General Hospital Psychiatry 60 (2019) 76–82

Contents lists available at ScienceDirect

General Hospital Psychiatry

journal homepage: www.elsevier.com/locate/genhospsych

Research paper

A stepped care intervention for non-specialist health workers' management of depression in the Mental Health in Primary Care (MeHPriC) project, Lagos, Nigeria: A cluster randomised controlled trial

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ARTICLE INFO

Keywords:
Depression
Primary care
Collaborative stepped care
Lagos

ABSTRACT

Background: The study aimed to evaluate the clinical effectiveness of a developed stepped care intervention for management of depression in primary care.

Methods: A cluster randomised controlled trial with primary care centres (PHCs) as unit of randomization. Five PHCs were randomised to stepped care intervention (SCI) group and another 5 PHCs were randomised to enhanced usual care (eUCA) control group. Participants were adults (18–60 years) with clinically significant depression symptoms. The primary outcome was clinical recovery at 12th months follow up. The outcome assessors were blinded to the cluster allocation.

Results: There were 456 participants in SCI group and 451 in eUCA group. At 12 months, clinical recovery was significantly higher in the SCI group compared with the eUCA group (60.3% vs 18.2%, ARR 3.10, 95% CI 2.15–3.87). The SCI group also had significantly better quality of life and lesser rates of disability, death or deliberate self-harm compared to the eUCA group. Subgroup analysis within the SCI group showed no difference in clinical outcomes between participants receiving problem solving therapy (PST) and those receiving antidepressants.

Conclusions: Our study showed that stepped care intervention significantly improved clinical outcomes at 12 months. This lends support to growing evidence of clinically effective intervention for depression at primary care level in less resourced countries.

Trial Registration: http://www.isrctn.com/ISRCTN66243738.

1. Introduction

Depression is the most prevalent and the leading neuropsychiatric cause of burden of disease both globally and in low- and medium-income countries (LMICs) and is projected to be the second leading cause of burden of disease by 2020 [1]. Depression impacts on functioning, is associated with increased mortality, often co-morbid with other chronic diseases, and is responsible for a sizable proportion of disability associated with these conditions [1]. In Nigeria, about 10–25% of primary health centres (PHCs) attendees have clinically significant depressive symptoms [2,3]. Over 70% of people with depression in Africa do not receive any form of treatment for their condition [4]. This huge treatment gap had been reported to be due to factors like non-availability of mental health services at the community level, shortage of mental health work-force, lack of evidence-based depression management practice, high medication cost, poor adherence to prescribed intervention and stigma [5,6].

Studies have shown that low intensity psychological interventions like problem solving therapy (PST), are effective in LMICs, even when delivered by lay health workers [7,8]. Also, the stepped care model has been shown to be an ideal delivery model for treating depression in a pragmatic setting with a wide range of illness severity, differentials in patients' preferred treatment choices, and, a short supply of specialist mental health workers [9,10]. The stepped care approach emphasizes that while simple psychological intervention may be provided to all participants by trained non-medical personnel, non-responders or those

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https://doi.org/10.1016/j.genhosppsych.2019.07.012
Received 17 February 2019; Received in revised form 16 July 2019; Accepted 17 July 2019
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with severe cases be prescribed medication by medical personnel and referral to mental health specialist if necessary. The stepped care approach therefore does not only allow flexibility and choice for patients, it maximize utilisation of available personnel and reduce the cost of management. The WHO mental health gap (mhGAP) project adopted the stepped care approach [11]. Trials evaluating stepped care intervention (SCI) for management of depression and other mental illness are still few in number [12–14], and majorly conducted outside sub-Saharan Africa. Most had small sample size, low power, short follow up period of between 3 and 6 months and have not separately tested the effectiveness of the individual components of the SCI package.

In our previous study, we developed and tested the feasibility of an adapted SCI package for primary care workers' management of depression. The SCI package includes screening, psychoeducation, problem-solving therapy (as the main psychological treatment), which is to be complemented with antidepressants and referral to mental health specialist when necessary [15]. The primary objective of this study was to evaluate the clinical effectiveness of our developed SCI package. We tested the following null hypotheses; (1) that there will be no significant difference in the rate of recovery from depression in the SCI group compared with an enhanced usual care (eUCA) group at 12th months follow up; (2) that there will be no significant difference between the SCI group and eUCA group in terms of improvement in disability and quality of life, and rate of deliberate self-harm/suicidal attempts; and (3) that there will be no significant difference in the effectiveness of the two main components of the SCI (psychological therapy and antidepressants) in improving the clinical outcomes for depression.

2. Methods

2.1. Trial design

This was a two arm, cluster randomised controlled trial. A cluster randomization design was chosen for practical reasons as the intervention involves training staff at the hospital level and to reduce selection bias by preventing contamination by preference. The clusters were “Comprehensive Primary Health Care Centres” (CPHCs) in 2 administrative divisions of Lagos state, Nigeria. Lagos state with a population of about 20 million people has 5 administrative divisions (ADs) and 57 Local Council Development Areas (LCDAs). The Ikeja and Ikorodu ADs have a combine population of 8 million people spread over 25 LCDAs. Each of the LCDAs have an average of one CPHC and 3 other PHCs. Group allocation was in ratio 1:1. Although, the trial was initially registered as a 3-arm trial, the 3rd arm (mobile telephony arm) was later excluded due to logistic problems of deploying the mobile telephony technology on time.

2.2. Participants

Ten CPHCs (6 from rural and 4 from urban settings) were randomly selected for the study. CPHCS qualify for selection if they have at least 2 medical doctors, 10 nurses/midwives, 5 Community Health Officers (CHOs), 5 Community Health Extension Workers (CHEWs) and 2 pharmacy technicians. Both institutional and staff consents were obtained. All adults (aged 18 years and above) attending the CPHC were informed about the aims and objectives of the study and invited to be part of the screening exercise. Those who consented were screened in a private room at the clinics by trained research assistants using the Patient Health Questionnaire (PHQ-9) [16]. The PHQ-9 had been validated in Nigeria with good psychometric properties with a cut off score of 10 and above signifying clinically significant depression symptoms [3,17]. Those with PHQ-9 score 10 and above, who intended to stay in the project area for at least 18 months, were literate enough to read either English, pidgin English or any of the three local languages (Yoruba, Hausa or Igbo), and completed the written informed consent form were enrolled in the trial. Excluded were those below 18 years and elderly above 60 years (because it was noted that most of those above 60 years old were involved in another intervention that could bias the results of our study), clients with serious medical condition or disability necessitating specialist care, having any form of psychosis or under psychiatric care.

2.3. Intervention

The interventions included the following

a. *enhanced usual care* (*eUCA*) *group* — *Psychoeducation* delivered by trained CHEWs focusing on educating the patient about their symptoms, the association between depression with interpersonal difficulties, the need to share emotional symptoms with the carer and sharing personal difficulties with family members caring for them or other key people in their social network. In addition, they received a 4-paged information leaflets about depression, its causes, symptoms and ways of preventing and managing it. The leaflet which uses culturally appropriate graphical and pictorial illustrations were in English, pidgin English and the 3 major local languages spoken in Nigeria (Yoruba, Hausa and Igbo). It is designated an “enhanced” care as psychoeducation was not usual provided in the CPHCs. The health staff of the CPHCs offering eUCA were given a one-day training on providing psychoeducation, assessment of the patients for symptoms of depression, symptoms of psychosis and suicidality and referral to the mental health specialist if there were signs of psychosis or suicidal behaviors.
b. *Stepped care Intervention* (*SCI*) *group*: The Treatment manual for this group involves 4 steps; (i1) Step 1 — *Psychoeducation* as described for the eUCA group; (2) Step 2 — *Main single treatment* of either Problem-Solving Therapy in Primary Care (PST-PC) [18] or antidepressants medication. *PST-PC* consisting of 6 weekly individual sessions and 4 fortnightly booster sessions (making 10 sessions over a period of 14 weeks) was offered to those with moderate depression (PHQ-9 score 10–14), all pregnant women and breastfeeding mothers, all those with comorbid medical conditions and any patients not wanting antidepressants. The PST-PC was delivered weekly by the trained staff nurse according to the intervention manual. There was reassessment with the PHQ-9 after the 3rd and 6th sessions. Antidepressants was offered for cases of severe depression (PHQ-9 score > 14), and those qualified for, but refusing, PST-PC. Antidepressants were initiated and maintained by the primary care doctor only and as outlined in the intervention manual. Amitriptyline or Fluoxetine (if there were contra-indications to Amitriptyline) were the medication of choice as they were recommended by the WHO-mhGAP and readily available in the PHCs. Reassessment was after 6 weeks of antidepressants initiation. (3) Step 3 — *Combination treatment*. Those from step 2 without *mild improvement* (defined as at least 2 points reduction on the PHQ-9) after 3 sessions of PST-PC or *moderate improvement* (defined as at least 4 points reduction on the PHQ-9) after 6 sessions of PST-PC or 6 weeks of antidepressants were offered a combination of both the full sessions of PST-PC and antidepressants. (4) Step 4 — *Support and supervision from the mental health team*: The mental health team provided clinical support and supervision to the CPHC teams via mobile telephone and made site visits to each of the CPHCs once a month. The health staff of the CPHCs offering SCI were trained in delivering the full intervention using the mhGAP-IG training manual [19]. The training covered general introduction to depression, identification, methods of providing care for clients with depression, the overall structure of the intervention and the specific intervention components. It also covered evaluation for improvement in symptoms, assessment for symptoms of psychosis and suicidality and referral pathway to the mental health specialist for those having psychotic or suicidal symptoms. The structured training comprised of initial 5-days workshop and 2-days refresher course 4 weeks later. Training

methods included lectures, role plays and discussions groups and was standardized with the use of video/audiotapes.

2.4. Outcomes

At baseline, apart from the PHQ-9 scores, participants were evaluated for disability and quality of life. Disability was assessed using the 12-item version of the WHO Disability Assessment Schedule (WHODAS-12) [20]. The WHODAS is a generic assessment instrument for health and disability applicable in both clinical and general population settings. It produces standardized disability levels and profiles and is applicable across cultures. It has been validated and used in Nigeria with a score of above 12 considered as moderate to severe disability [21]. Quality of life was evaluated using the "overall quality of life" question of the WHO Quality of Life Brief Version (WHOQOL-bref) [22]. The scores range from "very poor" (1) to "very good" (5) with score 4 and above considered as good quality of life. It has been validated in Nigeria [23].

a) *Primary outcomes*: The primary outcome was recovery (PHQ-9 score < 6) at 12th months follow up.
b) *Secondary outcomes*: included (1) clinical recovery at the 4th and 6th months follow up. (2) reduction in disability (WHODAS score > 12) and improvement in overall quality of life (WHOQOL-bref overall QOL score > 3) at 12 months follow up; (3) rates of overall adherence to interventions, deaths, deliberate self-harm and referral to mental health services at 12th months follow up. Overall adherence to intervention was measured using logs of attendance (at follow up clinics and PST-PC sessions) and adherence to the PST-PC instructions and medications. A checklist and ranking system were produced giving a sum score of 1 for "poor adherence", 2 for "fair adherence and 3 for "good adherence. Assessment for adverse effects of medications, relapse and DSH/suicidal ideation were built into the clinic and PST-PC sessions.

2.5. Sample size

The sample size calculation was based on assumption of a minimum cluster size of 70, intra-cluster correlation (ICC) of 0.02 (so a design effect of 1.38) and modest study completion rate of 70% allowing for drop outs, possible deaths, families moving out etc. A total of 385 participants in each arm will have >80% power to detect an average improvement rate difference of 20% (60% recovery in SCI group vs 40% recovery in eUCA group) at a significance level of 0.05. No interim analysis was performed.

2.6. Randomization and minimization of bias

Randomization was done by an independent centre. Allocation was based on clusters. The CHPCs were stratified into urban and rural to ensure even distribution. Computer was used to generate the clusters using the random allocation rule and each cluster was then assigned a study number and the research coordinator was informed of treatment allocation, for onward information to the health workers. To minimise the possibility of selection bias we identified clusters and recruited them before randomization and we included all patients within a cluster meeting the eligibility criteria in the study. Also, the assessment of outcome measures was done by an independent group blinded to the allocation of clusters.

2.7. Statistical methods

Data analysis was considered at the cluster and individual levels. For the primary outcome, the differences in the proportion of cases who recovered at 12th months follow up between the intervention and control groups were estimated using multivariate mixed effects regression models and were presented as unadjusted and adjusted estimates. Clustering was accounted for using mixed effect models with CPHCs as random effect. There was adjustment for age, gender, educational status and presence of chronic illness and baseline PHQ-9 scores. This was also done for the secondary outcomes including the subgroup analysis carried out. All analysis was based on intention to treat (ITT) with the last available result carried forward as necessary regardless of the adherence to intervention. For binary outcomes, the impact was measured by prevalence ratio (RR) with 95% CI.

2.8. Role of funding source

The funder of the study had no role in the study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for decision to submit for publication.

3. Results

3.1. Study participants

From the ten CPHCs, a total of 15,439 adult attendees were assessed for eligibility and 1031 met the requirement, but 907 (87.9%) were eventually enrolled. There was no significant difference in the demographic data of the 124 who refused and the participants ($p = 0.825$ for mean age and $p = 0.848$ for gender). Recruitment took place between October 2014 and April 2015 and the trial ended after the 12th month follow up. The median number of participants per cluster was 91 (range 80–103). Fig. 1 showed the participants flow. At the end of the 12 months trial, a total of 140 participants (15.4%) had discontinued the trial because they were referred to the mental health specialists (either for symptoms of psychosis or suicidal behaviour) and a total of 161 (17.7%) were lost to follow up for various other reasons. There was no significance difference in the demographics (age and gender), and baseline PHQ-9 scores between those who dropped out of the trial and those who completed the study at 12 month follow up.

3.2. Baseline data

Table 1 also showed the baseline characteristics (sociodemographic and clinical) for the participants. The mean age was 34.3 (SD 11.9), 52.9% were females, 59.4% were married, 43.8% had at least secondary education and 11.8% had a chronic medical illness. The mean PHQ-9 score at baseline was 16.29 (sd 4.28), the mean WHODAS scores was 14.31 (sd 9.14) and the mean overall QOL scores was 2.53 (sd 1.02). On the whole, 307 participants (33.9%) scored >12 on WHODAS (and considered to have moderate to severe disability) and 116 (12.8%) scored >2 on Overall-WHOQOL (and considered to have good QOL). The participants' characteristics in the 2 arms were well matched.

3.3. Primary outcome

Table 2 showed comparison of the SCI and eUCA groups across clinical parameters. At the 12th month, the recovery rate in the SCI group was 60.3% which was significantly different from 18.2% in the eUCA group (ARR 3.10, 95% CI 2.15–3.87).

3.4. Secondary outcomes

Table 2 showed that across the 4th and 6th month follow up periods, the SCI group also had significantly higher recovery rates (43.2% at 4th month and 54.6% at 6th month) compared with the eUCA group (23.9% at 4th month and 26.2% at 6th month) with ARR 1.74, 95% CI 1.22–2.15 and ARR 2.03, 95% CI 1.45–2.50 respectively. At 12 months, the SCI group also had significantly lesser rates of disability (ARR 0.41,

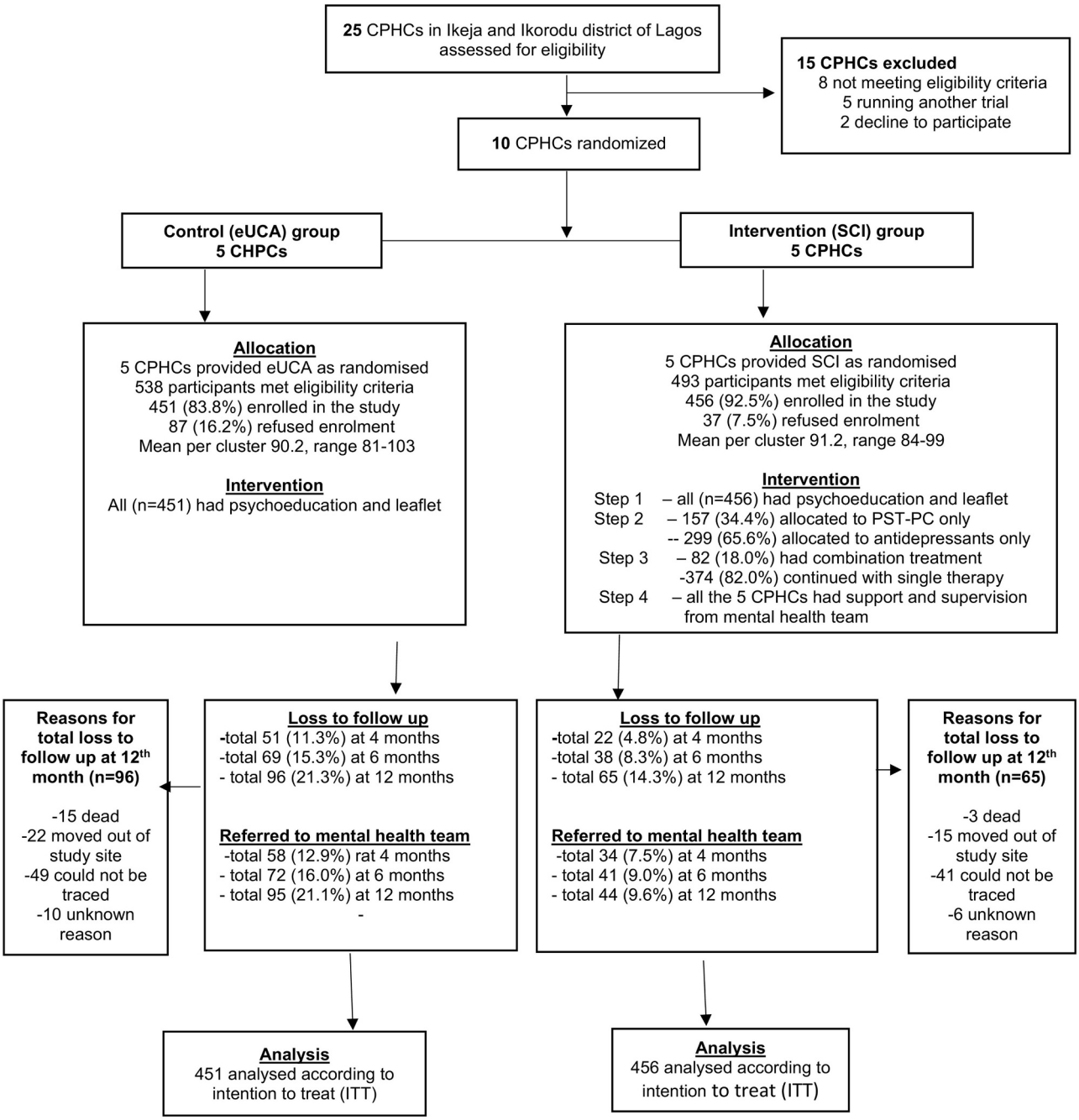

Fig. 1. Flow diagram for the trial.

95% CI 0.31–0.61) and improvement in overall QOL (ARR 5.83, 95% CI 4.21–8.45). Also at 12 months follow up, compared with the SCI group, the eUCA group reported significantly more deaths (3.3% vs 0.6%), deliberate self-harm (7.8% vs 2.2%), referral to mental health team (21.1% vs 9.6%) and lost to follow up (21.3% vs 14.3%). To test our third hypothesis, we performed a sub-group analysis within the SCI group and compared the clinical outcomes between participants allocated to PST-PC and those allocated to antidepressants in step 2 of the SCI Table 3 showed that there was no significant difference between the PST-PC and antidepressants sub-groups in the rates of clinical recovery from depression at 4th month (ARR 0.81, 95% CI 0.71–1.12), 6th month (ARR 0.90, 95% CI 0.81–1.10) and 12th month (ARR 0.85, 95% CI 0.80–1.12). Also at the 12th month, there was no difference in level of disability (ARR 1.39, 95% CI 0.88–2.41), improvement in overall quality of life (ARR 0.85, 95% CI 0.71–1.10), rates of reported deaths (ARR 0.94, 95% CI 0.12–10.21), deliberate self-harm (ARR1.25, 95% CI 0.33–4.14), referral to mental health specialist (ARR 1.15, 95% CI 0.61–2.00) and loss to follow up. (ARR 1.53, 95% CI 0.91–2.42). However, adherence was moderately better with antidepressants sub-group (ARR 0.83, 95% CI 0.72–0.98). A total of 52 (33.1%) of participants originally on PTS-PC in step 2 were later upgraded (switched) to Step 3 (with antidepressants added). This rate was significantly more than the 10.0% (n = 30) originally on antidepressants in step 2 who were upgraded (switched) to step 3 (with PST-PC added) (ARR 3.10, 95% CI 2.11–4.83).

3.5. Harms

All the 45 participants with reported deliberated self-harm and other 94 with psychosis were referred to the mental health specialists.

Table 1
Baseline parameters of the participants.

Variables	SCI group (n = 456)	eUCA group (n = 451)	Total (n = 907)
Sociodemographic characteristics			
Mean age (SD)	35.17 (SD = 12.01)	34.33 (SD = 11.91)	34.34 (SD = 11.94)
Age (41 year and above)	143 (31.4%)	110 (24.4%)	253 (27.9%)
Sex (females)	239 (52.4%)	241 (53.4%)	480 (52.9%)
Marital status (married)	255 (55.9%)	284 (63.0%)	539 (59.4%)
Religion (Christianity)	232 (50.9%)	252 (55.9%)	484 (53.3%)
Highest education (secondary and above)	192 (42.1%)	205 (45.4%)	397 (43.8%)
Presence of chronic illness (yes)	49 (10.7%)	58 (12.9%)	107 (11.8%)
Baseline clinical scores			
Mean total PHQ-9 scores (SD)	16.17 (SD = 4.18)	16.31 (SD = 4.12)	16.39 (SD = 4.28)
Mean WHODAS scores (SD)	14.32 (SD = 8.58)	14.04 (SD = 8.70)	14.31 (SD = 9.14)
*Moderate-severe disability (WHODAS > 12)	155 (34.0%)	152 (33.7%)	307 (33.9%)
Mean overall QOL scores (SD)	2.55 (SD = 1.04)	2.48 (SD = 1.04)	2.53 (SD = 1.02)
*Good QOL (WHQOL overall score > 3)	62 (13.6%)	54 (12.0%)	116 (12.8%)

Note: SCI = Stepped Care Intervention group; eUCA = Enhanced usual care group; PHQ-9 = Patient Health Questionnaire 9 item version; WHODAS = WHO Disability Assessment Scale; WHOQOL = WHO Quality of Life.

We investigated the 18 deaths within the 12 months follow up and none was adjudged by the Trial Steering Committee to be related to the study procedures.

4. Discussion

4.1. Interpretation

We set out to ascertain if our developed stepped care intervention would be clinically effective and lead to better outcome compared with enhanced usual care in the management of depression primary care. We also aimed to compare the effectiveness of the two main components of the intervention package (problem solving therapy and antidepressants) in improving the clinical outcomes for depression. We had evidence of effectiveness of our intervention as a total of 42.3%, 54.6%, and 60.3% of depressed patients on our SCI recovered at 4th, 6th and 12th months respectively compared to 23.9%, 26.2% and 18.2% recovery rates for clients on eUCA at the same time period. Thus, our SCI demonstrated not only sustenance of effect, but stability of benefits on long term basis with the highest adjusted risk ratio at the 12th month follow up. We also showed that apart from its effectiveness in alleviating depression, our SCI could effectively impact on the other complications of depression in reducing disability, improving overall quality of life, reducing rates of mortality and deliberate self-harm and reducing the percentage of cases that needed to be referred to the mental health specialists.

Although it was part of an overall package, we were able to provide evidence to further support earlier reports that problem solving therapy (PST) is an attractive option as a low intensity psychological therapy in low resource settings as it does not require extensive training or complex skills like cognitive behaviour therapy [7]. We found no significant differences in the clinical outcomes between the psychological intervention (PST-PC) and antidepressants, although the group with antidepressants had better adherence to therapy and were less likely to switch to combination therapy.

4.2. Generalisability

Our findings are consistent with earlier evidence of the benefit of stepped care intervention for management of depression in primary care [9]. It has earlier been shown that the stepped care model is acceptable to primary care patients and health care providers [13,24,25]. One unique feature of our study was that the CPHCs all have medical doctors as the head of the team. We have to admit that this may not be what is obtainable in other PHCs in LMICs where community health officers or a nurse may be the head of the team.

4.3. Limitations and strength

This result of this trial should be considered within the limitations. We have compared our stepped care intervention with an enhanced usual care rather than no treatment which is usually the case in most PHC setting in this environment. Also, with the design of our study, it will be difficult to determine the extent to which our positive results are

Table 2
Clinical outcome measures — differences between the SCI and eUCA groups.

Clinical variables	SCI (N = 456)	eUCA (n = 451)	Analysis			
			Unadjusted RR (95% CI)	*p* value	Adjusted RR* (96% CI)	*p* value
Primary outcome						
Recovery (PHQ-9 score < 6) at 12 months	275 (60.9%)	82 (18.2%)	3.32 (2.69–4.09)	<0.001	3.10 (2.15–3.87)	<0.001
Secondary outcome at 4th and 6th months						
Recovery (PHQ-9 score < 6) at 4 months	197 (43.2%)	108 (23.9%)	1.80 (1.48–2.19)	<0.001	1.74 (1.22–2.15)	<0.001
Recovery (PHQ-9 score < 6) at 6 months	249 (54.6%)	118 (26.2%)	2.08 (1.75–2.49)	<0.001	2.03 (1.45–2.50)	<0.001
Secondary outcomes at 12th months						
Disability (WHODAS score > 12)	35 (7.7%)	75 (16.6%)	0.46 (0.32–0.67)	<0.001	0.41(0.31–0.61)	<0.001
Good QOL (WHQOL overall score > 3)	225 (49.3%)	36 (8.0%)	6.18 (4.46–8.57)	<0.001	5.83 (4.21–8.45)	<0.001
Number of deaths	3 (0.6%)	15 (3.3%)	0.20 (0.06 to 0.68)	0.004	0.20 (0.07 to 0.65)	0.007
Number of reported deliberate self-harm	10 (2.2%)	35 (7.8%)	0.28 (0.14 to 0.56)	<0.001	0.28 (0.15 to 0.55)	<0.001
Referral to mental health team	44 (9.6%)	95 (21.1%)	0.46 (0.33 to 0.64)	<0.001	0.44 (0.30 to 0.65)	<0.001
Lost to follow up	65 (14.3%)	96 (21.3%)	0.67 (0.50 to 0.89)	0.007	0.66 (0.51 to 0.90)	0.008

Note: SCI = Stepped Care Intervention group; eUCA = enhanced usual care group.
* Adjusted for age, gender, educational status and presence of chronic illness and baseline PHQ-9 scores.

Table 3
Differences in outcomes between the groups allocated to PST-PC compared with those on antidepressants within the SCI group.

	Variables		Analysis			
	PST-PC (n = 157)	Antidepressants (n = 299)	Unadjusted RR (95% CI)	*p* value	Adjusted RR* (95% CI)	*p* value
Clinical recovery (PHQ-9 score < 6)						
At 4 months	73 (46.4%)	158 (52.8%)	0.88 (0.72 to 1.07)	0.202	0.81 (0.71 to 1.12)	0.250
At 6 months	102 (64.9%)	213 (71.2%)	0.91 (0.80 to 1.04)	0.201	0.90 (0.81 to 1.10)	0.248
At 12 months	115 (73.2%)	245 (81.9%)	0.89 (0.80 to 1.00)	0.039	0.85 (0.80 to 1.12)	0.055
Others at 12 months						
Disability (WHODAS score > 12)	21 (13.4%)	28 (9.4%)	1.43 (0.84 to 2.43)	0.205	1.39 (0.88 to 2.41)	0.235
Good QOL (WHQOL overall score > 3)	92 (58.6%)	195 (65.2%)	0.89 (0.77 to 1.05)	0.185	0.85 (0.71 to 1.10)	0.196
Good adherence (>2 on adherence scale)	82 (52.2%)	188 (62.9%)	**0.83 (0.70 to 0.99)**	**0.035**	**0.83 (0.72 to 0.98)**	**0.042**
Switched to combination therapy (step 3)	52 (33.1%)	30 (10.0%)	**3.30 (2.20 to 4.95)**	**<0.001**	**3.10 (2.11 to 4.83)**	**<0.001**
Referral to mental health team	17 (10.8%)	27 (9.0%)	1.20 (0.67 to 2.13)	0.617	1.15 (0.61 to 2.00)	0.635
Death	1 (0.6%)	2 (0.7%)	0.95 (0.09 to 10.42)	0.699	0.94 (0.12 to 10.21)	0.718
Deliberate self-harm	4 (2.5%)	6 (2.0%)	1.27 (0.36 to 4.43)	0.742	1.25 (0.33 to 4.14)	0.812
Lost to follow up	29 (18.5%)	36 (12.0%)	1.53 (0.98 to 2.40)	0.068	1.53 (0.91 to 2.42)	0.088

Note: Bold emphasis represent statistical significance.
Note: SCI = Stepped Care Intervention group; eUCA = enhanced usual care group; PST-PC = Problem Solving Therapy-Primary Care.
* Adjusted for age, gender, educational status and presence of chronic illness and baseline PHQ-9 scores.

attributable to our stepped care model, or just availability of the psychotherapy (PST-PC) and/or antidepressants. We had excluded patients over 60 years old due to logistic reasons. We had included only moderate to severe depression whereas persistent mild depression is very common in the primary care setting. Although we had used a screening instrument to assess clinical outcome, the PHQ-9 had been well validated and we deemed it most pragmatic in the primary care setting where there were no mental health specialists. Our analysis was by intention to treat, although there were missing data and some lost to follow up. However, this was also most pragmatic as it reflects the real life situation of managing depression (and other mental health problems) in the primary care, considering that many non-responding cases would probably either stop attending clinic on their own or have to be referred to the mental health specialist by the PHC workers. However, our study has many strengths. Our intervention was developed after several consultations with experts and stakeholders [15], we had a moderate sample size and we were able to follow up for 12 months to demonstrate sustainability of effects. Apart from the overall effect of the stepped care intervention, we had specifically evaluated for the effect of the different component of the intervention on recovery and other clinical outcomes.

4.4. Conclusion

The integration of mental health services into primary care is now widely acknowledged as the most feasible strategy to address the treatment gap for common mental disorders in LMICs [26,27]. As there are growing evidence that a stepped care intervention model that includes PST treatments work for depression in LMICs settings, translating these evidences into benefits for the patients in a scalable scale is the next step. Apart from clinical effectiveness, evidence is needed for cultural acceptability, local affordability, sustainability and easy integration into the primary care systems.

Funding

This work was supported by Grand Challenges Canada (Grant no. GMH 0084-04).

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.genhosppsych.2019.07.012.

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