

## **Title Page**

The effectiveness of a community health volunteer delivered low-intensity problem solving therapy mobile application based on the Friendship bench “Inuka” for the promotion of mental wellbeing in Kenya: A pilot cohort study

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## **ABSTRACT**

### **Introduction**

Sub-Saharan Africa (SSA) accounts for the largest treatment gap for common mental disorders in the world. An estimated 6.4 Billion US Dollars is required to bridge the gap in human resources, heralding the use of cost-cutting approaches such as the employment of non-specialised health workers and the use of digital technologies as a viable approach to delivering mental health interventions. Our study adopts both approaches and aims to evaluate a problem-solving therapy (PST) intervention that is delivered by community-health volunteers (CHVs), through a mobile application called 'Inuka', in Kenya.

### **Methods**

A pilot cohort study was carried out to evaluate a CHV supported problem-solving intervention for people with common mental health complaints. Participants were recruited from eighteen, level III health centres in primary care services in the county of Ruiru, Kenya. People who self-screened as eligible; scoring 8 or higher on the Self-Reported Questionnaire-20 (SRQ-20), aged 18 years or older, were conversant with written and spoken English and were familiar with the use of smart mobile devices, were consented. The intervention consisted of 4 chat-sessions delivered via digital chat by CHVs at the clinic on a Samsung phone. Growth models using multivariate multilevel modelling were used to analyse the continuous outcome data on the SRQ-20 and model change rate over time (baseline and 3-month follow-ups assessments). Multiple linear regression models were used to evaluate if sociodemographic variables predicted SRQ-20, Patient Health Questionnaire-9 (PHQ-9) and Generalised Anxiety Disorder-7 (GAD-7) score changes.

### **Results**

82 participants were recruited to the study, of which 60 completed post-intervention assessments at 4-weeks, and 51 completed their 3-months follow-up assessments. The intervention was found to be highly acceptable to participants based on their satisfaction rating of the Inuka program and the CHVs delivering the intervention. The multivariate multilevel growth model suggested that SRQ-20 scores decreased by 0.53 scores on average, in relation to time (between baseline and 3-month follow-up assessment points) 95 ( $p < .001$ ), while controlling for age, gender, marital status, educational attainment, income and suicidal ideation. The multiple linear regression analyses indicated that lower range income (earnings below Ksh.10,000 per annum) and the presence of suicidal ideation predicted higher SRQ-20 change scores. Higher change scores in the PHQ-9 was also found for those who indicated having suicidal ideation, compared to participants who did not. Those who were aged above 30 years were more likely to demonstrate high depression score changes, compared to those aged below 30 years. Finally, higher reduction in GAD-7 scores was found to be higher for women compared to men.

### **Discussion**

To our knowledge, this report is the first to pilot a PST intervention that is delivered by CHVs through a locally developed mobile application in Kenya, to which clinically meaningful

improvements were found for self-reported common mental health complaints. This report is also the first to outline efforts between the commercial and academic sectors to evaluate a mobile application in the SSA region. The findings of the pilot study indicate that the use of task-shifting approaches with digital technologies is a viable method for addressing common mental health complaints. Future research should evaluate the effectiveness of the intervention in a randomised controlled trial.

## INTRODUCTION

Mental health conditions affect the well-being of hundreds of millions of individuals worldwide, causing considerable disability and incurring high economic and social costs [1]. Low-and-middle income countries (LMIC) are disproportionately affected by the burden of mental disorders, with sub-Saharan Africa (SSA) experiencing the largest treatment gap for common mental health disorders. In the African continent 1 in 4 people suffer from depression and anxiety every year [2]. Paradoxically, 90% of people in SSA will not receive the mental health care they require due to a mostly fragmented and underdeveloped health-care systems, insufficient availability of mental health specialists, and as a consequence of poverty and the pervasive stigma surrounding mental illness in the region [3–5].

In 2011, the World Health Organisation (WHO) projected a shortage of 1.71 million mental health workers in low and middle income countries (LMICs), requiring an estimated 6.4 billion US dollars to bridge the gap in human resources[6]. For this reason, the World Health Organisation (WHO) have heralded task shifting as a keystone approach for bridging the gap in human workforce in poor resource settings. Task-shifting refers to the training of staff that are typically lower skilled and or have lower qualifications, to undertake activities that are either generally performed by higher qualified professionals or which they have not carried out before [7]. The task shifting approach is not only used to shift tasks from higher to lower cadre staff, but also to individuals living in the community, commonly referred to as non-specialist workers.

In the past decade, the evidence-base for cost-effective interventions for mental illness in LMIC has steadily increased [8]. A significant portion of the literature has focused on evaluating the efficacy of delivering self-help training and have found that the use of non-specialist workers was helpful in reducing mental illness in relation to trauma, depression and anxiety disorders in low resource settings in India and across Africa. A prime example comes from the Friendship Bench in Zimbabwe [9], in which community grandmothers were trained and supervised to deliver a problem solving therapy (PTS) intervention to treat common mental health disorders (CMDs). The study piloted and evaluated the effectiveness of the Friendship Bench model through a randomized controlled trial (RCT) in 24 clinics in Harare. The RCT demonstrated statistically significant improvements in depression, anxiety, quality of life and functioning among the 246 participants allocated to the intervention arm, when compared to the control group [9].

While task-shifting is championed for strengthening and expanding the workforce through promoting access to evidenced-based interventions at a lower cost [10,11], those seeking treatment are still required to attend health facilities or clinics. Consequently, treatment access barriers related to geographical distance, travel costs and stigma may continue to persist. Such limitations have

necessitated the need to explore the use of technological innovations such as mobile phone and web-based platforms in an effort to further reduce barriers for access to mental health care and ensure high-quality delivery [1]. The use of digital technologies may further, reduce the cost of delivering the intervention, the cost incurred by the client to access the intervention (e.g. travel costs), and expand the user's access to the intervention in relation to time and location [12,13].

Technological capacity is fast increasing in African continent. The SSA region has the fastest growing mobile phone use and coverage in the world, in which 444 million unique mobile subscribers and 250 million smartphone connections were registered at the end of 2014 [14]. The spread of inexpensive smartphones is likely to push internet penetration to 50% within a decade [15].

The evidence for internet-based interventions for the prevention and treatment of mental health conditions is steadily increasing, however very few of these research studies have focused on low income countries [16–18]. A study comparing the literature from low, middle and high income countries suggested that Short Message Service (SMS) solutions are prevalent in both high income countries and LMICs, while mobile app solutions are mostly used in high income countries [18]. A narrative review on the use of digital technologies for treating and preventing mental disorders in LMIC found that the existing evidence based largely came from acceptability and feasibility studies showing the potential effectiveness of online, text-messaging, and telephone support interventions. However, of the 49 studies identified, only 14% (n=7) of the studies were from Africa, compared to Latin America (19; 29%) and south Asia (5; 10%). Moreover, the studies that have been carried out in Africa have primarily focused on people with serious mental illness, with no identified studies on the prevention of mental health[4].

Given the dearth of research on preventative e-mental health interventions in LMIC, our study aims to evaluate the effectiveness of a non-specialist worker intervention through a mobile application for the reduction of common mental health complaints in a **non-clinical** sample in Kenya. To our knowledge, our study is the first to undertake this line of research in the SSA region. The objective of the study is to carry out a prospective cohort study to understand: (a) the acceptability of the intervention by the users, (b) evaluate the difference between self-reported common mental health complaints before and after the intervention and, (c) to understand which sociodemographic variables predict negative mental health.

## **METHODS**

### **Setting and participants**

A pilot prospective cohort study was carried out to evaluate a community health volunteer supported problem solving intervention for people experiencing common mental health disorders. In the first

quarter of 2017 participants were recruited from eighteen, level III health centres in primary care services in the county of Ruiru, Kenya, which covers a catchment population of 25,000. Ethical clearance was approved by the ICBE Secretary on behalf of the ICBE Board (2015-0032) on 14/02/2017 and the Amref Ethics and Scientific Review Committee on 10 Apr 2017 (KIAMBU/HRDU/AUTHO/2017/04/10/Njenga A).

The recruitment of participants was proceeded by a mental health campaign to aid the recruitment process. The aim of the campaign was to promote knowledge around mental health and wellness and the pilot study in the community, within health facility, which included standard primary care services, largely consisting of care pertaining to Reproductive, Maternal, Neonatal and Child health<sup>i</sup> The campaign involved three approaches. First, flyers were distributed to all clients (patients and family-members) who visited the health facility. Second, healthcare providers in the facility were also encouraged to talk about mental health and wellness and the proposed study to all the clients seeking preventive or curative health services (as well as outpatient/inpatient). Third, CHVs were encouraged to discuss mental health and wellness and psychological support during the routine “dialogue days” held in the community. Two approaches were utilised in the recruitment of participants. The first involved inviting people to the facility to learn more about Inuka, a chat-based platform based on the Friendship bench (ref) (see Inuka Intervention section for further details) enrol into the program, and self-screen. The second involved approaching house-holds in the community and encouraging people to screen themselves. Self-screening questionnaires were accessible from the primary health care facilities upon request, which were guided by community health volunteers

#### Inclusion criteria

The study included people who, scored 8 or higher on the Self-Reported Questionnaire-20[19], were aged 18 years or older, were conversant with written and spoken English, familiar and comfortable with the use of smart mobile devices (phone/tablet/touch-based screens), did not report experiencing suicidal ideation in the past 30 days on the SRQ-20[19] screening tool (item 17: “Think about suicide? yes/no”)<sup>ii</sup>, and were available for the full 4 weeks of the study. People who attended the clinic to self-screen were compensated for their time with a transport allowance of KSh 300 (the equivalent of 2.37 Euros). Those both willing to participate in the study and were eligible based on the criteria outlined, were invited to sign a consent form at the health facility. A tablet was provided to participants to access the intervention during the duration of the study. Upon recruitment, participants were asked to indicate their availability on a calendar to confirm their schedule for the four-week programme. Participants received regular calls to remind them of their weekly appointment.

#### CHVs

CHVs were recruited to deliver a PST intervention via a text based mobile application. CHVs were recruited from an existing pool of 15 CHVs, from the Community Health Strategy Unit, in the Kiu constituency. CHVs were appointed if they were able to both speak and write English, and if they owned a smart phone and used it regularly for communication. Those that did not meet the criteria were excluded. Community extension workers identified five CHVs who could be trained to deliver the intervention, on the pilot study. CHVs were recompensed KSH 300 per session on the study. A senior training specialist, with previous experience on the Friendship Bench[20] was invited to deliver a three-day training as follows: introduction to problem-solving therapy (Day 1), step-by-step guide to problem-solving therapy (Day 2), and mock-sessions to practice PST involving face-to-face interactions (Day 3). CHVs were provided with a standard text-material or scripts to guide their interactions with the end-user, and were encouraged to practice to ensure that their communication was spontaneous and steeped in contextual information provided by the end-user. All five CHVs recruited were female and were aged between 33yrs–42yrs and had at least a secondary school education. One of the CHVs fell ill at the start of the pilot study and as a result was unable to continue delivering the intervention. The remaining four CHV continued their participation until the end. At the end of each day, a group session consisting of CHVs, a psychologist and a member of the research team was organised to understand the CHVs experience of delivering the intervention, and for supervision purposes. The outputs from these meetings were not formally documented. Each CHV also received two one-to-one sessions with the psychologist during the duration of the study in order to check on their mental health.

### **Inuka Intervention**

The program consisted of structured PST sessions that were delivered to end-user using text-based chat on the Inuka mobile application. The methodology of the Inuka intervention follows the structure of a low-intensity face-to-face PST intervention, which has in recent years been adapted to be delivered by non-specialist workers to address common mental health complaints in a range of populations in the African and Asian continent [8,21]. The low-intensity PST intervention was identified as a suitable approach for delivering via telephone due to the approach's simple step by step approach [22]. The efficacious PST approach used on the Friendship Bench intervention [9] was translated to be delivered through the Inuka mobile application. The Inuka intervention had five features: (1) matching the client with the coach, (2) screening and support, (3) decision support for CHVs, (4), and (promotion), described in Table 1. The Inuka intervention is a proof-of-concept mobile application solution that is designed to prevent mental illness. The intervention consisted of 4 chat-sessions that were delivered through a chat-based service using a "Samsung" phone at the clinic. The users and care providers did



not meet face to face during the entire period of the study. However, end-users had to come back to the clinic for scheduled sessions

<b>Table 1.</b> A summary of the five principles of the Inuka intervention.	
Principle	Descriptions
Matching	Person seeking psychological support (service-user) is matched with a service provider.
Screening & support	Service-user is screened for common mental complaints using the SRQ-20 and is engaged in a structured conversation based on problem-solving therapy via a test-based chat with the service-provider.
Decision support for CHVs	The service-provider is provided with a set of structured scripts on what to say in each step and how to build rapport via chat. The application also requires the service provider to fill out an action card in which the challenges of the user and the next steps are summarized.
Referral	If the service provided is deemed insufficient by the user or if the service provider deems the user's presentation to be severe, the users can be referred to mental health professionals for diagnosis and treatment, with their consent.
Promotion of psychological (self)care	The Inuka app supplies information and self-assessment that is contextualized for local settings to create awareness and lower the barrier for seeking help.

### **Development and evaluation of Inuka**

The development and evaluation of the Inuka platform was undertaken through close collaborations between the commercial and academic sectors. A working prototype of the Inuka platform was developed and tested between 2015-2017, by Philips in collaboration with the University of Zimbabwe (the development and testing of the Inuka app will be outlined in another paper). The pilot study data

collected while the platform was owned by Philips who are represented in this paper HV. At present the Inuka platform is independent of Philips and is a social enterprise start-up owned by RvD (inuka.io). Academic collaborations have been extended to the London School of Hygiene and Tropical Medicine to do the data-analysis and academic publication of the completed work.

## **Measures**

Participants were assessed at baseline, at the end of the intervention at 4 weeks, and were subsequently followed up at 3 months. The study largely used locally validated screening tools including the SRQ-20, Patient Health Questionnaire-9 (PHQ-9), and Generalised Anxiety Disorder-7 (GAD-7) that were also adopted in the Friendship Bench study in Zimbabwe[20].

## **Primary outcome**

### ***Common mental health conditions symptoms***

SRQ-20 was developed by WHO as a screening tool for common mental disorder [19]. It was primarily developed for use in primary health care settings, especially in developing countries. This instrument consists of 20 yes/no questions pertaining to the month before the interview. Answers indicate whether symptoms in four scales – anxiety and depression, somatic symptoms, reduced vital energy, and depressive thoughts – were present or absent. Higher scores indicate worse symptoms. The four SRQ-20 subscales were evaluated globally. The SRQ-20 was administered at baseline, during the first and last session (after the last 4 session) of the intervention and at the 3-month follow-up assessments. The SRQ-20 was validated in Kenya (ref)

## **Secondary outcome**

### ***Depression***

PHQ-9[23] is a self-reported scale that was used to measure symptoms of depression. The PHQ-9 is a 9-item scale that is used to screen and to diagnose patients with depressive disorders. The 9-items are each scored on a 0–3 scale with the total score ranging from 0–27 with higher scores indicating more severe depression. The PHQ-9 has been shown to have good psychometric properties[23,24]. The PHQ-9 was administered at baseline, during the first and last session (after 4 weeks) of the intervention and at the 3 follow-up assessmentsThe PHQ-9 was validated in Kenya (ref).

### ***Anxiety***

GAD-7 [25] is a measure of anxiety based on seven items which are scored on a 4 points scale (from zero to three). Total scores across the items range between 0 to 21. The cut-off scores for mild, moderate and severe anxiety symptoms are 5, 10 and 15 respectively [13]. Internal consistency of the GAD-7 was estimated at 0.92 and convergent validity was established by means of correlations with two other

anxiety measures.[25] The GAD-7 was administered at baseline, during the first and last session (after 4 weeks) of the intervention and at the 3 follow-up assessments. GAD-7 was validated in the SSA region (ref)

### ***Other forms<sup>iii</sup>***

#### *Sociodemographic*

Demographic data on gender, age (captured through five age brackets), educational attainment and income data were collected at baseline assessments based on the original Friendship Bench RCT.

#### *Trauma checklist*

The Confounders questionnaire is a checklist of nine potentially traumatic events experienced in the past 30 days (e.g. Have you lost your loved one). Participants are required to respond to each item with a 'Yes' or 'No'. The number of 'yes responses' were tallied for each participant. The questionnaire was administered at baseline assessments.

#### *Session and program rating questionnaires*

The Inuka program and the CHVs were rated on a scale of 1-4. Responses were indicated on separate forms, one in relation to session satisfaction and the other in relation to program satisfaction. The questions on the forms were the same, with exception to the component of the intervention being rated (CHV or program). Higher responses indicated higher satisfaction.

### **Statistical analysis**

Growth models using multilevel modelling on Python (version 3.6.10), a programming language software was used to analyse the continuous outcome data (SRQ-20 scores). Growth modelling was used to model change rate over time taking into account possible non-independence of repeated measurement by incorporating random effects. Baseline predictors of changes over time were modelled with an interaction term between the predictor and the dummy variable that model the time effect. Multiple linear regression models was performed on the Rstudio (version 1.1.456), to investigate if age, gender, income, marital status, suicidal ideation predicted pre-and post-therapy score changes for using the SRQ-20, PHQ-9 and GAD-7 self-reported questionnaires. A complete case analysis approach was used in the study.

## RESULTS

### Participant characteristics

A total of 240 people were approached to take part in the study, of which 40 refused, 38 were ineligible, and 162 agreed to be screened. From the 162 people screened, a total of 80 people (49%) were eligible, while the remaining 82 people did not meet the inclusion criteria and were therefore ineligible to take part in the study. of the 80 people enrolled on the study 20 (25%) participants were lost to follow-up assessments at 4-weeks. The 60 participants who completed post-intervention (4 weeks) assessments were included in the study. A consort flow diagram of recruitment, and assessment in the study can be found in Figure 1.

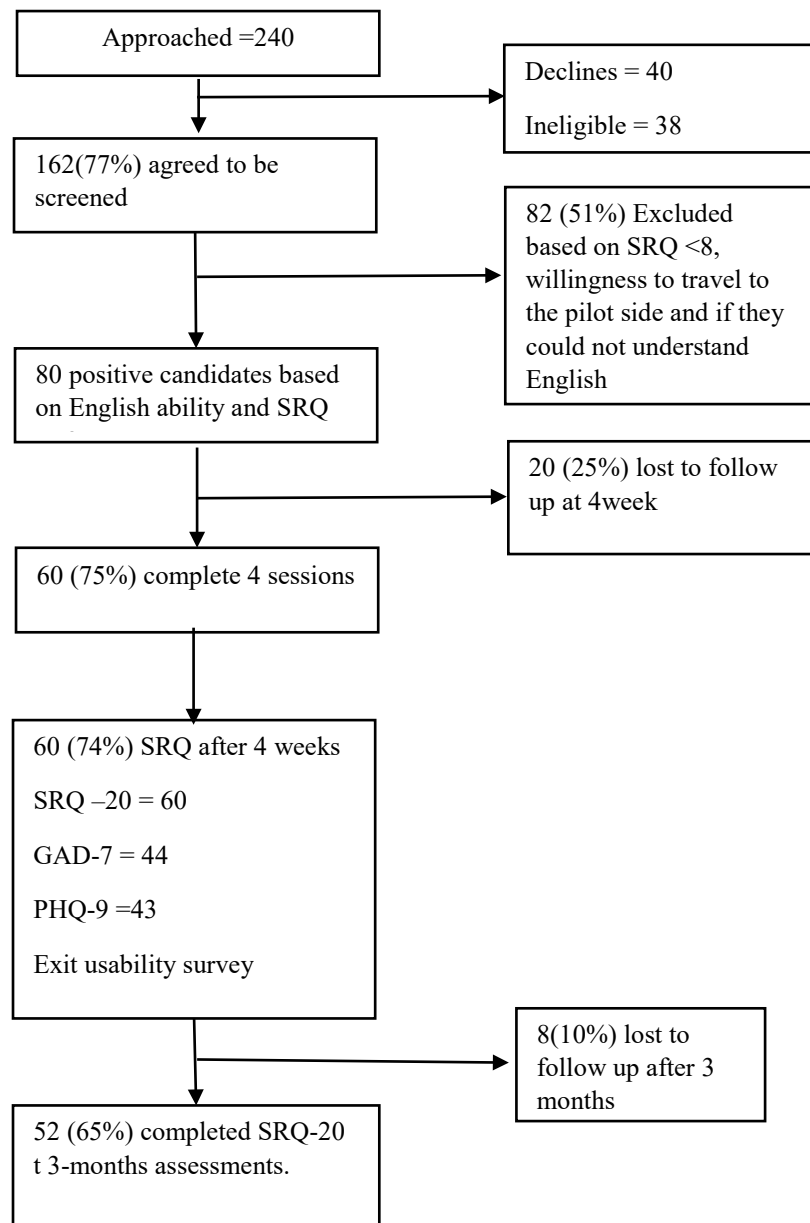


Figure 1. Consort flow diagram of participant recruitment and assessment in cohort pilot study

Participants were largely female, people aged between 21 and 30, single, secondary school educated, employment, and living on an income of less than Ksh. 10,000 per annum. The most prevalent reason attributed to seeking treatment, as reported on the Confounders questionnaire was “relationship issues with family” (50%), feeling “heartbroken” (48%), and “losing / relative losing a job” (45%) (See Table 2, for full participant characteristics and a breakdown of reasons for seeking treatment). Participants reported finding out about the study through CHVs, friends and relatives or through the mental health campaigns in the waiting bay of clinics.

**Table 2**

Baseline characteristics of participants enrolled on the Inuka study (N=60). Figures are numbers (percentages) of participants unless otherwise indicated.

Baseline characteristics	<i>N (%)</i>
Gender	
Female	38 (63)
Male	22 (37)
Age group <sup>a</sup>	
20 year old or younger	5 (8)
21-30 years old	37 (62)
31-40 years old	12 (20)
41-50 years old	5 (8)
51 years old or older	1 (2)
Marital status <sup>b</sup>	
Single	33 (55)
Married	22 (37)
Divorced or Separated	5 (8)
Level of education <sup>c</sup>	
No formal education	1 (2)
Primary School	9 (15)
Secondary School	24 (40)
College or tertiary intuition	21 (35)
University degree	5 (8)
Income	
Less than Ksh.10,000	46 (77)
More than Ksh.10,000	14 (23)
Occupational status <sup>d</sup>	

Employed	26 (43)
Unemployed	22 (37)
House-wife	7(12)
Student	5 (8)
Suicidal status	
Yes	15(25)
No	45(75)
Trauma checklist <sup>c</sup> (n=46)	
Lost your loved one	13 (28)
Lost or any of your close relative lost his/her job	20 (43)
Heartbroken	22 (48)
Relation issues with family member or relative?	23 (50)
Undergoing some treatment or has been ill for some time (e.g., heart failure, HIV/AIDS, diabetes)?*	9(20)
Family member or relative undergoing some treatment or has been ill for some time (e.g., heart failure, HIV/AIDS, diabetes)?	19(41)
Facing challenges with substance/drug abuse?	2(4)
Family member or relative currently facing challenges with substance/drug abuse?	17(37)
Experienced a traumatic event?	17(30)
Other issue that has caused you distress?	19(41)

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*Note: SD= standard deviation, IQR= Inter-quarter-range. <sup>a</sup> As assessed by the T questionnaire.*

*Some baseline characteristics were merged for the analysis:*

*<sup>a</sup>20 years of old and younger, and 21-30 years old were merged to form a new category “30 years and below” (n=42). All other categories were merged to form a second “31 years of age or older” category” (n=18).*

*<sup>b</sup>Single, divorced and separated categories were merged to form a new category “single (n=38), while ‘married’ stayed the same.*

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\*45 out of the 46 people who completed this questionnaire provided a response for this item

<sup>c</sup>No formal education, primary school, secondary school categories were merged to form a new category “secondary School or below” (n=34), while college or tertiary intuition and university degree were merged for form a second category “college or university educated” (n=26).

<sup>d</sup>Reason for seeking treatment was derived through the confounder’s questionnaire. Only 46 out of 60 participants enrolled to the study completed this questionnaire.

### Session completion

60 participants completed all 4 sessions of the Inuka intervention in which an average of 41.79 minutes was spent during each session. On average men spent 1.56 minutes longer compared to women, Table 3 reports the average time spent in minutes in each Inuka session, by gender.

**Table 3**

Average time (in minutes) spent per session by gender

Session	Average time (mins) spent in session (n=60)		
	Male	Female	Overall sample
Session 1	54.73	55.21	55.03
Session 2	47.09	45.39	46.02
Session 3	43.14	39.87	40.43
Session 4	28.41	26.68	27.52
Mean	43.34	41.78	41.79

### Satisfaction with CHVs and the Inuka Programme

After the final and fourth session, participants rated the Inuka program and the CHVs on a variable scale of 1-4, with higher numbers indicating better satisfaction. The average rating per question is presented in Table 3. The most common rating for each question was a 4 (highest rating of satisfaction), accounting for 48%-99% of responses. All participants indicated that they would definitely (a score of 4) or generally (a score of 3) recommend the program to a friend. And all but one person said that they would definitely come back to the program if they had to seek help again (score of 4). The finding suggest that participants were highly satisfied with, CHVs delivering the intervention and the overall program.



<b>Table 3</b>		
Participants average rating on a scale of 1-4 of satisfaction in relation to CHV and the Inuka program.		
Survey questions (n=47)	CHV	Program
1. How would you rate the quality of the session/program you received?	3.67	3.63
2. Did you get the kind of session/program you wanted?	3	3.70
3. To what extent has the session/program met your needs?	3.39	3.39
4. How satisfied are you with the amount of help you received/ during the program?	4	3.96
5. Has the session/program you received helped you to deal more effectively with your problems?	3.78	3
6. In an overall, general sense, how satisfied are you with the session/ program you received?	3.96	4
7. If a friend were in need of similar help, would you recommend our program to him or her?	-	3.85
8. If you were to seek help again, would you come back to our program?	-	3.93

### Paired- samples t-tests

A paired samples t-test was calculated to investigate if there is a difference in mean scores between pre-and post-treatment scores on the SRQ-20, PHQ-9 and GAD-7 questionnaires. The findings indicated that there was a significant difference between pre-and post-scores on the SRQ-20, ( $t(59)=6.94, p<.001$ ), PHQ-9 ( $t(27)=3.98, p<.001$ ), and GAD-7 ( $t(27)= 3.33, p<.001$ ). The corresponding means and standard deviations (SD) can be found in Table 5. The data analysis will largely focus on the main outcome variable SRQ-20. However, we will also explore the predictors of pre-and post score change in relation to symptoms of depression (PHQ-9) and anxiety (GAD-7), in addition to common mental health complaints (SRQ-20).

**Table 5**

Mean, standard deviation and range of for the SRQ-20, PHQ-9 and GAD-7 for pre and post treatment

	Pre-treatment		Post-treatment	
	M	SD	M	SD
SRQ-20 ( <i>n</i> =60)	12.13	2.75	7.50	5.33
PHQ-9 ( <i>n</i> =43)	11.86	6.28	6.62	6.13
GAD-7 ( <i>n</i> =45)	11.89	4.72	7.00	6.65

*Note: SD= standard deviation, SRQ-20= Self-reported Questionnaire 20; PHQ-9- Patient Health Questionnaire-9 and GAD-7=General Anxiety Disorder-7.*

### Random effects model

A multivariate multilevel growth model was fitted using pre and post measurement of the SRQ-20 as the dependent variable. SRQ-20 scores decreased on average by 0.53 scores in relation to time (baseline and three-month follow-up assessment point)  $< .001$  (95% CI: -3.954 -, -2.636), while controlling for age, gender, marital status, educational status and income suicidal ideation.

### Predictors for SRQ-20 change scores

An MLR investigating if age, gender, income, marital status, suicidal ideation and baseline SRQ-20 scores predicted SRQ-20 change scores is reported in Table 6. The findings indicate that the model is significant, with all predictors accounting for 25% of the variance in SRQ-20 change scores. In the model, income was found to be a significant predictor, suggesting that SRQ-20 change scores were higher for participants reporting a lower range income (earnings below Ksh. 10,000 per annum) compared to higher range income (above Ksh. 10,000). Suicidal ideation was a highly significant predictor of SRQ change. These findings suggest that SRQ-20 scores are higher in participants who did not expressed suicidal ideation compared to those who did.

**Table 6**

Summary of a Multiple Linear Regression Model for Variables Predicting SRQ-20 change scores

Variable	<i>B</i>	<i>SE B</i>	<i>CI 95</i>
Age	-0.09	1.41	-2.676-2.854
Gender	-1.71	1.39	-4.440- 1.021
Income	-3.17	1.53	-6.162- 0.180*
Marital status	0.43	1.34	-2.208-3.062
Suicidal ideation	4.44	1.46	1.584-7.288**

$R^2 = 0.25$ ;  $F$  for change in  $R^2 = 2.87^*$

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*Note: Age was centred at the means. SRQ= Self-reported Questionnaire;. T1= first assessment point at baseline.*

\* $p < .05$ . \*\* $p < .01$ .

### **PHQ-9 change scores predictors.**

An MLR investigating if age, gender, income, marital status, suicidal ideation and baseline PHQ-9 scores predict PHQ-9 change scores is reported in Table 7. The findings indicate that the model is significant, with all predictors accounting for 57% of the variance in PHQ-9 change scores. In the model, age was found to be a significant predictor, suggesting that PHQ-9 change scores were higher for people above 30 years of age compared to people under 30 years of age. Suicidal ideation was a highly significant predictor of PHQ-9 change scores. These findings suggest that PHQ-9 score change was higher in participants who did not expressed suicidal ideation compared to those who did. PHQ-9 scores reported at baseline was also a significant predictor for PHQ-9 change scores.

### **Suicidal ideation**

Following on from the MLR findings indicating that suicidal ideation predicted higher score change pre and post intervention for the PHQ-9 questionnaire, a McNemar test was carried out to investigate if there was a difference in proportion in relation to suicidal ideation as reported in item 9 of the PHQ-9 questionnaire. Anyone scoring more than 0 (1-3) on the 4-point scale were coded as a 1 to indicate the presence of suicidal ideation, and everyone scoring 0, were

coded as 0 indicated absence of suicidal ideation. The McNemar test showed that the pre-and post-tests proportion were not different ( $\chi^2(1, N = 29) = 1.22, p = 0.25$ ).

**Table 7**

Summary of a Multiple General Linear Model Analysis for Variables Predicting PHQ-9 change scores

Variable	<i>B</i>	<i>SE B</i>	<i>CI 95</i>
Age	-5.89	2.26	-1.460 – 10.323*
Gender	-1.78	2.72	-7.107- 3.538
Income	-0.37	2.44	-5.166- 4.417
Marital status	-0.28	2.14	-4.468-3.911
Suicidal ideation	4.63	2.19	0.335-8.923*

$R^2 = 0.57$ ;  $F$  for change in  $R^2 = 4.57^{**}$

*Note: Age was centred at the means. PHQ-9= Patient Health Questionnaire, T1= first assessment point at baseline.*

\* $p < .05$ . \*\* $p < .01$ .

### **GAD-7 change scores predictors.**

An MLR investigating if the following predictors: age, gender, income, marital status, suicidal ideation and baseline GAD-7 scores, predicted GAD-7 change scores. is reported in Table 8. The findings indicate that the model is significant, with all predictors accounting for 46% of the variance in GAD-7 change scores. In the model, gender was found to be a significant predictor, suggesting that GAD-7 change scores were higher for female participants compared to male participants. Income as a predictor was close to reaching statistical significance ( $p=.08$ ), in which higher GAD-7 scores were higher for people who have a lower income (less than 10,000 ksh p/a), which is consistent to the findings from the SRQ-20 model.

**Table 8**

Summary of a Multiple General Linear Model Analysis for Variables Predicting GAD-7 change scores

Variable	<i>B</i>	<i>SE B</i>	<i>CI 95</i>
Age	1.11	2.80	-4.371 – 6.590
Gender	-7.52	3.65	-14.678—0.367*
Income	-5.68	3.13	-11.825- 0.463
Marital status	-0.62	2.81	-6.130 4.880
Suicidal ideation	2.85	2.88	-2.794- 8.494

$R^2 = 0.46$ ;  $F$  for change in  $R^2 = 2.98^*$

*Note: Age was centred at the means. GAD-7= General Anxiety Disorder-7, T1= first assessment point at baseline.*

\* $p = .05$ . \*\* $p < .05$ . \*\*\* $p < .01$ .

## DICUSSION

### Summary of findings

Our pilot prospective cohort study evaluated the acceptability, feasibility, and clinical effectiveness of a low-intensity PST intervention delivered by CHVs through a mobile application called ‘Inuka’, in Kenya. Participant ratings on the session satisfaction and the program rating questionnaires indicated that they were highly satisfied with the CHVs delivering the intervention, and the mobile application, demonstrating acceptability for the overall programme. Of the 80 participants recruited to the study, 60 participants completed all sessions. Moreover, all but one CHV (who fell ill at the start of the project), continued their role to the end of the study. This indicates that the use and delivery of the intervention was feasible. Pre-and post-treatment scores indicated lower CMD, anxiety and depression symptoms at the end of the intervention, when compared to baseline. A multivariate random effects model indicated that CMD symptoms were lower after treatment, compared to baseline symptoms even when controlling for participant sociodemographic variables. MLR models

exploring predictors of symptom score change, revealed that lower-range income (earnings below Ksh.10,000 per annum) compared to higher-range income (above Ksh. 10,000), and reports of suicidal ideation at baseline, compared to no reports of suicidal ideation, predicted higher SRQ-20 change scores. Higher symptom score changes in the PHQ-9 was also predicted by participants who reported suicidal ideation, compared to participants who did not. Interestingly, higher PHQ-9 scores were also predicted by an age above 30 yrs, compared to an age below 30 yrs. Finally, higher symptoms score change on the GAD-7 was predicted by the female gender, compared to the male gender. In the same model, we also found a trend that indicated that lower-range income predicted higher GAD-7 change scores, compared to higher-range income

### **Strength and limitation of the study**

To our knowledge, this report is the first to pilot a PST intervention that is delivered by CHVs through a locally developed mobile application in Kenya. The study found preliminary evidence of clinically meaningful improvement in **CMD** symptoms. This report is also the first to outline efforts between the commercial and academic sector to evaluate a mobile application in the SSA region. There are a number of limitations that should be highlighted. First, the study was conducted as a single-arm, naturalistic, follow-up study in which no control condition was used. An **RCT** with an appropriate control group is therefore required to robustly investigate the efficacy of the intervention. Another limitation is that the intervention was only offered to people who were conversant in writing and speaking English. While the English language, one of two official languages of Kenya (the other being Swahili), was perceived as appropriate to address a multilingual population of the country, Swahili remains the most commonly used language, therefore our findings cannot be generalised to non-English speakers in this setting. Moreover, a sample size calculation was not performed at the start of the study. As a result, it was not possible to determine if there was enough power to detect an effect. Lastly, acceptability and feasibility data for the CHVs delivering the intervention was not available in this study. A qualitative exploration of the CHVs experience of delivering the intervention was explored in previous phases of testing (such outputs will be outlined in another paper). The current study forms one phase of testing, in an ongoing iterative process of developing, improving and testing the intervention [29].

### **Strengths and limitation in relation to other studies**

Our findings build on the efficacious PST intervention that is delivered by non-specialist workers on the Friendship Bench, [20,30]. Our findings indicate that a PST intervention is effective at reducing CMD symptoms when delivered through a digital mobile application by a CHV. This format of delivery may therefore increase the reach of the PST intervention to sub-populations who would otherwise not access mental health services or support. Africa's fast-growing mobile network and smartphone use has led more people in the continent to turn to their mobile devices to access health care advice. A 2015 study that surveyed 4500 young people across Ghana, Malawi, and South Africa, found that young people frequently used their mobile devices in the event of sickness, personal health crises, or in response to the health concerns of a friend or relative [31]. Many respondents also used their mobile devices to contact other household members, friends, or neighbours to seek advice, recommendations, or support. These findings suggest that people in low-resource settings not only have access to mobile devices, but also rely on these devices to seek informal support for their health-care needs in the absence of readily available services. Therefore, the use of digital technologies offers a viable approach to delivering targeted programmes to prevent or treat mental health conditions [31].

Our finding suggest that the Inuka intervention was highly acceptable to participants. Taken together with the clinical improvements observed in the study, CHW delivered PST appears to lead to improvements in CMD symptoms. Our findings align with the results of a Cochrane review on the effectiveness of non-specialist health workers in delivering interventions for the care of mental, neurological and substance-abuse disorders in LMIC. The review found that non-specialist workers were able to improve outcomes of depression, post-traumatic stress and alcohol-use disorders [8]. While the use of digital technologies in expanding mental health services in LMIC has largely focused on the training and education of non-specialist workers, the care-coordination and delivery of mental health prevention and treatment interventions by non-specialist workers is on the increase in LMIC [32]. A recent example comes from a trial investigating internet-based behavioural activation that is either supported by lay counsellors (treatment group) or is unsupported with minimal online psychoeducation (psychoeducation group) for depression in Indonesia. The trial found that the intervention was effective in reducing depression in the treatment group compared to the psychoeducation group, with an effect size of 0.24 that was sustained over time at 3 months, and 0.27 at 6 months [33]. While

the design of our study does not allow for the same conclusions to be drawn, our study is to first to empirically evaluate this format of delivering PST in the SSA region, and to demonstrate a reduction of symptoms post-intervention.

The study's objective to understand if sociodemographic variables predicted change-scores, revealed that the presence of suicidal ideation at baseline, income, age and gender significantly predicted PHQ-9, GAD-7 and/or SRQ-20 change scores. The presence of suicidal ideation predicted higher change scores, for both the SRQ-20 and PHQ-9. A follow-up analysis was carried out to investigate if the prevalence of suicidal ideation was different between pre and post-intervention, however the analysis was not significant. It is worth noting that only 29 out of the 60 participants reported suicidal ideation at baseline. It is highly possible that the study was not well sampled to detect a difference. A 2020 systematic review and meta-analysis of six trials based in high income countries (1567 unique participants) found that the participants assigned to the iCBT condition experienced significantly reduced suicidal ideation compared with controls (standardized mean difference,  $-0.29$ ; 95% CI,  $-0.40$  to  $-0.19$ ;  $P < .001$ ) [34]. Similar findings were also found in a trial evaluating a mobile PST intervention for suicide prevention in Sri Lanka [35]. The findings suggested that face-to-face training in problem solving, meditation, mental health assessment, and a mobile-phone follow-up, significantly reduced suicidal ideation and depression compared with the control group [35]. Taken together with our findings, CBT and PST appears to be effective in reducing CMD and depression symptoms in people who reported suicidal ideation and may be helpful for reducing suicide. However, further research is required before such conclusions can be made to the context in Kenya.

The study's finding that the female gender predicted higher GAD-7 change scores, compared to the male gender, was supported by a systematic review on the predictors of treatment outcomes for patients with common mental health disorders. The study reported that being female was associated with positive treatment outcomes for patients receiving psychological therapies in community settings, in high-income countries [36]. The same review however found that age and socioeconomic status did not have a significant impact on outcome. While socioeconomic status was not found to have an impact on treatment outcomes, socioeconomic status was found to impact baseline depression scores which is itself a predictor for outcome [36]. However, research findings from high income countries and LMIC are not aligned in



respect to the impact of socioeconomic status on mental health outcomes. While research from high income settings largely suggest that low socioeconomic status results in a higher risk of developing and experiencing CMDs [37], research from LMIC indicate an inverse relationship between indicators of low socioeconomic status and CMDs [38,39]. While the link between socioeconomic status and mental health remains unknown, the findings of our study indicate the intervention is acceptable to people who earn less than Ksh 10,000 a year.

Lastly, the study's finding that older age (30 years of age or older) compared to younger age (under 30 years of age), predicted higher PHQ-9 change scores, runs contrary to the literature suggesting that younger populations may benefit more from digital mental health interventions [4]. A meta-analytic review investigating if guided internet based interventions resulted in clinically relevant changes for clients, found that higher age was weakly associated with better response to psychological intervention for depression [31,40]. While the cause of our findings remains unclear, factors that both enhance engagement and increase with age, such as motivation or previous access to treatment, may moderate the association between age and treatment outcome [40].

### **Implication for policy and clinical practice**

The SSA region has the highest treatment gap for mental illness, requiring huge sums of money to bridge. For this reason, it is imperative to increase capacity for cost effective approaches such as task-shifting and digital technologies, in order to help support and expand services in fragile and low resource settings. The use of digital technologies in healthcare is increasingly adopted in the global north, in which the trajectory of health and mental health care will include models of shared delivery. Not investing in technology in the region may therefore have unwelcome consequences, widening the inequalities gap between the global north and the global south, in the not too distant future.

### **Future research**

We propose a more robust evaluation of the Inuka intervention to address the limitations of our study. First, future research projects should evaluate the intervention through a randomised controlled trial that is adequately sampled. Future research should also seek to conduct in-depth qualitative interviews with both end-users and the non-specialist workers delivering the intervention, to gain a comprehensive understanding of the acceptability, usability and the

implementation of the Inuka intervention. The Inuka program should also be expanded to allow users to access the intervention from a personal digital device from home, in order to unlock the full benefits of adopting digital technologies in health care. Lastly, the Inuka programme should also be adapted for delivery in Swahili in order to increase the reach of the intervention.

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## FOOTNOTES

### **Author contribution**

The concept work was developed the concept of the work by Robin van Dalen (RvD) and Dixon Chibanda (DC). The methodology of the study was developed by XXXX and contributed to by XXXX. Asmae Doukani (AD) developed the analysis plan, with significant contribution from Francesco Sera and Hristo Valve (HV). Data collection and data management was carried out by Annie Njenga and overseen by RvD. The data analysis was carried out by HV. AD prepared all iterations of the manuscript, with significant contributions from [list all authors in order of contribution]

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**Conflict of interest:** All authors have completed the ICMJE uniform disclosure form at [www.icmje.org/coi\\_disclosure.pdf](http://www.icmje.org/coi_disclosure.pdf) and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

**Ethical approval:** Ethical clearance was approved by the ICBE Secretary on behalf of the ICBE Board (2015-0032) on 14/02/2017 and the Amref Ethics and Scientific Review Committee on 10 Apr 2017 (KIAMBU/HRDU/AUTHO/2017/04/10/Njenga A).

**Transparency declaration:** The lead author (AD) affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the

study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

**Data sharing statement:** Data available upon reasonable request.

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<sup>i</sup> Level 3 facility are generally ran by a least one one doctor, with clinical officers and nurses. Some of the services offered include, maternity in-patient services with a ward, curative services, laboratory services, pharmacy, TB Clinics, diabetes & hypertension clinics, comprehensive care clinics for patients living with HIV, baby well clinics, antenatal and postnatal services as well as issue referral letters to other facilities.

<sup>ii</sup> People who selected “yes” on this item were referred to a clinical officer who would appropriately follow-up the person.

<sup>iii</sup>The ‘confounders questionnaire’, and the ‘service-user satisfaction with the provider and program’ were not psychometrically validated. For this reason, the data generated through these questionnaires were only used to describe the sample of participants and were not used in any of the statistical analyses.