Quintile 1), an indicator for poor economic status, had significantly poor outcomes as compared to those in the Quintile 2.

On quality of life, there was a significant increase in all WHOQoL-BREF domain scores over time. Post hoc tests demonstrated that there were significant differences in all pair wise comparisons. The estimated effect size using partial Eta squared for all the WHOQoL-BREF domain scores for both complete cases only and the imputed missing values ranged from 0.180 to 0.454. Table 2 presents adjusted results using the multilevel linear mixed model. In all the WHOQoL-BREF domain scores and after controlling for all other factors the effect of time was significant which indicated there was a significant increase in quality of life over time. Fig. 2 (column B) summarizes the changing patterns of the various domains of QoL. Across all domains of quality of life, better outcomes were associated with male gender, being married, having some education, being self-employed, age < 20 years and increasing wealth index. However, there were a few exceptions on the environmental domain where self-employed was a risk factor. In social quality of life no significant differences ( $P > 0.05$ ) were found between depression and suicidality, mania/hypomania, alcohol and substance abuse.

Table 3 summarizes the means of different outcomes across the three assessments and the percentage change over baseline for the different mental disorders outcomes.

The leading improvements in DSM-IV diagnoses with leading reductions in symptoms at 6 months were in cannabis use (66.1%) and depression (49.0%), psychosis (40.7%), followed by other conditions

but with the least reduction for Khat (10.2%). Specifically on epilepsy there was a 45.3% decrease in seizures in the previous 28 days accompanied to a 27.9 reduction in the number of days the patient did not take medication. However, for nearly all indicators the clinical outcomes for seizures were better at 3 months follow up than at 6 months follow up.

Fig. 2 (column C) gives a graphic visualization of the changing patterns in seizures. There was an overall decrease in the number of days that the patients did not take anti-epileptics; there was an increase in the number of days the patients took medication; there was an increase in the longest period of days between which a seizure occurred. All these changes were significant across the assessment times. It is to be noted that outcomes were better at 3 months than at 6 months.

Table 4 summarizes how these outcomes varied with socio-demographic variables. There was a wide variation in independent socio-demographic predictors of different outcomes. However, there was consistency in improvement over time in all the outcomes ( $P < 0.05$ ) except for khat.

## 4. Discussion

### 4.1. The preamble

We present the first study in Kenya that demonstrates: (1) the feasibility that nurses and clinical officers can implement the WHO-mhGAP-IG; (2) that the mhGAP-IG as applied by trained, supervised supported nurses and clinical officers can be effective in producing favorable disability, quality of life and clinical outcomes as measured by instruments with good psychometric properties; and (3) that these outcomes are affected by various socio-demographic indicators. In

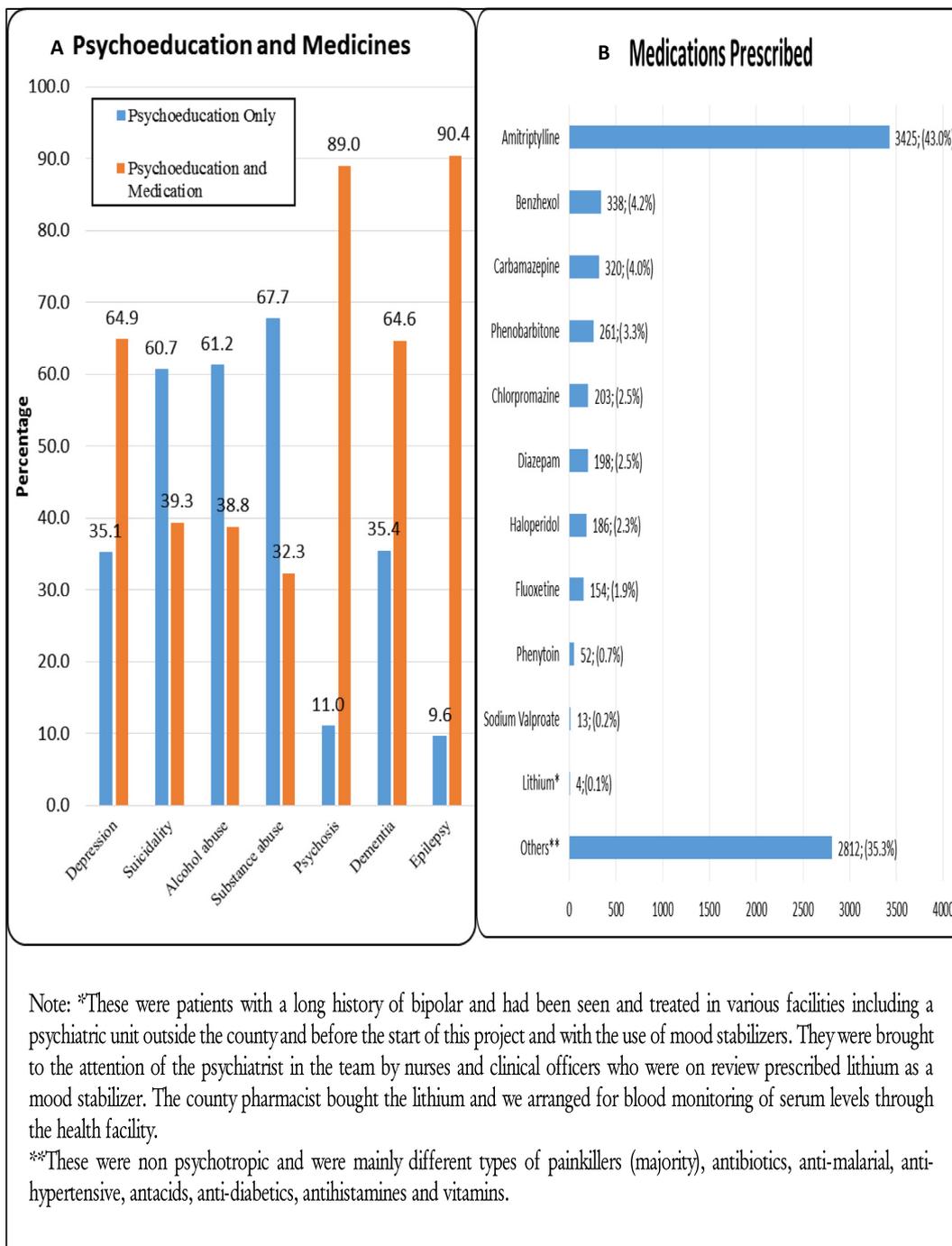


Fig. 1. Graphic summary of managements prescribed.

summary, we present the first evidence in Kenya that it is feasible that trained, supported and supervised nurses and clinical officers can be effective in producing significant disability, quality of life and clinical outcomes using the mhGAP-IG but subject to various socio-demographic indicators. Further, we present evidence for the feasibility that: (1) trained lay research assistants drawn from the local communities can use assisted DSM-IV oriented diagnostic instrument; and (2) it is possible to achieve > 50% follow up rates up to 6 months.

More specifically, our study responds to the challenge to fill a global gap which was recently identified in a systematic review on the mhGAP-IG that called for data on monitoring and evaluation of the mhGAP-IG [3].

4.2. Feasibility to apply the mhGAP-IG DSM-IV diagnoses

While the primary aim of this study was not epidemiological we did demonstrate the feasibility to generate DSM-IV diagnoses that the nurses and clinical officers have to deal with on routine basis if mental health is to be implemented using the mhGAP-IG. We have also highlighted the non-feasibility to use the MMSE to monitor dementia in a setting where there are no clinicians with the requisite clinical skills to interpret scores on the MMSE. In addition, the MINI-Plus does not have a dementia category, which for purposes of categorizing dementia in our study, required us to use the mhGAP-IG criteria. That dementia was the 2nd common condition is not surprising as the individuals that came forward for screening had at least 35% aged 60 and above. The

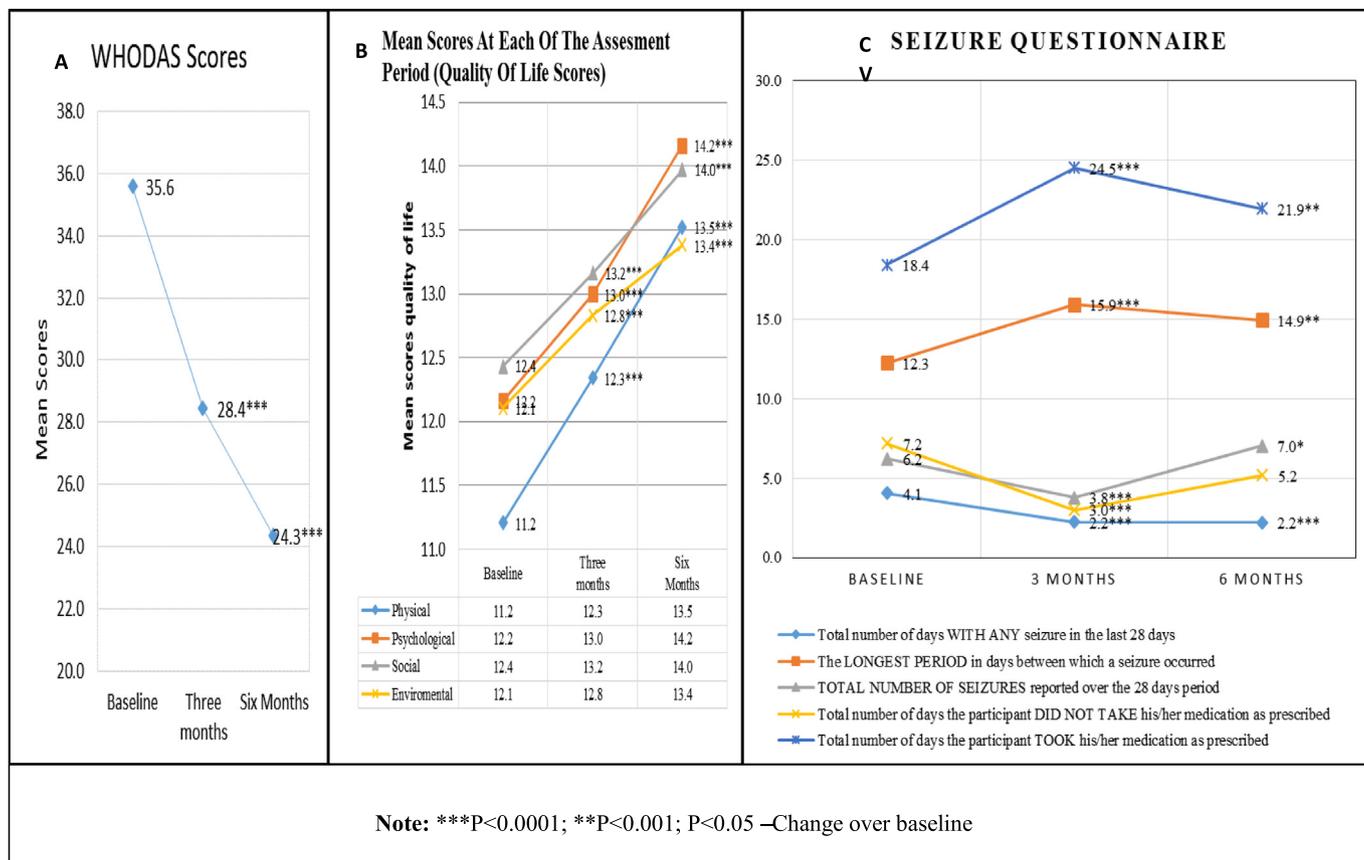


Fig. 2. Graphic summary of outcomes.

overrepresentation of the 60 and above reflects those who were retired in the communities and were available at the time of the study. Also this study took place in a community in which developmental deficits have been found to affect about 25% of the population [50], most likely related to environmental factors. It was therefore not surprising we found young people who screened positive for dementia, albeit much less than those aged 60 and above. We think the epilepsy, the third most common single condition found in this study at 7.2% shares the same explanations as for dementia, but also its dramatic presentation such that it is relatively much easier to pick it out. The high Co-morbid DSM-IV disorders (in a quarter of all the participants who received DSM-IV diagnosis), suggests the clinical need to be aware of more than one psychiatric disorder existing in the same individual. Equally noteworthy is the co-morbidity of 35.3% with non-psychiatric disorders for which drugs for physical conditions were prescribed. This suggests the need for integrated mental and physical disorders management which to some extent was already being provided to the study participants. This needs to be formalized as a matter for routine practice.

#### 4.3. Follow-up rates

We explain the high follow up rates at 3 months as follows: There was improvement at 3 months which was objective as per our instruments and/or subjectively deemed satisfactory by the study participants; Recovery is subjective and is balanced with other demands of life e.g. to earn money for the family or be involved in other social activities i.e. recovery is relative and context determined either by the patient and/or the caregiver(s) who support patients at family level against other equally critical demands and the expenses incurred in going to the hospital [51].

#### 4.4. The interventions

The mhGAP-IG provides for both psychosocial (which are Cognitive Behavioral Therapy (CBT) based) and biological interventions – which involve use of medicines [1]. The trained nurses had the choice to apply either or both of these interventions. The nurses and clinical officers made their own clinical judgment leading to different degrees of application of both of these interventions for different DSM-IV diagnoses. In our study, psychoeducation was mainly prescribed in suicidality, alcohol and substance abuse and biological interventions mainly in epilepsy (which needs medications to control seizures) and psychotropic drugs to control disturbed behaviors in psychotic conditions (90.4% and 89.0% respectively were put on drugs) followed by major depression at 64.9%.

Overall, our findings indicate that the clinical officers and the nurses practiced a holistic approach to the patients with psychosocial interventions being applied in all conditions. It is noteworthy that the trained nurses and clinical officers did not use psychotropics to the exclusion of psychosocial interventions although in some cases they used only psychosocial interventions. It is not surprising that medication in addition to psychosocial interventions were predominantly used in psychosis, dementia and epilepsy conditions that present with overt and disturbed behavior requiring immediate control.

The availability of psychotropic drugs and their use at the health-care facilities could only happen because the psychotropic drugs were made available by the County Government as part of their contribution to this study training, supervision and support provided by AMHRTF team. This suggests the key role of policy makers in providing logistical support and the need for them to be part and parcel of this kind of study. Depression was the most common condition found in this study, which explains why an antidepressant was the most commonly used biological intervention. Affordability and sustainability informed the

**Table 2**  
Estimates from Multilevel linear mixed Models Assessing Predictors of Patient Change over Time for Disability (WHO-DAS) and Quality of Life outcomes (WHO-QoL BREF).

Parameter	Category	WHODAS	Quality of Life			
		WHODAS	Physical	Psychological	Social	Environmental
		β (95% C.I)	Quality of Life	Quality of Life	Quality of Life	Quality of Life
Gender	Female <sup>a</sup>	Ref				
	Male	-0.8 (-1.9-0.3)	0.4 (0.3-0.6)***	0.4 (0.2-0.5)***	0.2 (0.0-0.4)*	0.3 (0.2-0.5)***
Marital status	Married <sup>a</sup>					
	Single	-1.2 (-2.8-0.3)	-0.4 (-0.5-0.2)***	-0.4 (-0.6-0.2)***	-1.1 (-1.3-0.9)***	-0.5 (-0.6-0.3)***
	Others <sup>b</sup>	-1.5 (-2.8-0.2)*	-0.3 (-0.5-0.2)***	-0.1 (-0.3-0.1)	-0.6 (-0.8-0.4)***	-0.1 (-0.3-0.0)
Education level	No formal education <sup>a</sup>					
	Primary education	-4.5 (-5.9-3.0)***	0.8 (0.6-0.9)***	0.6 (0.4-0.7)***	0.2 (0.0-0.4)	0.2 (0.1-0.4)**
	Secondary education	-2.5 (-4.4-0.7)**	0.6 (0.3-0.8)***	0.3 (0.0-0.5)*	-0.2 (-0.4-0.1)	0.5 (0.3-0.7)***
	Tertiary	-8.4 (-11.5-5.3)***	1.3 (0.9-1.7)***	1.2 (0.8-1.6)***	0.8 (0.3-1.2)**	1.4 (1.1-1.8)***
Employment status	Self-employed <sup>a</sup>					
	Employed	1.1 (-0.2-2.3)	-0.4 (-0.5- -0.2)***	-0.2 (-0.3-0.0)*	-0.1 (-0.3-0.1)	0.1 (0.0-0.3)
	Unemployed	2.3 (1.1-3.4)***	-0.5 (-0.7-0.4)***	-0.2 (-0.4-0.1)**	-0.4 (-0.6-0.3)***	0.0 (-0.1-0.1)
Age category	20 and below <sup>a</sup>					
	21–30 years	-0.8 (-4.1-2.5)	0.0 (-0.4-0.5)	-0.1 (-0.5-0.4)	0.0 (-0.5-0.4)	0.1 (-0.3-0.4)
	31–40 years	0.5 (-2.9-3.9)	-0.6 (-1.0-0.1)**	-0.4 (-0.8-0.1)	-0.5 (-1.0-0.0)*	-0.1 (-0.5-0.2)
	41–50 years	-0.6 (-4.1-2.9)	-0.7 (-1.1-0.2)**	-0.4 (-0.9-0.0)	-0.7 (-1.2-0.2)**	-0.3 (-0.7-0.1)
	51–60 years	0.7 (-2.8-4.2)	-1.0 (-1.4-0.5)***	-0.3 (-0.7-0.2)	-0.6 (-1.1- -0.1)*	-0.1 (-0.5-0.3)
	60 and above	4.3 (0.8-7.8)	-1.4 (-1.8-0.9)***	-0.3 (-0.8-0.1)	-0.8 (-1.3-0.3)**	-0.2 (-0.5-0.2)
Socio-economic status	Quintile 1 <sup>a</sup>					
	Quintile 2	-2.2 (-3.9-0.5)**	0.3 (0.1-0.5)**	0.1 (-0.1-0.3)	-0.1 (-0.3-0.1)	0.2 (0.0-0.4)*
	Quintile 3	0.8 (-0.8-2.4)	0.2 (0.0-0.4)*	-0.1 (-0.3-0.1)	0.1 (-0.1-0.3)	0.2 (0.0-0.3)
	Quintile 4	0.8 (-0.8-2.4)	0.8 (0.6-1.0)***	0.4 (0.2-0.6)***	0.6 (0.4-0.8)***	0.6 (0.4-0.7)***
	Quintile 5	-0.8 (-2.4-0.8)	1.2 (1.0-1.4)***	0.6 (0.4-0.8)***	1.0 (0.8-1.2)***	0.8 (0.7-1.0)***
Diagnosis	Depression <sup>a</sup>					
	Suicidal behavior	-10.3 (-14.4-6.1)***	0.7 (0.2-1.2)**	0.4 (-0.2-0.9)	-0.4 (-1.0-0.2)	-0.1 (-0.5-0.4)
	Mania/hypomania	-5.2 (-10.0-0.3)*	1.2 (0.6-1.8)***	1.1 (0.5-1.7)***	0.3 (-0.4-1.0)	1.0 (0.4-1.5)***
	Alcohol abuse	-11.1 (-13.4-8.8)***	1.5 (1.3-1.8)***	1.8 (1.5-2.1)***	1.3 (0.9-1.6)***	0.9 (0.6-1.1)***
	Substance abuse	-12.5 (-15.9-9.1)***	0.7 (0.2-1.1)**	0.5 (0.1-0.9)*	0.3 (-0.2-0.8)	0.0 (-0.4-0.3)
	Psychosis	-4.7 (-7.1-2.3)***	0.7 (0.4-1.0)***	0.6 (0.3-1.0)***	-0.1 (-0.5-0.2)	0.5 (0.3-0.8)***
	Epilepsy	-4.6 (-6.5-2.6)***	0.5 (0.3-0.8)***	1.1 (0.8-1.3)***	0.4 (0.2-0.7)***	1.0 (0.7-1.2)***
	Comorbid	-2.7 (-3.8-1.6)***	0.4 (0.2-0.5)***	0.2 (0.1-0.4)***	-0.1 (-0.3-0.0)	-0.1 (-0.3-0.0)
Time	Assessment	-5.7 (-6.7-4.8)***	1.2 (1.1-1.3)***	1.0 (1.0-1.1)***	0.8 (0.7-0.9)***	0.7 (0.6-0.7)***
Intercept		44.9 (40.7-49.2)***	9.7 (9.2-10.2)***	10.5 (10.0-11.0)***	12.0 (11.4-12.5)***	10.8 (10.4-11.3)***

<sup>a</sup> Reference category.

<sup>b</sup> Divorced/separated/widowed.

\* P < 0.05.

\*\* P < 0.001.

\*\*\* P < 0.0001.

**Table 3**  
Percentage change over baseline.

Condition (measure)	N (%)	Mean scores across assessments			P-value	Percentage change over baseline	
		Baseline	3 months	6 months		3 months	6 months
1. Depression (PHQ-9)	1292 (48.8)	16.0	11.2	8.2	< 0.001	-30.2%	-49.0%
2. Alcohol (ASSIST)	219 (7.6)	24.9	18.4	17.9	< 0.001	-26.0%	-28.1%
3. Tobacco (ASSIST)	81 (2.8)	24.0	20.5	18.2	< 0.001	-14.5%	-23.8%
4. Khat (ASSIST)	44 (1.5)	16.3	18.5	14.7	0.168	13.3%	-10.2%
5. Cannabis (ASSIST)	31 (1.1)	22.4	13.6	7.6	< 0.001	-39.3%	-66.1%
6. Suicidality (BSS)	113 (3.9)	11.6	10.8	7.6	0.041	-6.9%	-34.5%
7. Affectivity (WERCAP)	215 (7.4)	24.3	15.6	15.2	< 0.001	-35.8%	-37.5%
8. Psychosis (WERCAP)	215 (7.4)	33.3	19.7	19.8	< 0.001	-40.9%	-40.7%
9. Epilepsy (SEIZURE EXTRACTION QUESTIONNAIRE)	185 (6.4)					-	
a. Total number of days with any seizure last 28 days	-	4.1	2.2	2.2	< 0.001	-44.6%	-45.3%
b. The longest period in days between which a seizure occurred	-	12.3	15.9	14.9	< 0.001	29.9%	21.8%
c. Total number of seizures reported over the 28 days period	-	6.2	3.8	7.0	< 0.001	-38.9%	13.4%
d. Total number of days the participant did not take his/her medication as prescribed	-	7.2	3.0	5.2	0.218	-58.2%	-27.9%
e. Total number of days the participant took his/her medication as prescribed	-	18.4	24.5	21.9	< 0.001	33.0%	19.1%

Note; Positive % means increase of scores and Negative scores means reduction in scores.

**Table 4**  
Socio-demographic factors associated with the changes in clinical outcomes over time (Multilevel linear mixed model).

Variable	Category	Depression (N = 1292)	Alcohol (N = 219)	Tobacco (N = 81)	Khat (N = 44)	Cannabis (N = 31)	Suicidality (N = 113)	Psychosis (N = 215)	
								Affectivity	Psychosis
Gender	Male#								
	Female	n/s	n/s	n/s	n/s	s*	n/s	n/s	n/s
Marital Status	Married#								
	Single/never married	s**	n/s	n/s	n/s	s**	n/s	n/s	s*
	Other†	n/s	n/s	n/s	s*	n/s	n/s	n/s	n/s
Education level	No formal education#								
	Primary	s**	n/s	n/s	n/s	n/s	n/s	n/s	n/s
	Secondary	n/s	n/s	n/s	n/s	s**	s**	n/s	n/s
	Tertiary	s**	s**	n/s	n/s	n/s	n/s	n/s	s*
Employment status	Self-employed#								
	Employed	s***	n/s	n/s	n/s	n/s	n/s	s**	s***
	Unemployed	n/s	n/s	n/s	s**	n/s	n/s	s***	s***
Age	20 and below#								
	21–30 years	n/s	n/s	n/s	n/s	n/s	n/s	n/s	s*
	31–40 years	n/s	n/s	n/s	n/s	n/s	n/s	n/s	n/s
	41–50 years	n/s	n/s	n/s	n/s	n/s	n/s	n/s	n/s
	51–60 years	n/s	n/s	n/s	n/s	n/s	n/s	n/s	n/s
Wealth index	60 and above	n/s	n/s	n/s	s***	n/s	n/s	n/s	s*
	Quintile 1#								
	Quintile 2	n/s	n/s	s*	n/s	s**	s*	n/s	n/s
	Quintile 3	n/s	s***	n/s	n/s	n/s	n/s	n/s	n/s
	Quintile 4	s***	n/s	s*	n/s	n/s	n/s	s*	n/s
Time	Quintile 5	s***	n/s	n/s	n/s	n/s	n/s	s**	s**
	Assessment	s***	s***	s***	n/s	s***	s*	s***	s***

Note: # - reference category; † - divorced/separated/widowed; n/s-not significant. \*P < 0.05; \*\*P < 0.01; \*\*\*P < 0.001.

choice of Amitriptyline given that this anti-depressant can be obtained cheaply – about 5 US cents for 25 mg. Clinical contacts were on a monthly basis over the 6 months follow-up. Fluoxetine was used in only a few patients but for only those who did not respond to Amitriptyline or could not tolerate its side effects. The dose was titrated against clinical response and side effects. All medications were given under supervision by a relative who had received psychoeducation to avoid overdose (accidental or deliberate). This supervision by a family caregiver is feasible in the community in which this study was done because the extended social support system is largely intact. Affordability, family supervision, support, understanding the need for medications, side effects and compliance with treatment were critical.

The significance of the use of medicines for physical conditions rather than mental disorders in 35.3% of the patients is that physical and psychological conditions were being treated concurrently even though these participants had primarily been screened and diagnosed for mental disorders. Though the patients were referred for possibility of mental disorders, they also presented with physical conditions that the nurses and clinical officers diagnosed and managed. This calls for a formal policy and practice for integrated services.

#### 4.5. Effectiveness of the Nurses and Clinical Officers in the application of mhGAP-IG

These favorable outcomes found in our study suggest that the mhGAP-IG, as applied by trained nurses and clinical officers may be an effective tool for psychosocial and clinical outcomes and that the improvement is sustained over the 6 months follow up for those who completed the follow ups. We will now discuss each of these outcomes in some detail.

1. **Disability:** The married had better outcomes than the divorced/separated and widowed, possibly because the latter had more stresses related to less resources and to the stresses of divorce, separation and widowed. The same explanation applies to those who were self-employed with better outcomes as compared to those who were not employed. We posit that younger people have more

flexibility in responding to the interventions, compared to those who were over 60 years. We further posit that better economic status as reflected by higher health index and employed status enabled better resources for better outcomes compared with low wealth index. Our findings suggest a relationship between disability and mental disorders in that their outcomes were intertwined.

2. **Quality of life (QoL):** It is not surprising that the QoL domain that showed the least improvement was the environmental domain. One possible reason for this is that environmental factors are external to the patient and less amenable to manipulation by the patients. Our finding that males had better outcomes (after controlling for other variables) in all the four domains of QoL than females does not agree with other findings that found females improved better [52]. We consider that our male patients had better access to resources and opportunities than females. Young participants may have better flexibility than older participants in responding to mhGAP-IG psychosocial interventions [53,54]. An example is lesser flexibility in dementia in older participants, who are more prone to irreversible structural brain changes compromising brain functions. We are of the opinion that the better outcomes observed for higher education, self-employment and higher wealth index are a reflection of endowment with better resources. Social support within married arrangements could be the explanation for better resources compared with other marital status.

3. **Clinical outcomes:** The 49% improvement at 6 months for depression is more than the 40% expected on placebo or reported from Chile [55]. This suggests that our interventions had more than a placebo effect. That for khat there was a deterioration of symptoms in the first three months but a 10% improvement at 6 months, can be expected in a culture where khat is widely used as a social and a legal drug and therefore an initial denial of any harmful effect. The 66.1% reduction in cannabis use can be explained in probable ways: It was of short duration and least habit forming; it was mostly not co-morbid with other conditions. There are effective drugs for controlling psychotic symptoms, epileptic seizures and depression. This explains that more than two thirds, these three conditions received a combination of psychoeducation and medications than any

other conditions. This was more so for psychosis and epilepsy. We did not track scores for any changes in dementia as screened using the mhGAP-IG for two reasons: dementia is not covered under MINI-Plus and the MMSE can only be administered by clinicians.

It is notable there was overall improvement on the key outcome measures of intervention on epilepsy. This is more so given that we were operating in a context where epilepsy is highly stigmatized [56–58]. We presume that following the initial reduction or cessation of seizures, there was a slacking in taking the anti-epileptics hence there were better outcomes at 3 months than at 6 months. The control of seizures is directly related to taking anti-convulsants. This calls for psychoeducation for continued taking of anti-convulsants even if no seizures occur. This suggestion on continued psychoeducation for epileptics finds support from a study in Guinea-Bissau in West Africa [59]. In this study from West Africa there was a significant drop in 88.8% of the research participants at two years follow up. The patients had been managed by trained community health volunteers (and therefore sustained effort for continued taking drugs) using the mhGAP-IG model.

#### 4.6. Limitations

Our ability to compare and contrast our findings with other findings is limited by the paucity of global data on research design similar to ours involving complex interventions for various disorders happening at the same time and using different instruments. This paucity of data has been articulated in a recent systematic review [3]. This study did not have a control group or condition that would have allowed a better understanding of the determinants of outcomes either for different groups or a particular condition and therefore limited certainty on the role of the intervention in explaining the outcomes. However, there was an overriding clinical indication for the interventions provided here. Epilepsy and psychotic conditions definitely need intervention and cannot be left to intervention as usual when the only way to provide intervention is to prescribe at least the most commonly used a psychotropic drug which is what we did in this study. This was a complex intervention strategy and the improvements in all conditions and in QoL and disability could not all have occurred by chance. When it comes to depression, it has been found that only up to 40% of improvement could be by chance [55]. Equally significant and overriding is an ethical issue that would have denied the application of the evidence-based mhGAP-IG which is gaining global use in LMIC and therefore important for global comparison [3,60]. Also being a complex interventional study it would have been difficult to control for all the factors with no prior knowledge on what to control for in specific conditions or groups. Another limitation is that we did not use mixed methods to explain through qualitative methods the various trends and associated factors found in this study. Finally the mental disorders studied here are limited to the priority conditions identified in the mhGAP-IG version that we used in this study. However, there is still need for further studies that also employ qualitative and clinical trial techniques to determine what best explains the protective and risk factors observed in this study. There is also need for better controlled clinical trials to determine which elements of the mhGAP-IG that best explain the observed apparent effectiveness.

#### 5. Conclusions

We have three main conclusions: (1). Our research question is answered in the affirmative; (2). We have laid grounds for future research and service improvement, fully aligned with the WHO Mental Health Action Plan 2013–2020 [61] and the United Nations Sustainable Development Goals [62]; (3) Our study provides strong support to the effect that the mhGAP-IG recommendations are based on evidence about screening methods and intervention work.

#### List of abbreviations

DAS II	Disability Assessment Schedule II
QoL	Quality of Life
PHQ	Depression using patient health questionnaire
MMSE	Mini Mental State Examination
MINI	Mini-International Neuropsychiatric Interview
BSS	Beck Suicide Scale
WERCAP	Washington Early Recognition Center Affectivity and Psychosis
mhGAP-IG	mental health Global Action Programme Intervention Guide
WHO	World Health Organization
LMICs	Low and Middle Income Countries
HICs	High Income Countries
AMHRTF	Africa Mental Health Research and Training Foundation
CHW	Community Health Workers
TH	Traditional Healers
FH	Faith Healers
PRIME	Prevention through Risk Identification, Management, and Education

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#### Conflict of interest

None.

#### IRB approval

Maseno University Ethics Review Committee granted approval. The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional guides on the care and use of laboratory animals.

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