Treatment of maternal depression in low-income women: A feasibility study from Kilifi, Kenya

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Abstract

Aims of the study:

To test the feasibility of a group psychosocial intervention called Learning Through Play

(LTP) plus Culturally adapted Cognitive Behaviour Therapy (CaCBT) for depressed Kenyan mothers with children aged 0-36 months.

Methods used to conduct the study:
This study was a single-arm mixed methods feasibility study to test an integrated parenting intervention for maternal depression in a low-income rural area of Fumbini village in Kilifi District of Kenya. Women between the ages of 18 and 45 years with children up to three years were screened for depression using the Patient Health Questionnaire (PHQ-9). Those scoring above 10 on PHQ-9 were interviewed using the Revised Clinical Interview Schedule (CIS-R) to confirm the diagnosis of depression. Assessments were carried out at baseline and at the end of the intervention (3 months), followed by qualitative interviews with 12 women. Qualitative interviews were analysed using thematic analysis from a socio-constructionist theoretical lens.

Results of the study:
The LTP Plus was both feasible and acceptable with high satisfaction among the participants. Qualitative results showed that the women perceived the intervention as beneficial in reducing the symptoms of depression, coping with stress and negative emotions. The results also indicated a reduction in scores on PHQ-9, GAD-7 with an increase in perceived social support, health-related quality of life and an improvement in mothers' knowledge about child development at the end of the intervention.

Conclusions drawn from the study and clinical implications:

This study represents the first feasibility research on integrated parenting intervention in Kenya. The results indicated that culturally adapted LTP plus CaCBT is feasible and acceptable in a low-income setting of Kenya. There is now a need to study the clinical and cost-effectiveness of LTP plus CaCBT in an appropriately powered larger randomised control trial, with a longer follow-up period.

Key Words: Cultural adaptation, child wellbeing, Cognitive Behaviour Therapy, low-income, Kenya, Learning Through Play, maternal depression.

What's Known:

Maternal depression is the leading cause of disease burden in women worldwide with adverse effects on the children of depressed mothers, especially in a low- and middle-income country like Kenya.

What's New:

To the best of researchers' knowledge, this is the first feasibility study for maternal mental health and child wellbeing intervention in Kenyan context, especially among the rural, low-income and socio-economically disadvantaged mothers. The Learning Through Play (LTP) plus Culturally adapted Cognitive Behaviour Therapy (CaCBT) treatment for maternal depression is a low-cost, community-based and culturally relevant intervention that is novel to existing treatment options in the country. Therefore, the present study has set the foundation for scale-up of culturally adapted intervention for maternal mental health that can increase access to low-cost, evidence-based and sustainable maternal intervention in Kenya and other low- and middle-income countries.

Introduction

Positive early child development is crucial to the foundation of adult health and wellbeing[1]. Maternal depression has a significant association with poor child growth and development[2, 3]. The most pivotal context of nurturing care is the immediate home environment where parents and other family members need to provide optimal and supportive health care setting[1, 4]. Poverty is linked to psychological symptoms through avenues including economic stressors, impaired parenting and exposure to community violence, lack of healthcare resources and facilities[5-7]. However, some studies have identified protective strategies that may buffer the impact of poverty on child development. These coping strategies include mobilising the family, seeking social support[5] and positive parenting[3, 6]. Parenting programs have been designed to enhance positive parenting skills, and these have shown to be effective in a range of child outcomes[3, 8].

Rates of maternal depression around childbirth are high in Africa, ranging from 16.4% to 39%[9]. Previous studies from LMICs show that depressed women are less likely to engage

in preventive programs than psychologically healthy mothers[7, 10]. Depressed women are less likely to seek antenatal care, and their infants have about twice the number of diarrhoeal episodes in the first six months of life[11]. Social stress, lack of social and emotional support and social isolation are important risk factors for maternal depression[2].

Parenting programmes can play a vital role in improving knowledge and parenting practices and reducing negative parenting towards children[3, 8]. However, there are significant gaps in knowledge regarding the efficacy of parenting programs for improving child outcomes in LMIC[7, 10]. Parenting and psychological interventions can be delivered during home visits, clinic visits or community-based sessions[12]. These can be made effective by adapting the curriculum that is culturally relevant for LMICs[12, 13]. Integrated parenting interventions have shown improvements in maternal mental health and children's cognitive, social and emotional development in certain LMICs[14]. Parenting programs have been delivered in different formats, such as group interventions, individual face-to-face, self-administered, or television programs[3, 8]. Learning through Play (LTP) program is a parenting intervention developed in Toronto, Canada for health visitors to train parents for their children's healthy upbringing. It has been adapted in various countries, including LMIC[15]. Some studies have shown a positive effect of parenting interventions on mothers' knowledge and attitudes, regarding child development and reducing depressive symptoms[15]. Although psychological treatments are effective in several low and middle-income countries (LMICs)[15], we are not aware of an integrated parenting intervention addressing maternal depression in Kenya. Therefore, the present study was conducted to determine the acceptability and feasibility of Learning Through Play (LTP) plus Culturally adapted Cognitive Behaviour Therapy (CaCBT) intervention for maternal depression in a low-income setting of Kilifi District in Kenya.

Methods

Design

The study adopted a mixed-methods single-arm feasibility study with an embedded qualitative and quantitative design. The Medical Research Council (MRC) recommends

mixed methods studies as the first step in developing and evaluating the feasibility of complex interventions[16].

Study Area and Population

The study was conducted in Kilifi District in the Coast Province of Kenya with an area coverage of 12,245.90 km and 1,453,787 population[17]. In Kenya, there is a total fertility rate of 3.5 live births per woman with high infant mortality rate and deaths of children under five years old (30.6=infant deaths and 40.0=per 1,000 live births)[18]. Contributing factors to maternal challenges include poverty, illiteracy, lack of access to health facilities, poor hygiene, and the high cost of acquiring appropriate health care[17]. Although, there seems to be no significant data on the rates of maternal depression in Kenya and its specific regions, however, the Kilifi District was chosen for this feasibility study based on existing research network in the region in preparation for future scale up.

Quantitative study

Participant Selection

Women between the ages of 18 and 45 years with children up to 36 months were invited to participate in the study through a house-to-house survey by trained research assistants. The study took place from May 2010 to February 2011. Women who gave consent were assessed for depression using the PHQ-9[19]. Those scoring above 10 on PHQ-9 were interviewed using the CIS-R (Clinical Interview Schedule- Revised)[20] to confirm the diagnosis of depression.

Exclusion Criteria

Women with a diagnosed significant physical or learning disability, postpartum or other forms of psychosis and receiving psychiatric care, or children with serious medical or psychiatric illnesses were excluded from the study.

Assessments

Assessments were carried out at baseline and at three months (end of the intervention). In addition to a demographic form, Patient Health Questionnaire (PHQ- 9)[19], Generalised Anxiety Disorder (GAD7)[21], Clinical Interview Schedule Revised (CIS-R)[20], Oslo social support scale[22], EuroQoL-5 Dimensions (EQ-5D)[23], The Learning through Play (LTP) Knowledge, Attitude and Practices (KAP) Questionnaire[24], and brief Verona Service Satisfaction Scale[25] were administered.

The Learning Through Play (LTP) Plus Training

The LTP Plus is a 12-session group intervention that integrates two interventions—Learning Through Play (LTP) and Culturally adapted Cognitive Behaviour Therapy (CaCBT). The community-based multimodal psychosocial intervention LTP Plus includes a supportive component, an educational component (healthcare advice), problem-solving techniques (to address maternal depression and child-related difficulties), and a parenting programme that aims at the child's psychosocial development through mother-child attachment to promote early childhood development.

- *Learning Through Play (LTP):* The central feature of the programme is a pictorial calendar devised for parents, depicting eight successive stages of child development from birth to 3 years, with illustrations of parent-child play and other activities that promote parental involvement, learning, and child attachment. In each stage, five key areas of child development are depicted: (a) sense of self, (b) physical development, (c) relationships, (d) understanding, and (e) communication. Information about each area is written in a simple, low-literacy language, with accompanying pictures that serve as visual cues.
- *Culturally adapted Cognitive Behaviour Therapy (CaCBT)*: CaCBT is grounded in the standard framework of cognitive-behavioural theory[26] and uses techniques of active listening, changing negative thinking, guided discovery (i.e. questioning style to both gently probe for health beliefs and to stimulate alternative ideas), behavioural tasks, and homework (i.e. trying things out between sessions, putting what has been learnt into practice), while educating participants about depression, correlates and management, social support, and practical advice on using

appropriate healthcare[26]. The psychological component was integrated with the Learning Through Play (LTP) weekly sessions. A similar intervention has been successfully used in low-income setting[15].

Two group facilitators jointly led the LTP Plus intervention groups. Of these, one was a school-teacher who was already trained in LTP and the other, a local priest who had received two weeks' training in the use of both the LTP alongside the CaCBT treatment manual. The sessions were delivered weekly in a local child centre, and each group session lasted 60-90 minutes. A qualified CBT therapist offered the community workers/facilitators session-by-session weekly supervision throughout the study.

Quantitative Data Analysis

A total of 17 women were recruited into the intervention study after an initial screening for depression on PHQ-9 and were later interviewed using the CIS-R to confirm the diagnosis of depression. All outcome variables were continuous, and changes in outcome from baseline to 12 weeks and were all found to be approximately normally distributed. Therefore, changes between timepoints were assessed using the paired t-test.

Qualitative study

After the three months of quantitative assessments at the end of the intervention, all the participating women were approached for interviews by a trained research assistant. A total of 12 women gave consent and participated in semi-structured qualitative interviews. All interviews were conducted in the local language and then translated into English by a bilingual community worker (N) and cross-checked by a general practitioner (AB) to ensure reliability. The use of local language helped to explore participants' defined meanings of their experiences[27]. Interviews were analysed using thematic analysis[28] from a socio-constructionist theoretical lens[29, 30].

Results

Quantitative Results

Of all the women approached to participate in the study, n=19 fulfilled the eligibility criteria of whom 17 agreed to participate. The mean age of the participating women (n=17) was 28.2 years (SD 8.6). The mean number of years of formal primary education was 5.9 years (SD 4.0). Attendance at the sessions was high, and 10 (59%) participants attended all the 12 sessions. Four (23%) mothers attended 11 sessions, and three (18%) mothers attended only one session. Out of the three mothers who only attended one session, two mothers had found full-time jobs, and one of the women said that the group was too large.

Among the women that completed the study, the results demonstrated a significant decrease in PHQ-9 scores (baseline (Mean=13.6, SD=2.9), end-of-intervention (Mean=4.2, SD=2.4), P<0.001), and GAD-7 scores (baseline (Mean=8.6, SD=3.0) to week 12 (Mean=3.7, SD=2.2), P<0.001) over time (Table 1). Improvements were observed in social support (baseline (Mean=9.1, SD=2.2) to week 12 (Mean=11, SD=1, p < 0.001)) and health-related quality of life (baseline (Mean=0.61, SD=0.22) to week 12 (Mean=0.77, SD=0.18)), although the change for this last outcome did not quite reach statistical significance (Table 1). Mothers' knowledge about child development increased from baseline (Mean=35.4, SD=2.1) to week 12 (Mean=40.8, SD=0.4) (Table 1).

Table 1: Changes in PHQ-9, GAD-7 and OSLO social support for completers

N=14	**Baseline Mean (SD)**	**12-weeks Mean (SD)**	**Change Mean (95% CI)**	**P**
PHQ-9	13.6 (2.9)	4.2 (2.4)	-9.4 (-11.3, -7.5)	<0.001
GAD-7	8.6 (3.0)	3.7 (2.2)	-4.9 (-6.5, -3.2)	<0.001

OSLO Social Support	9.1 (2.2)	11.0 (1.0)	1.9 (1.1, 2.8)	<0.001
EQ-5D	0.618 (0.22)	0.77 (0.18)	0.16 (-0.02, 0.34)	0.08
KAP	35.4 (2.1)	40.8 (0.4)	5.4 (4.1, 6.6)	<0.001

The analyses were repeated, including the three non-completers in the analysis (Table 2). These analyses also indicated significant reductions in PHQ-9 and GAD-7 scores, and significant increases in OSLO, and KAP scores. There was also slight evidence of an increase in EQ-5D, although the result did not quite reach statistical significance. In this extended group, PHQ-9 scores decreased from a mean of 13.9 at baseline to a mean of 6.2 at 12-weeks.

Table 2: Changes in PHQ-9, GAD-7 and OSLO social support for all patients (including non-completers)

N=17	**Baseline Mean (SD)**	**12-weeks Mean (SD)**	**Change Mean (95% CI)**	**P**
PHQ-9	13.9 (2.9)	6.2 (5.0)	-7.8 (-10.2, -5.3)	<0.001
GAD-7	8.6 (2.9)	4.6 (3.0)	-4.0 (-5.6, -2.4)	<0.001
OSLO Social Support	8.9 (2.1)	10.5 (1.5)	1.6 (0.8, 2.4)	<0.001

EQ-5D	0.60 (0.20)	0.73 (0.18)	0.13 (-0.02, 0.27)	0.08
KAP	35.9 (2.1)	40.3 (1.2)	4.4 (3.0, 5.9)	<0.001

Satisfaction

As shown in Table 3, all participants were either satisfied or very satisfied with the kind of support and treatment they received and expressed that the intervention had helped in improving their symptoms and coping with their problems. The participants also endorsed that they would recommend this treatment and support if a friend required a similar help.

Table 3: Results of Patient Satisfaction Survey at Week 12: n=14

	Questions	**Mean**	**SD**
1.	Did you get the kind of support and treatment you wanted? 1. No, definitely not. 2. No, not really. 3. Yes, generally. 4. Yes, definitely.	3.71	0.469
2.	How do you feel about the effect of the support and treatment in helping to relieve your symptoms? 1. Very dissatisfied 2. Dissatisfied 3. Satisfied 4. Very satisfied	3.00	0.001
3.	How do you feel about the effect of the support and treatment in helping with your other problems? 1.Very dissatisfied 2. Dissatisfied 3. Satisfied 4. Very satisfied	3.07	0.267
4.	If a friend were in need of similar help, would you recommend this support and treatment to her?	3.79	0.426

	1.No definitely not. 2.No, I don't think so. 3.Yes, I think so. 4.Yes, definitely.		
5.	Have the services you received helped you to deal more effectively with your problems? 1.No, they seemed to make things worse. 2.No, they didn't really. 3.Yes, they helped somewhat. 4.Yes, they helped a great deal.	3.14	0.363
6.	To what extent has the help you received met your needs? 1.None of my needs have been met. 2.Only a few of my needs have been met. 3.Most of my needs have been met. 4.Almost all of my needs have been met.	3.00	0.000
	Satisfaction total score for 12 weeks	19.57	1.09

Qualitative Results

Of the 17 participating women, 12 agreed to further participate in the semi-structured interviews. Each interview lasted for approximately 25-30 minutes. The mean age of the women was 29 years, 10 were married, one single mother and one divorced. The qualitative arm adopted a critical realist and socio-constructionist lens to explore participants' perception of realities and experiences of the intervention[30]. The study's use of semi-structured interviews, epistemology and exploratory scope influenced the choice for thematic analysis[29, 30]. Braun and Clarke's six-step process of thematic analysis involving familiarisation with the dataset, coding, categorisation of codes, development and definition of themes alongside writing up of the findings were adopted for the study[28]. The thematic analysis of datasets showed four central themes emerged from the women's accounts:

1. Perceived positive outcomes from help-seeking behaviours
2. Socio-economic factors as drivers of maternal depression
3. Perceptions of the usefulness of LTP Plus

4. Lack of access to care

- ***Perceived positive outcomes from help-seeking behaviours***

Participants' accounts showed that all families allowed them to attend the LTP Plus intervention, and most of them attended all sessions. Ten out of the twelve women had earlier discussed their worries/low moods with at least one person: four approached preachers, three had discussed with a friend or neighbour and two approached community healthcare workers. Those who had done so reported the interactions as positive. Two of the participants said:

"*Yes, I talked to a neighbour who encouraged me, that this [the current situation] was normal and will end soon*" (P-11)

"Yes, I approached a preacher and got [felt] better" (P-1).

The above extracts showed how help-seeking behaviours commence from family, relations and community members with the culture-specific assumption that mild to moderate maternal depression as 'normal'. It also reflects the essential role of preachers and how mental health is religiously and culturally construe within the communities.

- ***Socio-economic factors as drivers of maternal depression***

Financial instability and lack of basic resources were recognised as key contributory factors to developing stress and depression. Women talked about the need to become self-sufficient in agriculture to beat hunger. Some of the women wanted personal financial support for starting a local business such as a local grocery or vegetable shop or books/school uniform store, fried potato shop, or purchasing a sewing machine/dairy cow, in order to support their families and children. Almost all of the women had difficulty in meeting their basic daily needs and those of their families. For example, the following participants said:

"I wish to be supported in starting a local grocery shop in my area because shops are very far away. And from the profit, I would be able to fulfil my needs and feed and educate my children as well" (P-3).

"In my opinion, the greatest problem here is hunger; therefore, I would request the organisation to help us in practising modern agriculture…" (P-7).

Considering that the participants in the present study are low-income women, the above extracts suggests that maternal depression is largely triggered due to the high levels of anxiety associated with the lack of basic resources such as food and shelter for mother and child. The extracts also depicted that the women are eager to acquire self-sustaining skills partly contained in the LTP Plus intervention packages.

- ***Perceptions of the usefulness of LTP Plus***

The interviews indicated that the women had developed effective coping strategies alongside gaining new knowledge about maternal depression and child development. Two participants reflected on the parenting skills they have learned in the following extracts:

"It [the training] was about child development and pregnant mothers…about their anger, stress and depression" (P-3)

"The training touched on life challenges that can cause sadness, depression etc.… And it helped me a lot" (P-15)

The above excerpts show that participants internalised and articulated the core aims of LTP Plus intervention, providing mothers with valuable parenting skills and enhancing the mother-child relationship. It also adopts a problem-solving approach that changes negative thinking and treats depressive symptoms.

While talking about the benefits of the LTP Plus intervention, all of the women had depression at the start of the intervention. All of them said that they felt better and could cope well with emotions and negative feelings at the end of the LTP Plus training and all

of them seemed motivated in sharing the knowledge they gained with other depressed women in the community. For example, one participant said:

"Yes, I passed through such a situation [depression and sadness] during my pregnancy. But the training helped me reduce the worries of life…This training is important for all women … I will share the knowledge I gained with others as well" (P-11)

The above excerpt reflected the levels of the participant's enthusiasm to share their newly learned parenting skills to other women in the community who might experience similar parenting challenges and maternal depression.

However, during the LTP Plus intervention, participants wanted a better and quieter venue for future group interventions and wanted longer, more extended sessions which women believed would result in better and lasting outcomes.

"I did not like the venue because it was very noisy. The training should be conducted in a quiet place next time… the time of sessions was not sufficient and should be increased to think and discuss more things" (P-8)

The above excerpt constituted an essential feedback for future LTP Plus intervention. The conduciveness and serenity of training venues could be accounted for as an important aspect of planning and implementation.

- ***Lack of access to care***

The issue of conducive and palatable atmosphere for delivering psychosocial interventions could be extended to the debate on improving access to specialist/hospital care. For example, most participants expressed the need for a nearby hospital. Excerpts from two participants are showed below:

"I would ask the organisation to build a nearby hospital for us because we walk for about ten kilometres to approach healthcare and there is a shortage of health workers and medicines…." (P-15)

"I request for a nearby hospital because the one we have in Kilifi is far away." (P-16)

The above excerpt suggests that maternal depression contributes to mothers' anxiety levels due to lack of healthcare facilities in near proximity.

Discussion:

Living in a rural area of Kenya can be challenging, particularly for a woman with a young child. In addition to workforce shortages, access to healthcare is another challenge due to the scarcity of health care facilities. Thus, WHO recommends task-shifting strategies to deal with the shortages of health workforce[31]. Our study demonstrated that LTP Plus intervention could be delivered efficiently by lay community workers trained to provide the intervention. The results indicate that women perceived the intervention as beneficial. In addition, the results of the quantitative study showed that there was a reduction in depression and anxiety and improvement in health-related quality of life. The group intervention recorded low attrition. Several measures such as local knowledge of the facilitator, childcare facility and engaging families of the participants helped keep them engaged and retained during the intervention. Evidence exists to support this finding of a reduction in maternal depression with group psychological interventions[15, 32, 33]

Similar to the present study, two previous studies have attempted to use non-specialists to offer low-cost and effective intervention for maternal depression in Nigeria[32, 33]. The first study examined a potential low-cost intervention using the Expanding Care for Perinatal Women with Depression (EXPONATE) trial to test the effectiveness and cost-effectiveness of the treatment package for perinatal depression delivered by community midwives in primary care using mobile phones and were followed up to 12-months postpartum period[33]. The second also used non-specialists primary maternal care providers in an EXPONATE trial to measure high versus low-intensity intervention for perinatal depression for over a period of 6 months postpartum in Ibadan Nigeria[32]. Both studies showed positive outcomes in the depressed mothers[32]. However, none of the above studies seems to demonstrate the effectiveness of the HOME Inventory [24] in an integrated group intervention which screens for potential child growth and developmental

delays.

Furthermore, the results from the present study confirm previous findings from low-income settings of Pakistan which showed that LTP Plus intervention could be successfully integrated into the routine work of the community health workers, and they do not consider it to be an additional burden[15, 34]. For example, in our recent cluster RCT[35], we conducted an integrated parenting intervention for maternal depression and child development in a low-resource setting with 774 mothers (aged 18 to 44 years) who had children (aged 0-30 months) in Karachi, Pakistan. The RCT concluded that low-cost integrated parenting interventions delivered by non-specialist health workers are effective, efficient and enhances access to mental health care for depressed mothers which transcends into their children's healthy growth and development.

Poverty, lack of childcare and mental health facilities were reported as great barriers[6, 15]. Reducing these barriers often help in enabling depressed mothers of young children to maximise care provision in low-income areas with scarce resources [15, 31]. It is also pertinent to mention that the LTP Plus CBT intervention took place during the school term to attract mothers with other school-going children and to minimise dropouts. As evidenced in the previous study[36], a positive relationship with group facilitators and understanding the local context are reported to be an important factor for keeping the participants engaged in the intervention.

Strengths, Limitations, and Future Directions

So far, this is the first feasibility study conducted among depressed women in a rural area of Kenya. The study was successful in engaging and retaining participants in the parenting group intervention. Feedback from the brief adapted Verona Service Satisfaction questionnaire demonstrates favourable results indicating that this type of intervention is acceptable to Kenyan women. Another strength of this study was the ability to engage low-income, low-literacy participants in the group intervention and retain them for up to 3 months at follow-up assessments.

The main innovative feature of this feasibility study was the involvement of minimally

trained community workers (CWs) who, although currently not involved in the treatment of maternal depression, are often actively involved in other community programmes and belong to the local community themselves. Therefore, the acceptance of LTP Plus intervention by the CWs was partly because it serves as an opportunity for them to contribute to the wellbeing of their community which they considered did not add much to their existing workload. The use of non-mental health professionals for interventions in low-resource settings is supported in the literature [31-33].

The present feasibility study has a very small sample size, a non-randomised approach, and limited dataset which are major limitations. For example, there was no data collected to compute the cost of intervention delivery and overall cost per QALY gained (EQ-5D) over the 12 weeks period. Future studies should also focus on cost-effectiveness of the intervention delivery. More so, the intervention venue was reported to be noisy with large number of participants joined together in a group session. Thus, a venue with a conducive atmosphere with minimal distraction and a smaller number of participants per group, or perhaps a one-on-one session, should be considered in future intervention. Another limitation is that the study took place in a single geographical rural area in Kenya with a predominantly Christian African population and so the results may not be generalisable to other populations in Kenya. Benefits gained early during treatment likely tend to decline in six months or beyond; therefore, future studies should have a longer follow-up.

The global mental health expectation has brought to the forefront the importance of developing low-cost, evidence-based interventions which can be scaled up in low-income countries [31]. We believe that the LTP Plus programme once tested in a full RCT can be successfully integrated into the existing primary care setting, at minimal extra cost. Using community workers (CWs) rather than mental health professionals also demonstrates the ecological validity of the intervention [31, 32]. That is, its potential to produce results that can be generalised to community settings. However, our experience has shown that for the intervention to be accepted by CWs, it has to facilitate, rather than add to, their already considerable workload. The results also indicate the acceptability of LTP Plus intervention to low-income Kenyan women. We intend to study the clinical efficacy and cost-effectiveness in a larger trial in the future to reach a wider group.

Key Points

Group parenting and psychological interventions can help reduce maternal depression and improve mother-child attachment, home environment and child outcomes.

LTP Plus Programme if found to be an effective intervention, has the potential to be integrated into existing health care setting in Kenya and is culturally acceptable to Kenyan women.

LTP+CaCB intervention has potential for taskshifting. For example, Community Workers (CWs) can deliver LTP+CaCB.

Effectiveness of LTP Plus needs to be tested in an appropriately powered larger trial in Kenya.

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Ethical Statement

The study was given ethical approval by the Kenya Ministry of Science and Technology and the Institutional Review Board of the Centre in Africa for Learning and Living (CALL). Informed written consent was obtained from all the participants separately for qualitative and quantitative interviews.

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Appendix: CONSORT checklist of information

Table 4:

CONSORT checklist of information

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
Title and abstract			
1a	Identification as a randomised trial in the title	Identification as a pilot or feasibility randomised trial in the title	
1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	
Introduction			
Background and objectives:			
2a	Scientific background and explanation of rationale	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	
2b	Specific objectives or hypotheses	Specific objectives or research questions for pilot trial	

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
Methods			
Trial design:			
3a	Description of trial design (such as parallel, factorial) including allocation ratio	Description of pilot trial design (such as parallel, factorial) including allocation ratio	
3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	
Participants:			
4a	Eligibility criteria for participants		
4b	Settings and locations where the data were collected		
4c		How participants were identified and consented	
Interventions:			
5	The interventions for each group with sufficient details to allow replication, including how		

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
	and when they were actually administered		
Outcomes:			
6a	Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	
6b	Any changes to trial outcomes after the trial commenced, with reasons	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	
6c		If applicable, prespecified criteria used to judge whether, or how, to	

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
		proceed with future definitive trial	
Sample size:			
7a	How sample size was determined	Rationale for numbers in the pilot trial	
7b	When applicable, explanation of any interim analyses and stopping guidelines		
Randomisation:			
Sequence generation:			
8a	Method used to generate the random allocation sequence		
8b	Type of randomisation; details of any restriction (such as blocking and block size)	Type of randomisation (s); details of any restriction (such as blocking and block size)	
Allocation concealment mechanism:			
9	Mechanism used to implement the random allocation sequence (such as sequentially		

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
	numbered containers), describing any steps taken to conceal the sequence until interventions were assigned		
Implementation:			
10	Who generated the random allocation sequence, enrolled participants, and assigned participants to interventions		
Blinding:			
11a	If done, who was blinded after assignment to interventions (eg, participants, care providers, those assessing outcomes) and how		
11b	If relevant, description of the similarity of interventions		
Analytical methods:			
12a	Statistical methods used to compare groups for primary and secondary outcomes	Methods used to address each pilot trial objective whether qualitative or quantitative	

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Not applicable	
Results			
Participant flow (a diagram is strongly recommended):			
13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	
13b	For each group, losses and exclusions after randomisation, together with reasons		
Recruitment:			
14a	Dates defining the periods of recruitment and follow-up		

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
14b	Why the trial ended or was stopped	Why the pilot trial ended or was stopped	
Baseline data:			
15	A table showing baseline demographic and clinical characteristics for each group		
Numbers analysed:			
16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	
Outcomes and estimation:			
17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any	

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
		estimates. If relevant, these results should be by randomised group	
17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Not applicable	
Ancillary analyses:			
18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory	Results of any other analyses performed that could be used to inform the future definitive trial	
Harms:			
19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)		
19a		If relevant, other important unintended consequences	
Discussion			

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
Limitations:			
20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	
Generalisability:			
21	Generalisability (external validity, applicability) of the trial findings	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	
Interpretation:			
22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	
22a		Implications for progression from pilot	

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
		to future definitive trial, including any proposed amendments	
Other information			
Registration:			
23	Registration number and name of trial registry	Registration number for pilot trial and name of trial registry	
Protocol:			
24	Where the full trial protocol can be accessed, if available	Where the pilot trial protocol can be accessed, if available	
Funding:			
25	Sources of funding and other support (such as supply of drugs), role of funders		
26		Ethical approval or approval by research review committee, confirmed with reference number	