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The effectiveness of a solution-focused approach (DIALOG+) for patients with severe mental illness and epilepsy in Uganda: A randomised controlled trial

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ABSTRACT

A patient centred, solution-focused approach, DIALOG+ was assessed for effectiveness among patients with severe mental illness (SMI) and epilepsy in Uganda. Fourteen clinicians and 168 patients attending Butabika National Mental Referral Hospital and outreach clinics in Kampala, Uganda were randomised equally to receive DIALOG + once a month for six months or an active control (DIALOG scale only). The primary outcome was subjective quality of life measured by the Manchester Short Assessment of Quality of life (MANSA) at six months and secondary outcomes assessed at six and twelve months. A generalised linear model with a fixed effect for treatment and the baseline MANSA score and a random effect for clinicians to account for clustering was used to analyse effectiveness of the intervention. The primary outcome was assessed in 154 out of 168 patients (91.7%). Patients in the DIALOG + arm had significantly higher subjective quality of life with a medium Cohen's d effect size of 0.55 and higher adherence to medication after 6 months as compared to the control group. DIALOG + intervention could be a therapeutically effective option for improving quality of life for patients with severe mental illness and epilepsy with the potential to enhance routine review meetings in low-resource settings.

1. Introduction

Mental Neurological and Substance use (MNS) disorders, are a rubric that encompass severe mental illness (SMI), epilepsy and other related brain conditions, and are a major public health burden in developing Countries like Uganda (Altevogt et al., 2010; Mugisha et al., 2019). MNS disorders are often chronic and associated with disability, premature mortality and severe impact on social and economic wellbeing (Altevogt et al., 2010; Mugisha et al., 2019; Prince et al., 2007; Kakooza-Mwesige et al., 2017). In developing countries, MNS disorders are often treated together in an effort to leverage the limited resources in this setting (Altevogt et al., 2010). Severe mental illness contributes 14% to the global burden of disease and occurs in 3% of individuals globally with a lifetime prevalence of 10.1%. (Prince et al., 2007). In Uganda, the prevalence of all mental illness in adults is estimated at 24.2% (Kigozi et al., 2010).

Epilepsy contributes 0.5% of the global burden of disease (Leonardi and Ustun, 2002) with 5 million people diagnosed each year globally (Kakooza-Mwesige et al., 2017) In Uganda it is the most common MNS disorder treated by mental health professionals, alongside psychosis, bipolar disorder and severe depression (Alitubeera et al., 2020).

The increasing burden of mental disorders within low-resource settings necessitates a mental health services shift to the implementation of resource-oriented approaches for these chronic and debilitating conditions (Priebe et al., 2007, 2019). Various low-cost approaches have been tested as alternative forms of care for people with SMI and have been shown to be effective in high-income countries (Priebe et al., 2015). One such intervention is a patient centred, solution focused approach that addresses patient's concerns referred to as DIALOG+. Crucially the approach identifies and mobilises the resources available to the person,

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either personally, or within their community (Priebe et al., 2013).

A cluster-randomised controlled trial (RCT) of DIALOG+ with community-based patients with psychosis found that the patients in the DIALOG + arm had better subjective quality of life (SQOL) at 3, 6 and 12 months than the active control arm. The DIALOG + patients also had significantly fewer unmet needs at 3 and 6 months, fewer general psychopathological symptoms at all-time points, and better objective social outcomes at 12 months (Priebe et al., 2007). In resource rich settings like the UK, DIALOG + requires limited training and no service reorganisation thus making routine meetings with clinicians therapeutically more effective (Priebe et al., 2007). However, there are few studies that have explored the effectiveness of this low-cost intervention in low- and middle-income countries.

This study aimed to assess the effectiveness of DIALOG + among patients with severe mental illness and epilepsy in, Uganda. The primary objective was to investigate whether the DIALOG + intervention, used once a month for 6-months, would improve quality of life at 6 months. The secondary objectives were to determine whether DIALOG + led to patient improvements in: objective social functioning, internalised stigma, medication adherence, symptom severity and service usage at 6 and 12 months.

2. Methods

2.1. Study design

This was a pragmatic cluster randomised controlled trial of DIALOG + compared to an active control (DIALOG scale only). The study was carried out at Butabika National Mental Referral Hospital in Kampala and its surrounding outreach clinics. The study received ethical approval from both the Makerere University College of Health Sciences (#REC REF 2018-096) and Queen Mary University of London (QMERC 2018/67) Research Ethics committees. The trial was conducted as part of a wider NIHR funded group involving six low and middle-income countries (Uganda, Bosnia and Herzegovina, Colombia, Peru, Argentina and Pakistan) focused on the development and effectiveness of psychosocial interventions for severe mental illness. The trial was registered (ISRCTN25146122) and the protocol was published elsewhere (Priebe et al., 2019).

2.2. Participants

Mental health professionals working in Butabika Hospital or the outreach clinics, with no plans to leave the post for the next 6 months, were identified and invited to participate in the study. These clinicians were involved in identifying and screening possible patient participants for the study by confirming a clinical diagnosis of SMI using the International Statistical Classification of Diseases and Related Health Problems (ICD-10).

Patients were eligible to participate if they had a clinical diagnosis of either SMI or epilepsy, were aged 18–65 years, had received care for at least 6 months, lived within a 20 km radius of Kampala or its outreach clinics, and had the ability to communicate in Luganda or English. If willing to participate, the patients' capacity to consent was assessed by research assistants using the University of California San Diego Brief Assessment for Capacity to consent (UBACC) with a cut off score of 14 or above indicating capacity. We excluded inpatients, patients without a phone contact and those with a primary diagnosis of substance use disorder, organic psychosis and/or neurocognitive disorder. The Manchester Short Assessment of Quality of life (MANSA) scale was used to determine level of subjective satisfaction with life. Those who had an average score of five or below, reflecting a rating of least satisfied with all life domains, were then enrolled into the study. Written informed consent was obtained from all clinicians and patients and baseline assessments were conducted for all enrolled participants.

2.3. Randomisation and masking

Randomisation was conducted after completion of baseline assessments by an independent UK-based statistician according to a computer-generated randomisation list. The unit of randomisation was the clinician. Twelve patients were matched with one clinician according to the patient's preferred day of clinic review. Seven clinicians (and their matched patients) were then randomised to the intervention (DIALOG+), and seven (and their patients) to the active control (DIALOG scale) arm. The principal investigator, all the outcome assessors, and the data analysts were blinded to the clinicians' and patients' allocations.

2.4. Fidelity measures

To help the research team to assess if clinicians were delivering the intervention as it was intended; audio recording of at least one session per patient and record of attendance at each session were captured. Eighty-four of 128 randomly selected audio recordings the DIALOG + sessions were scored on the 19-item DIALOG + Adherence Scale created by the DIALOG + implementation scale group to support the wider implementation of DIALOG within routine services (https://www.elft.nhs.uk/dialog/resources) The items assess the behaviour of the clinician and each of the 19 items is rated 0 or 1 depending on whether the action is in accordance with the DIALOG + manual. Findings of this and other other measures recorded will be presented in another paper.

2.5. Procedures

Following randomisation, all clinicians received an Android tablet with the intervention software (DIALOG+) or control software (DIALOG scale) preloaded. The Dialog scale is a tablet computer-based structured assessment consisting of 11 domains (8 life domains and 3 treatment domains) (Priebe et al., 2007, 2012). The eight life domains include mental health, physical health, job situation, accommodation, leisure, partner/family, friendship, personal safety) and three treatment aspects (medication, practical help, meetings with healthcare professionals) (Mosler et al., 2020). The DIALOG + adds a 4-step approach based on solution focused therapy to DIALOG + to address patients' concerns.

Clinicians received up to 4-h separate group trainings on how to use the DIALOG+ and DIALOG scale (by members of the local research team) according to the arm in which they were allocated that was followed by individualised support supervision training. Separate refresher trainings were conducted three months later for the two arms to address any challenges faced by the clinicians and to ensure that the intervention was being delivered as intended. The main challenge observed was getting used to the tablet.

For the DIALOG + intervention, each monthly session began with the patient using the tablet to rate their satisfaction with eleven domains. The tablet enabled patients to be more actively involved in the meeting, with the tablet easily passed between the clinician and patient. Each satisfaction item was rated on a scale from 1 ("totally dissatisfied") to 7 ("totally satisfied"), and followed by a question on whether the patient wanted additional help with that domain. After the initial scale assessment by the patient, the ratings were summarised on the tablet screen, which allowed for comparisons with ratings from previous meetings. The clinicians offered positive feedback on any improving or high-scoring domains.

The rating scale assessment was followed by a four-step solution-focused approach to identify the patient's existing resources that could be used to address any concerns raised. The four steps include understanding the situation in the given domain, looking forward at the desired alternative scenarios, exploring available options and agreeing on actions. These four steps are further elaborated upon in a previous publication (Priebe et al., 2019).

In the control arm (DIALOG scale), clinicians administered the same scale ratings of the eleven domains using the tablet at the beginning of

each monthly session without further guidance on discussion and solution finding for their problems beyond what is normally done in the clinic.

Primary and secondary assessments were conducted by blinded researchers at six months. After the 6-month period, an optional phase commenced for clinicians and patients who were willing to continue with the intervention for the next 6 months. At 12 months, patients completed the 12-month secondary outcome assessments. However, due to the COVID-19 pandemic, there was a 4-week delay in completion of the 12 months' assessments for participants because of the country-wide lockdown that affected movement and service delivery across the country and therefore access to mental health services. But since all our participants were coming from within a 20 km radius, with a transport refund, it was possible to complete the assessments after partial lifting of the lockdown measures. The delivery of the intervention was not affected.

2.6. Outcomes

The primary outcome was subjective Quality of Life, (SQoL) measured on the MANSA at 6 months. For each item of the MANSA, patients rated their satisfaction with different life domains on a scale from 1 (could not be worse) to 7 (could not be better) (Björkman and Svensson, 2005; Priebe et al., 2011). SQoL was measured at baseline, 6 and 12 months together with secondary outcomes of symptom severity, medical adherence, objective social function, and internalised stigma.

Symptom severity was measured by the Brief Psychiatric Rating Scale (BPRS). Each symptom was rated between 1 and 7 where a higher score indicated increasing severity of symptoms (Overall and Gorham, 1988).

Adherence to medication was measured by the Medication Adherence Rating Scale (MARS), which consisted of ten questions with simple Yes/No scoring. Individuals were considered compliant if they responded with a "No" to all questions apart from question seven and eight, which should have been answered with a "Yes" for compliance. This scale was designed and first validated for patients with schizophrenia (Fialko et al., 2008).

Social functioning was measured by the Social Outcome Index (SIX). The index contained objective data on the patient's employment status, accommodation status, living situation and social contacts. A total score was obtained by adding the individual scores from all 4 questions. The total score ranged from 0 to 6. Higher scores reflected a more positive social situation (Priebe et al., 2008).

Internalised stigma in people with mental illness was measured with the 29-item Internalised Stigma of Mental Illness Inventory (ISMI), which was developed with substantial consumer input. Each item is scored on a scale of 1–4: strongly disagree (1), disagree (2), agree (3), or strongly agree (4) (Boyd et al., 2014).

2.7. Statistical analysis

A formal sample size calculation was conducted. To detect a medium effect size of 0.5 and setting power at 80% for 5% significance, the total number of patients required was 64 per group (n = 128). After accounting for clustering based on an ICC of 0.01, a conservative design effect of 1.04 and allowing for a drop-out rate of 17% (which represents 2 patients per clinician), a total of 168 patients were required.

The statistical analysis plan was completed by the study team and trial statistician and signed off prior to any unblinding or analysis taking place. The baseline socio-demographic variables were described and compared using means, median and proportions. Differences in baseline characteristics of the study population were tested using Student's T-test for continuous normally distributed variables while Chi-square tests were used to test for difference between categorical variables in the intervention and control arms. The primary outcome MANSA was analysed using a generalised linear model with a fixed effect for treatment and the baseline MANSA score, and a random effect for clinicians to account for clustering. The same approach was used to analyse all other continuous outcomes including SIX, BPRS, ISMI, MARS where the scores were analysed using a generalised linear model with a fixed effect for treatment and the associated baseline value and a random effect for clinicians to account for clustering. The Cohen's d statistic was calculated as a standardised effect size measure. All analyses were performed using Stata version 15.1. Statistical tests and confidence intervals were two sided. Between-group comparisons were calculated and presented with 95% confidence intervals. The statistical significance level was set at the 5% level.

The trial was prospectively registered as (ISRCTN25146122) and monitored through weekly meetings and site meetings between the UK and Uganda team.

3. Results

Recruitment and assessment for eligibility took place between December 06, 2018 and March 07, 2019. A two-stage screening procedure was used for screening patients and the main reasons for exclusion are indicated in the CONSORT flow chart (Fig. 1) A total of 786 patients and 29 clinicians were assessed for eligibility and out of these we enrolled 168 patients and 14 clinicians from Butabika Hospital and its out-reach clinics. The Clinician participants included one medical officer, eleven psychiatric clinical officers (11) and two psychiatric nurses (2). Each clinician was assigned 12 patients and then randomised to either the intervention or the control arm.

The primary outcome was assessed in 154 out of 168 patients (91.7%) at 6 months (DIALOG+, n = 77; control, n = 77), and in 136 out of 168 (80.9%) at 12 months (DIALOG+, n = 70; control n = 66) as detailed in Fig. 1. There were no significant differences at baseline between the patient demographic and clinical characteristics as well as the clinicians' sociodemographic characteristics between the intervention arms and the control groups (See Table 1).

Of the patient participants recruited, 53.6% were females, the unmarried/single made up 59.5% of the sample. The majority (37.8%) of the participants had at least attained a secondary school education. These and other patient participant sociodemographic characteristics shown in Table 1 below.

Out of the 14 clinicians in the study, nine were females and all these clinicians were full time employees of the hospital with a median of 17.5 years of clinical practice as shown in Table 2 below.

3.1. Implementation of the intervention

A total of 118 patients had more than three sessions during the initial 6-month intervention phase. In this phase 58/84 (69%) participants in the intervention arm had more than one session with their clinician as compared to 60/84 (71.4%) in the control group. Seven individuals randomized did not further participate but were however included in the intention to treat analysis.

During the optional phase, from month 6–12, a total of 67 patients had meetings with the clinician. In the intervention arm, 24/84 (28.6%) participants had meetings with their clinician compared to 43/84 (51.2%) of the control group.

3.2. Main findings

DIALOG + had a significant positive effect on the primary outcome (SQoL as measured on the MANSA) at 6 months. Patients in the DIALOG + arm had significantly higher subjective quality of life after 6 months compared to those in the active control group (Table 3). The effect size was medium to large (0.55). The difference in QoL between the intervention and control group did not remain significant at 12 months (secondary outcome).

For the other secondary outcomes (Table 4), only adherence as measured by the MARS was statistically significant between the intervention and control groups at 6 months, with the intervention group

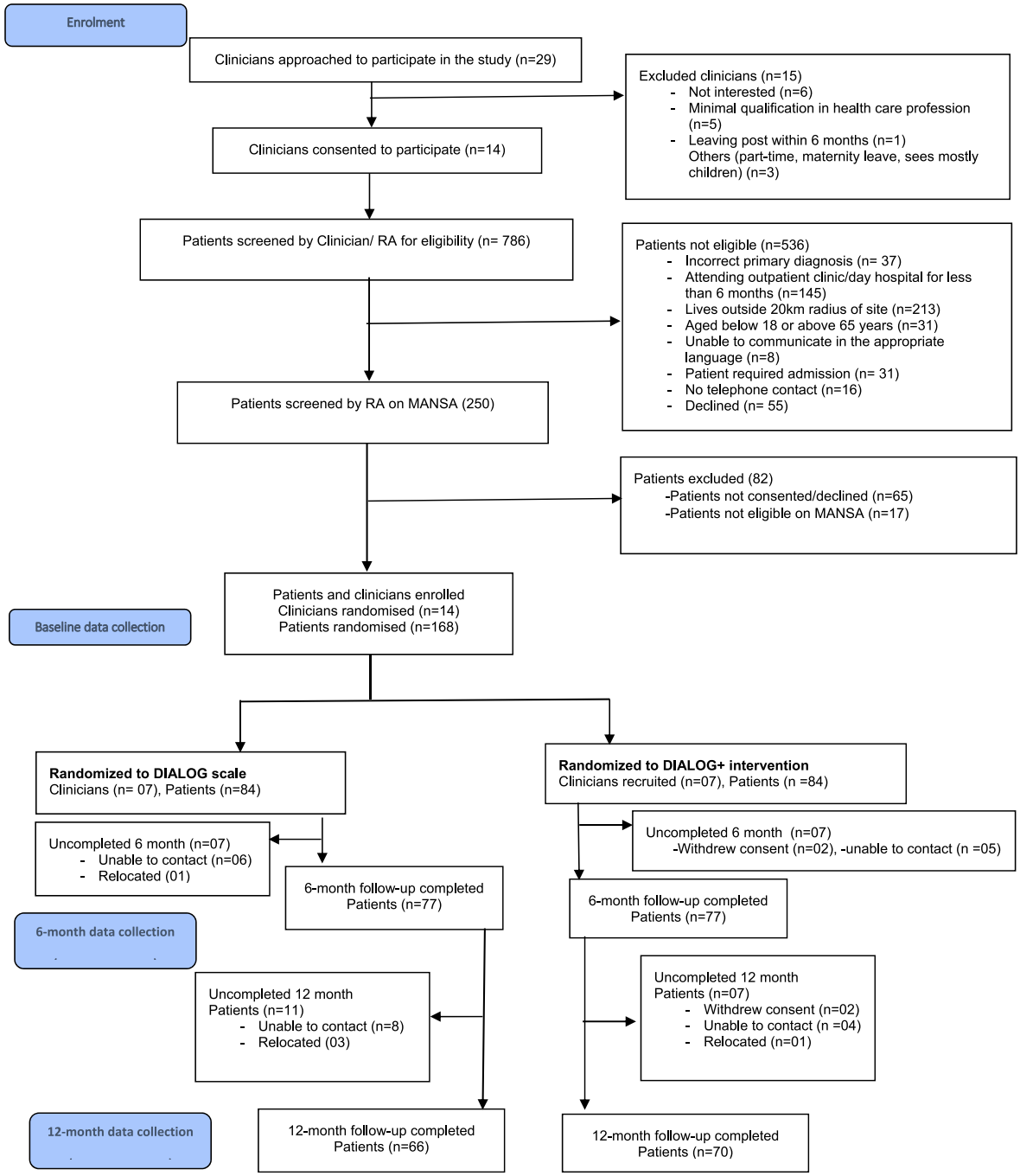

Fig. 1. CONSORT flow chart.

having higher levels of adherence with a small effect size (d = 0.36). All other secondary outcomes, although showing improvements from baseline to 6 and 12 months in both groups, did not significantly differ between the intervention and control.

3.3. Adverse events

A total of 16 serious adverse events were reported to the IRB during the study and they were not deemed to be due to the study. Eleven were recorded under DIALOG+ and 5 events under the control group. This included four patients who were admitted for physical health problems, 11 readmitted for mental health problems and one patient was reported missing from home but was later found.

4. Discussion

4.1. Main findings

This study set out to determine the effectiveness of a resource-oriented intervention (DIALOG+) in a resource-limited setting for patients with SMI and epilepsy. DIALOG + had a positive effect on improving Subjective Quality of Life and medication adherence after six months of using the intervention, with a medium to large effect size. On average patients in the intervention group improved by 1 point to 6 out of the 11 domains, or went from “totally dissatisfied” to “total satisfied” on one domain. All other secondary outcomes did not significantly differ, although in all cases, both groups improved as compared to baseline.

Table 1
Socio-demographic characteristics of the patient participants.

Characteristics	Group		Total N = 168 (%)
	Intervention N = 84 (%)	Control N = 84 (%)	
Gender n (%)			
Female	49 (58.3)	41 (48.8)	90 (53.6)
Male	35 (41.7)	43 (51.2)	78 (46.4)
Age in years, mean (SD)	36.6 (10.7)	36.8 (11.5)	36.7 (11.0)
Marital Status n (%)			
Single/Unmarried	49 (58.3)	51 (60.7)	100 (59.5)
Married/cohabiting	24 (28.6)	22 (26.2)	46 (27.4)
Separated	9 (11.9)	7 (8.3)	16 (9.5)
Widowed/widower	2 (2.4)	4 (4.8)	6 (3.6)
Education n (%)			
No formal education	1 (1.2)	6 (20.0)	7 (4.2)
Primary Education	27 (32.1)	22 (26.2)	49 (29.1)
Secondary Education	36 (42.9)	29 (34.5)	65 (38.7)
Tertiary/further education	20 (23.8)	27 (32.2)	47 (28.0)
Accommodation n (%)			
Independent Accommodation	77 (91.7)	74 (88.1)	151 (89.9)
Supported Accommodation	7 (8.3)	10 (11.9)	17 (10.1)
Living situation n (%)			
Living alone	8 (9.5)	6 (7.1)	14 (8.3)
Living with a partner	58 (69.1)	58 (69.1)	116 (69.1)
Living with friend(s)	18 (21.4)	20 (23.8)	38 (22.6)
Employment Status n (%)			
Employment (part/full time)	44 (52.4)	44 (52.4)	88 (52.4)
Unemployed/voluntary	35 (41.7)	37 (44.0)	72 (42.9)
Student	5 (5.9)	3 (3.6)	8 (4.7)
Primary diagnosis (ICD-10) n (%)			
Schizophrenia	18 (21.4)	23 (27.4)	41 (24.4)
Bipolar Disorder	37 (44.1)	38 (45.3)	72 (44.7)
Major depressive episode (F32, F33)	9 (10.7)	7 (8.3)	16 (9.5)
Epilepsy	20 (23.8)	16 (19.1)	36 (21.4)

Table 2
Socio-Demographic characteristics of Clinician participants.

Clinician demographics	Intervention (N = 7)	Control (N = 7)	Total (N = 14)
Age in years (IQR)	49 (36, 53)	44 (43, 48)	45 (36, 50)
Gender n (%)			
Female	4 (57.1)	5 (71.4)	9 (64.3)
Male	3 (42.9)	2 (28.6)	5 (35.7)
Marital Status, n (%)			
Single/Unmarried	1 (14.3)	0 (0.0)	1 (7.1)
Married	4 (57.1)	7 (100.0)	11 (78.6)
Co-habiting/Civil partnership	1 (14.3)	0 (0.0)	1 (7.1)
Widow/widower	1 (14.3)	0 (0.0)	1 (7.1)
Cadre/type of clinician			
Psychiatric clinical officer/ medical officer	5 (71.4)	6 (85.7)	11 (78.6)
Nurse officer	2 (28.6)	1 (14.3)	3 (21.4)
Employment status, n (%)			
Full time	7 (100.0)	7 (100.0)	14 (100.0)
Years in practice Median (IQR)	20 (7, 24)	17 (12, 20)	17.5 (12, 21.3)

4.2. Strength and limitations

The main strength of this study was the pragmatic nature of the trial, which allowed for the testing of our intervention in a generalizable setting. To our knowledge this is the first RCT to look at psychosocial interventions for SMI disorders in Uganda, with previous studies having focused on particular disorders like the group support psychotherapy intervention employed for the management of depression (Nakimuli-Mpungu et al., 2015). The intervention (DIALOG+) was implemented by health workers as part of their routine clinical assessments and as such included a wide range of patients utilising the WHO classification of MNS disorders, which includes epilepsy. This helps to increase the generalisability of the results, not only for Uganda but for other LMICs where services treat a range of SMI disorders. Secondly, within the trial, an active control group was used as a comparator, rather than treatment as usual. This helped to control for non-specific factors such as use of the computer tablet during the routine consultation, increased time and attention of clinicians and the impact of repeated quality of life measures. Thirdly, although it was not possible to blind clinicians delivering the intervention, all the outcome assessors were blinded to the trial arm allocation. The follow up rate was very high, >90% at 6 months, with >80% followed up at 12 months, even with the COVID-19 pandemic restrictions.

Despite these strengths, there are a number of limitations that need to be considered. Firstly, the pragmatic approach taken allowed clinicians to carry out DIALOG + assessments on days other than their specific clinic days of the usual schedule and this may have contributed to variable implementation of the intervention and control. However, there were similar number of sessions attended for both arms. Secondly, there was involvement of the researchers in scheduling and reminding patients about their appointments, which would not routinely happen. This however, occurred for both patients in the intervention and control groups. Lastly, although the drop-out rate was very low, COVID-19 lockdown restrictions disrupted not only the delivery of mental health services, but also disrupted the 12-months assessments, but these were eventually completed within one month of the final follow up period.

4.3. Interpretations of results

These findings are consistent with those reported in the original DIALOG + trial from the 'EPOS' study (Priebe et al., 2017), which found that DIALOG + improved SQoL at six months. DIALOG + guides discussion between clinicians and patients to reach an agreement, making them active participants in their own care (Priebe et al., 2017).

Although the positive effect of DIALOG + on SQoL was not maintained at 12 months, it is important to note the time just before the 12-month assessment happened with the onset of the COVID-19 pandemic. Participants could not be assessed as scheduled because of a country-wide lockdown. The changes in MANSA score seen in the first months could have easily been affected by the onset the COVID-19 pandemic and subsequent lockdown. This lockdown had effects on the implementation of the intervention as evidenced by fewer optional sessions being conducted among the two groups.

A post-hoc sensitivity analysis was conducted to assess the impact of attendance of additional intervention or control treatment, after patients were categorised as to whether they did or did not attend additional meetings. This analysis did not find statistically significant differences on subjective quality of life. Alternatively, the results could suggest that

Table 3
Quality of life measured using MANSA score at baseline, 6 and 12 months.

Quality of Life(Mansa score)	Intervention		Control		β coefficient	95% confidenceintervals	P	Cohen's d
Baseline	84	4.0 (0.8)	84	4.0 (0.7)				0.31
6 months	77	5.1 (0.7)	77	4.6 (0.9)	0.36	0.04to 0.67	**0.03**	0.55
12 months	70	4.9 (0.7)	66	4.7 (0.7)	0.08	- 0.14 to 0.31	0.47	0.25

Table 4
Secondary outcomes as assessed on the SIX, BPRS, ISMI and MARS.

Outcome	Intervention Mean (SD)		Control Mean (SD)		β coefficient	95% confidence intervals	P	Cohen's d
Social Outcomes(Total SIX score)								
Baseline	84	4.6 (1.1)	84	4.5 (1.2)				
6 months	77	5.0 (1.1)	77	4.8 (1.1)	0.03	(-0.30, 0.36)	0.86	0.09
12 months	70	4.7 (1.0)	66	4.6 (1.0)	0.1	(-0.25, 0.44)	0.59	0.10
Total BPRS score								0.26
Baseline	84	43.0 (8.8)	84	41.0 (8.9)				
6 months	77	34.2 (9.0)	77	36.8 (10.1)	−3.2	−6.50, 0.39	0.05	0.03
12 months	70	29.7 (6.2)	66	29.8 (6.7)	−0.5	−2.54, 1.62	0.67	0.02
Total ISMI score								0.09
Baseline	84	2.1 (0.5)	84	2.1 (0.5)				
6 months	77	1.8 (0.5)	77	1.9 (1.5)	- 0.09	−0.28, 0.09	0.33	0.21
12 months	70	2.0 (0.4)	66	1.8 (0.4)	0.10	−0.05, 0.26	0.19	0.32
Total MARS score								0.08
Baseline	84	6.8 (1.8)	84	6.9 (1.8)				
6 months	77	8.0 (1.3)	77	7.5 (1.7)	0.53	0.07, 0.99	**0.02**	0.36
12 months	70	7.9 (1.7)	66	8.0 (1.6)	- 0.07	- 0.61, 0.47	0.79	0.03

DIALOG + can bring about rapid change to quality of life, as shown by the medium to large effect size between the intervention and control group. However, six months, may not be sufficient to maintain the gains demonstrated over a longer period of time. Further research is needed to assess the impact of continued session, or "booster sessions" to maintain the initial gains.

Factors related to the onset of COVID-19 pandemic, such as access to essential needs, effects on leisure and relationships and access to medication, especially among people with mental health problems, affected subjective quality of life, and thus the minimal change seen in MANSA scores after twelve months (Cappo et al., 2020).

The effect size on the MANSA was a moderate to large effect, indicating that patients improved by 1 point on 6 out of the 11 items, or up to 6 points on a single item. This moderate to large effect size, suggests that DIALOG + which is a brief intervention, may have similar effect or even larger effects on subjective quality of life as compared to more time consuming and cost intensive therapies like cognitive behaviour therapy (Mueser et al., 2008).

4.4. Secondary outcomes

Of all the other secondary outcomes, only the difference in medication adherence scores at 6 months was statistically significant compared to the control group. This could possibly be attributed to the SFT, which enables the patients to discuss with clinicians their concerns that promotes the empowerment of patients to take charge of their own care. In this study patients in both arms were helped to access other services which has the effect of making routine care more effective and thus increasing medication adherence.

All other outcomes, including, objective social functioning, and internalised stigma, did not significantly differ between the intervention and control group apart from the symptom severity. This is contrary to Priebe et al. (2017) (Priebe et al., 2017) who reported significantly better objective social outcomes at 12 month follow up suggesting possibly changes to outcomes like housing and employment that take longer to improve. However, within the current trial, patients reported having fewer concerns related to housing, and most lived with family members, thus creating a ceiling effect on the measure of objective social situation. Likewise, Priebe et al. (2017) (Priebe et al., 2017) found that DIALOG + tended to improve general psychopathological symptoms in patients with psychosis as was demonstrated in this study as well at 6 months though was not the case at 12 months. The present study took the wider definition of MNS, including patients with epilepsy whose levels of psychopathology is usually low as compared to other mental disorders.

4.5. Implications and future directions

The results of this study indicate that structuring routine meetings via DIALOG + can be therapeutically effective, even in low-resource where the economic burden of caring for people with SMI is high. The lack of a significant difference between the intervention and control group at 12 months, suggests that more research is needed in order to assess the optimal length of time and frequency of the intervention delivery. During the optional phase, the DIALOG scale was more often applied as compared to the full DIALOG + intervention, although this could imply that the scale may be easier to incorporate in routine settings in the long-term due to time constraints. This needs further investigation as the continuation phase also coincided with the start of the COVID-19 pandemic with the associated restrictions. This study, however, underscores the need to make the meetings between mental health professional and patients in low resource areas more meaningful. Though DIALOG+ is more effective and thus preferential, the DIALOG scale could also be good to be use when the full DIALOG + intervention isn't feasible, e.g., due to time constraints.

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Data statement

The authors will ensure that the study dataset is available for sharing on request following the publication of the paper. Prior to making the

dataset available to interested individuals, the dataset will be pseudonymised and any potentially identifiable data removed.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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