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RESEARCH ARTICLE

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Culturally adapted psychological intervention for treating maternal depression in British mothers of African and Caribbean origin: A randomized controlled feasibility trial

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Abstract

Background: Women are likely to suffer from maternal depression due to childbirth difficulties and parenting responsibilities, leading to long-term negative consequences on their children and families. British mothers of African/Caribbean origin uptake of mental healthcare is low due to the lack of access to culturally appropriate care.

Methods: A mixed-methods randomized controlled feasibility trial was adopted to test the appropriateness and acceptability of Learning Through Play plus Culturally adapted Cognitive Behaviour Therapy (LTP+CaCBT) for treating maternal depression compared with Psychoeducation (PE). Mothers ($N = 26$) aged 20–55 were screened for depression using the Patient Health Questionnaire (PHQ-9). Those who scored >5 on PHQ-9 were further interviewed using the Revised Clinical Interview Schedule to confirm the diagnosis and randomized into LTP+CaCBT ($n = 13$) or PE ($n = 13$) groups. Assessments were taken at baseline, end of the intervention at 3- and 6-months post-randomization. $N = 2$ focus groups (LTP+CaCBT, $n = 12$; PE, $n = 7$) and $N = 8$ individual interviews were conducted (LTP+CaCBT, $n = 4$; PE, $n = 4$).

Results: The LTP+CaCBT group showed higher acceptability, feasibility and satisfaction levels than the PE group. Participants experienced the intervention as beneficial to their parenting skills with reduced depression and anxiety in the LTP+CaCBT compared to the PE group.

Conclusions: This is the first feasibility trial of an integrated online parenting intervention for British African and Caribbean mothers. The results indicated that culturally adapted LTP+CaCBT is acceptable and feasible. There is a need to study the clinical and cost-effectiveness of LTP+CaCBT in an appropriately powered randomized control trial and include the child's outcomes.

Trial registration. www.ClinicalTrials.gov (no. NCT04820920).

KEYWORDS
African, Caribbean, child wellbeing, maternal depression, maternal mental health, psychological intervention

1 | INTRODUCTION

The National Health Service (NHS) has called for better maternal healthcare for black mothers in the United Kingdom (UK) following a recent report revealing that black women are four times more likely than white women to die in pregnancy or childbirth (MBRRACE-UK, 2020). Factors such as mental health diagnosis, domestic violence, substance abuse and lower socio-economic status increased mothers' risk of death during or up to 1 year postpartum (MBBRACE-UK, 2020). During the COVID-19 pandemic in the United Kingdom, there were racial disparities in infection rates (Jidong, Husain, Roche, et al., 2021). The UK Obstetric Surveillance System (UKOSS) study revealed that black pregnant women were eight times more likely to be hospitalized with COVID-19 (Knight et al., 2020). In the context of mental health, another study found that 46% of Black and Black British parents reported increased anxiety levels during the pandemic (Best Beginnings, Home-Start UK and the Parent Infant Foundation, 2020).

Despite these well-documented racial inequalities in maternal health outcomes for Black mothers and their infants, the quality of care received also appears poorer than other ethnic groups in the United Kingdom (Dare et al., 2022). An earlier study highlighted that despite health visitors' prolonged contact with African immigrant women residing in Southeast London, signs of maternal depression were not identified by health visitors and related this to the lack of acknowledgement of women's silence regarding their emotional struggles (Babatunde & Moreno-Leguizamon, 2012). This could be partly due to a lack of linguistic expression of their lived experiences (Jidong et al., 2020). Evidence has also suggested that Black Caribbeans in the United Kingdom are less likely to receive a formal diagnosis for common mental health disorders such as depression and are often under-represented in primary care mental health services (Edge & Rogers, 2005; Spector, 2001). These women were significantly more likely to report social risk for perinatal depression than their white British counterparts (Edge & Rogers, 2005).

When considering the under-diagnosis of maternal depression in Black mothers and the lack of representation in statutory mental health care services in the United Kingdom, it is important to keep in mind systemic racism and colonial foundations that institutions were built on (Jidong, Bailey, Sodi, et al., 2021). When considering treatment for psychological disorders, it is notable that much of the evidence base disproportionately represents western, educated, industrialised, rich demographic (WEIRD) populations (Ahsan, 2020; Jidong, Bailey, Sodi, et al., 2021). Routinely practiced therapeutic models such as cognitive behavioural therapy have been based on Eurocentric models of knowledge and meaning-making, and often, clinical research, which informs these treatment protocols lacks the acknowledgement of the role racial trauma and oppression has on African and Caribbean people (Ahsan, 2020; Jidong, Bailey, Sodi, et al., 2021). For example, illness and social identity were found to be closely associated in Black Caribbean populations in the United Kingdom and having depression may be regarded as a sign of weakness and a threat to a woman's ability to cope, in that she has historically had to embody a sense of mastery and control in overcoming adversity (Edge & Rogers, 2005; Jidong, Husain, Ike, et al., 2021).

Key Practitioner Messages

- Women are predisposed to maternal depression due to childbirth difficulties and parenting responsibilities.
- Children and families of depressed mothers suffer long-term negative consequences.
- The culturally adapted LTP+CaCBT intervention is acceptable and feasible for treating maternal depression.
- The intervention is sustainable and ecologically friendly as it can be delivered with minimal resources by trained facilitators or community health workers.

Furthermore, African immigrant women do not seem to express signs of maternal depression (Jidong, Husain, Roche, et al., 2021). Still, they explain symptoms as something else in their daily lives, and almost half pertain to the notion 'that you have to get on with it' (Babatunde & Moreno-Leguizamon, 2012). However, the limitation of Babatunde and Moreno-Leguizamon's (2012) study is that this may not be generalizable to the wider population or Black British-born mothers. Nonetheless, the findings from the study offer an understanding of the cultural sensitivity in identifying unhealthy coping mechanisms for Black mothers and the disconnect in current perinatal care practices. Their study, suggests its inadequacy in detecting low mood in Black women especially in their early motherhood stages and the developmental impact this may have on their children.

More so, coping strategies may differ among minority ethnic people in High-Income Countries (HICs) like the United Kingdom. For example, some ethnic minorities in the United Kingdom originate from countries with higher levels of religiosity (e.g., Jidong et al., 2022). Religion was thought to help with building resilience for the first wave of immigrants invited to work in Britain from the West Indies, who for many, faced unjust discrimination and prejudice (Shafiq et al., 2021). One review investigating coping mechanisms in African Caribbean communities in the United Kingdom with long-term health conditions found spirituality and religion to be prominent coping strategies (Shafiq et al., 2021). Religion offered comfort with the unknown, and prayer was considered to bring hope and inner peace (Bhui et al., 2008). Some participants reported illness was perceived as a test from God and illnesses such as depression can affect individuals

because of a lack of faith in God (Marwaha & Livingston, 2002). Religious rituals and practices were believed to help strengthen the mind and these practices distract them from thoughts about their condition and assist in coping and maintaining a positive outlook (Bache et al., 2012).

1.1 | African and Caribbean cultures

Historical events such as the colonization of Africans in Africa and the slavery of the African and Caribbean people in the West have tremendously shaped their traditional values and cultural beliefs. However, both African and Caribbean cultures promote and manifest a greater sense of personhood through connection to spiritual and social agencies. The former includes connection to God, spirit and ancestors, while the latter includes connection to family, community, and humanity (Kpanake, 2018). Although there are so many similarities between African and Caribbean people, there are also attitudinal features that seem to distinguish them. For example, an early study of personality expansion by Green (1970) showed that Caribbean people are likely to be more confident, active, secure, outgoing and realistic than Africans, which might have been orchestrated by the related freedom afforded by transplantation. In contrast, Africans tend to be unrealistically attracted to glory when desiring success.

In terms of parenting, the African and Caribbean cultural difference was further illustrated in Green's (1970), participants were asked 'when do you think you will be old enough to be a good parent?' (p.199); Caribbean participants estimated 5 years younger than the Africans. Thus, the African cultural practice of heavy bride-price deterred young men from early marriage. Consequently, young African women are also reluctant to assume marriage responsibilities due to trading and food provision alongside childbearing.

Recently, research has begun building on the knowledge base for non-western populations. A systematic review of psychological interventions for maternal depression among women of African and Caribbean origin found four key themes of interventions to focus on; such as enhancing parents' confidence and self-care, effective mother–child interpersonal relationship, culturally appropriate maternal care and the option for internet-mediated care for maternal depression (Jidong, Husain, Roche, et al., 2021). It is important to consider these factors responsive to African and Caribbean communities whilst utilizing culturally specific knowledge to develop a purposeful and meaningful treatment that is sensitive to the psychological needs of Black mothers and their infants but also considers the historical-political context, and sociological aspects of Black identity. Therefore, Jidong, Husain, Roche, et al. (2021) study recommended an evidence-based, culturally adapted psychological intervention for maternal depression that is being tested in the present study. Hence, our research question is whether 'Learning Through Play plus Culturally adapted Cognitive Behaviour Therapy' (LTP+CaCBT) is acceptable and culturally appropriate for treating maternal depression compared with 'Psychoeducation' (PE) in British mothers of African and Caribbean origin?

2 | METHODS

2.1 | Design

This study adopts mixed methods randomized controlled feasibility trial to examine the appropriateness and acceptability of LTP+CaCBT for treating maternal depression in British mothers of African and Caribbean origin in the United Kingdom. Randomized controlled trial is recommended as the 'gold standard' for testing intervention (Hariton & Locascio, 2018). Weiss' (1997) Theory of Change (ToC) underpins the project's design and intended outcomes. Thus, the ToC helped to examine how change happens because of LTP+CaCBT intervention, what that means to the participants and the wider systems or actors that influence it.

The present study is also underpinned by the Medical Research Council's (MRC) new framework for developing and evaluating complex interventions using mixed methods to assess the feasibility and acceptability of the intervention and evaluation design to make informed decisions about the progression to the subsequent stages of evaluation (Skivington et al., 2021).

The Consolidated Standards of Reporting Trials (CONSORT) checklist of relevant information and procedures further underpins the study's design and methodological rigour (see Appendix A for CONSORT checklist).

2.2 | Ethical consideration and protocol registration

The study received ethical research approval (no. 2021/176) from Nottingham Trent University, UK, with a fully registered study's protocol on www.ClinicalTrials.gov (no. NCT04820920). Prospective participants were informed that their participation in the study was entirely voluntary. An e-consent was obtained separately from each participant for the intervention training and data collection. All participants were each compensated for their time with £10 Amazon vouchers for each of the 12 sessions and assessments.

An ethical concern that appeared to be common among the African and Caribbean communities is fear of mental health stigma and discrimination. Therefore, we named LTP+CaCBT and PE sessions as 'parenting training courses' and the community health workers delivering the sessions are called 'trainers/facilitators'. Certification of participation was issued to all participants on successful completion of the intervention.

2.3 | Participant selection

British African and Caribbean mothers between the ages of 20 to 55 years with children up to 3 years and have lived in the United Kingdom for over 12 months were invited to participate in the study through initial contact from religious organizations such as

Churches and Mosques, mother–child community organizations and flyers distributed to African/Caribbean restaurants and shops. Participants who gave consent were assessed for depression using the Patient Health Questionnaire (PHQ-9) (Spitzer et al., 1994). Those scoring above 5 on PHQ-9 were further interviewed using the Clinical Interview Schedule- Revised (CIS-R) (Lewis et al., 1992) to confirm the diagnosis of depression. A cut-off point of 5 or more on PHQ-9 is recommended as an indication of persistently high maternal depressive symptoms (Bitew et al., 2016). $N = 26$ participants screened and met the study's inclusion criteria were randomized into LTP+CaCBT ($n = 13$) or PE ($n = 13$) groups. The overall breakdown of participants' demographic information (Black African, $n = 19$; and Black Caribbean, $n = 7$). A sample size of 12 participants per group is recommended as a rule of thumb for a pilot feasibility study (Julious, 2005). However, the present study recruited 13 participants per group considering the possibility of attrition rates.

For the qualitative arm, $n = 2$ focus groups (LTP+CaCBT, $n = 12$; PE, $n = 7$) and 8 one–one interviews were conducted (LTP+CaCBT, $n = 4$; PE, $n = 4$) and data saturation was reached. Interviews were digitally-recorded and transcribed. The interview transcripts were analysed thematically using a socio-constructionist theoretical lens (Burr, 2015). The underpinning of the socio-constructionist theoretical lens implies that lived experiences of maternal depression and the healing process lie widely within the social realm and mothers' cultural beliefs (Burr, 2015). Therefore, the study assumed that participants' construing of LTP+CaCBT intervention and perception of their lived experiences or recovery would be influenced by the knowledge of their realities, which is a product of shared history, language, and socio-cultural space (Jidong, Bailey, Sodi, et al., 2021).

2.4 | Exclusion criteria

The study excluded participants with a diagnosed significant physical or learning disability, severe postpartum disorders, or other forms of psychosis that would prevent them from participating in the intervention and those receiving clinical psychological or psychiatric care such as psychotherapy or anti-depressants.

2.5 | Randomization

A simple random allocation was performed in excel, giving all participants equal chances of receiving LTP+CaCBT or PE interventions. This approach allows for a single sequence of random assignments in which participants were assigned in a 1:1 ratio. Simple randomization has also been recommended for small sample sizes (Kim & Shin, 2014). Participants were blind to whether they were assigned to experimental (LTP+CaCBT) or controlled (PE) groups. The study's design was unable to double-blind for group facilitators due to their involvement in manual adaptations and other preliminary processes. However, assessments were conducted by independent researchers who were not involved in the intervention delivery and were unaware of participants' assignments. A further independent statistician analysed the data sets.

2.6 | Assessments

Assessments were carried out at baseline, end of 12 sessions' intervention, 3- and 6-months follow-up. In addition to a demographic form, PHQ-9 (Spitzer et al., 1994); Generalised Anxiety Disorder (GAD-7) (Löwe et al., 2008); and the Verona Service Satisfaction Scale (Ruggeri et al., 2000); Consumer Satisfaction with Intervention Measure (Feldman et al., 2002) were administered.

2.7 | Materials

- *LTP*: This is a culturally relevant pictorial calendar activity for mothers, depicting eight successive stages of child development from birth to 3 years, with illustrations of mother–child play and other activities that promote parental involvement, learning, and child attachment. In each stage, five key areas of child development are depicted: (i) sense of self, (ii) physical development, (iii) relationships, (iv) understanding and (v) communication. Information about each area is articulated in a simple, low-literacy language, with accompanying pictures that serve as visual cues to the mothers (The SickKids Centre for Community Mental Health, 2015). The pictures have been adapted to reflect African/Caribbean culture so the participants could relate well to the calendar. The calendar is accompanied by a manual with a step-by-step guide for facilitators.
- *CaCBT*: This component is underpinned by cognitive-behavioural theory (Bernal et al., 2009). It uses techniques of active listening, changing negative thinking, guided discovery (i.e., questioning style to both gentle probe for health beliefs and stimulate alternative ideas), culturally appropriate behavioural tasks and homework (i.e., trying things out between sessions, putting what has been learnt into practice at home). Participants are further educated (noting traditional values and cultural beliefs) about maternal depression and anxiety, correlates and management, social support and practical advice on accessing appropriate healthcare (Bernal et al., 2009).
- *PE*: Is also 12 sessions of supportive and maternal educational components grounded on the theory and philosophy of group psychotherapy (with relevant topics on maternal mental healthcare advice and discussions). These problem-solving techniques are relevant to addressing maternal depression/anxiety and child-related difficulties. Also, it entails general parenting discussions that aim to improve the child's psychosocial development through mother–child attachment to promote early childhood development. PE materials were designed and developed to reduce maternal depression, considering the vulnerable nature of participants suffering from maternal depression.

2.8 | Cultural adaptation

The cultural adaptation of LTP+CaCBT was conducted in a multi-layers approach that harnessed numerous cultural beliefs and traditional values pertaining to parenting from African and Caribbean communities, as illustrated in Figure 1 below.

The systematic review of previous interventions for maternal depression (Jidong, Husain, Roche, et al., 2021) provided the researchers with background knowledge. In addition, the patient and public involvement (PPI) event and Focus Group Participatory Action Research (FG-PAR) were conducted with African and Caribbean mothers, caregivers, clinicians, and clinical researchers. The PPI and FG-PAR helped in co-adaptation that inputs culturally relevant case examples and pictorial illustrations in the LTP+CaCBT materials used in the intervention as depicted in Table 1 below.

2.9 | Intervention sessions

The LTP+CaCBT is a 12-sessions of online group-based psychological intervention that integrates two components—LTP and CaCBT (Notiar et al., 2021). This community-based multimodal psychosocial intervention includes a supportive component, an educational component (healthcare advice) and problem-solving techniques (to address maternal depression, anxiety, childbirth difficulties and parenting). The scope of group-integrated intervention addresses the instrumental role of collectivism in African and Caribbean parenting cultures.

Two group facilitators also known as community health workers led separate sessions. For example, one facilitator let the LTP+CaCBT and another facilitator led the PE group sessions to avoid contamination. Both facilitators received (a) 3 days (24 h) of extensive trainers' training on LTP+CaCBT and (b) 4 days (32 h) of Global Mental Health research intervention training. The facilitators were also involved in PPI events and LTP+CaCBT manual adaptation to ensure cultural appropriateness. The facilitators also received a 1-day (8 h) Theory of Change training workshop. One facilitator has a PhD in social science and the other has an MSc in Psychology.

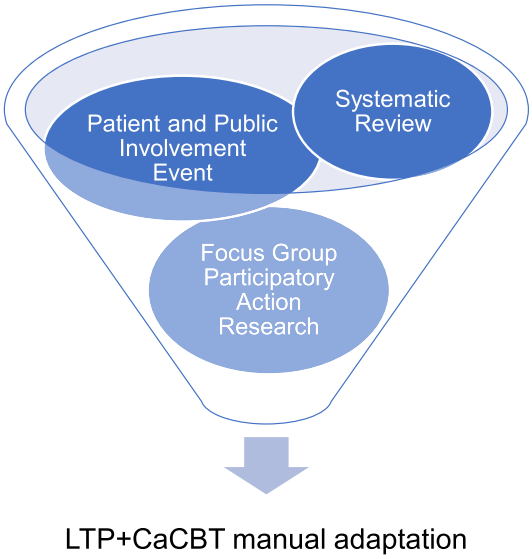

FIGURE 1 Process of cultural adaptation [Colour figure can be viewed at wileyonlinelibrary.com]

TABLE 1 The three-continuum covered in the PPI and FG-PAR for manual adaptation

Consultations	Collaborations	User-controlled
Explored participants' general views on the LTP+CaCBT materials. How could LTP+CaCBT integrate culturally relevant content into the project?	Discussed how service-users, the public and researchers could work together on the LTP+CaCBT project.	Ascertained the modalities of participatory action research for co-adaptation and co-validation of LTP+CaCBT materials. How could mothers/carers lead/determine how the intervention is planned and carried out?

Abbreviations: FG-PAR, Focus Group Participatory Action Research; LTP+CaCBT, Learning Through Play plus Culturally adapted Cognitive Behaviour Therapy; PPI, patient and public involvement.

The 12 sessions of the intervention (LTP+CaCBT and PE) were delivered separately online weekly using Microsoft Teams, and each group session lasted 60 min. A qualified maternal mental health expert offered session-by-session weekly supervision to the facilitators throughout the study.

2.10 | Data analysis

2.10.1 | Quantitative study

A total of $n = 26$ mothers were recruited into the intervention after an initial screening for depression at baseline. Of the $N = 26$ participants, only $n = 18$ (LTP+CaCBT, $n = 12$; PE, $n = 6$) completed the interventions and follow-up assessments (see Figure 2). All outcome variables were ranked ordered, and changes in outcome from baseline to end of intervention at 12 weeks, 3- and 6-months were expressed on ordinal measurement scales.

2.10.2 | Qualitative study

After quantitative assessments at the end of the intervention, all the participating mothers further undergo focus group discussions and individual interviews with trained research assistants. A total of $n = 19$ participants gave consent and participated in two focus groups (LTP+CaCBT, $n = 12$; PE, $n = 7$) and semi-structured individual interviews (LTP+CaCBT, $n = 4$; PE, $n = 4$). All interviews were conducted in the English language, audio-recorded and transcribed. Interviews

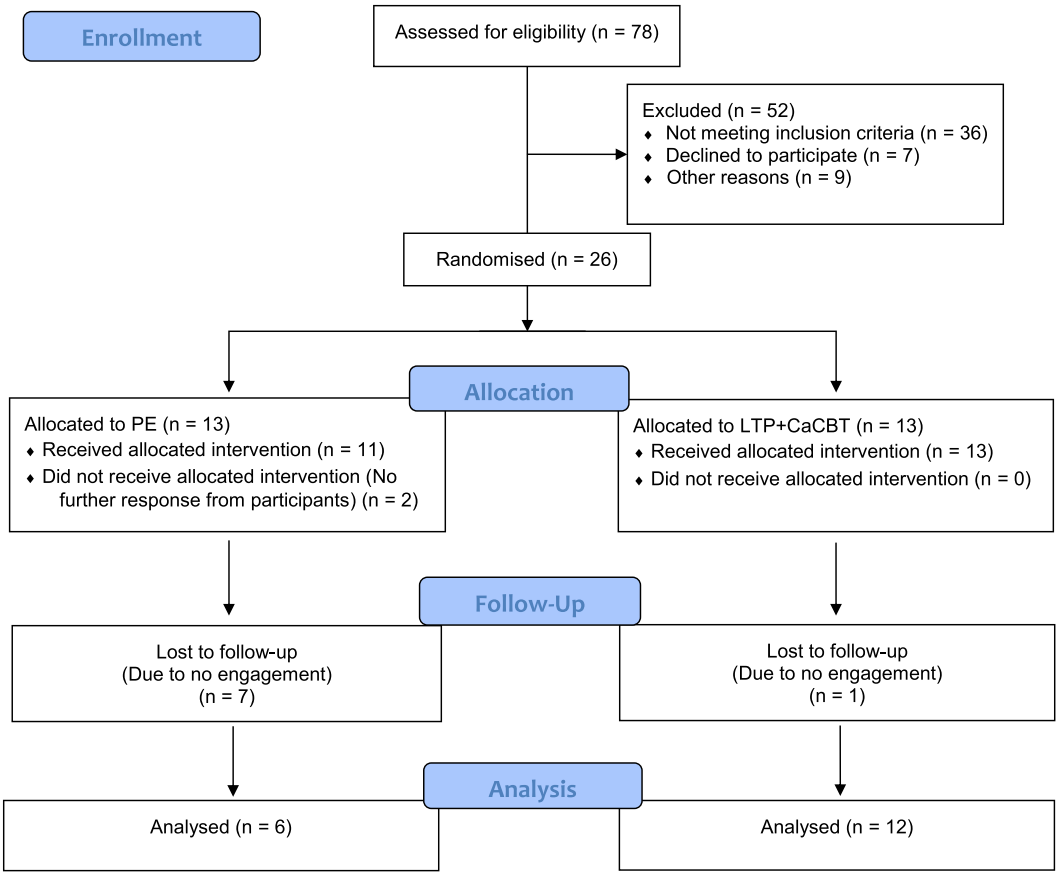

FIGURE 2 Consolidated Standards of Reporting Trials (CONSORT) flow diagram showing enrolment, randomization and inclusion of participants in the analysis [Colour figure can be viewed at wileyonlinelibrary.com]

were analysed thematically (Braun & Clarke, 2013) from a socio-constructionist theoretical lens (Burr, 2015; Harper & Thompson, 2011). The six-step process involved familiarizing with the dataset, coding, grouping code to theme, defining themes, refining and producing the final report. Interviews were conducted and analysed by independent team members who were not part of the intervention delivery.

3 | RESULTS

3.1 | Quantitative findings

Table 2 detailed the effectiveness of LTP+CaCBT and PE group integrated psychological intervention for treating maternal depression in British mothers of African and Caribbean origin expressed in frequencies. Although, of the $n = 18$ participants who undertook all 12 sessions of intervention, only $n = 13$ completed the Verona Service Satisfaction survey. Overall, participants found both interventions beneficial in alleviating maternal depression, and building parenting confidence that is transferable to their children's health and wellbeing.

Table 3 shows a detailed breakdown of the percentages of the effectiveness of LTP+CaCBT and PE group integrated psychological intervention for treating maternal depression in British mothers of African and Caribbean origin. Although, of the $n = 18$ participants who undertook all 12 sessions of intervention, only $n = 13$ completed the Consumer Satisfaction with Intervention Measure. However, all participants that filled the survey were confident that the interventions were acceptable, effective, non-intrusive, high quality and satisfaction and were delighted to recommend the intervention to others.

To evaluate the feasibility of the LTP+CaCBT intervention in reducing depression and anxiety among British mothers of African and Caribbean origin in the United Kingdom, descriptive statistics of depression and anxiety symptoms in both conditions. Table 4 shows the descriptive categories of the medians (*Md*).

As seen in Table 4, we observed a reduction in depressive symptoms in the treatment group from baseline ($Md = 3.00$, $n = 13$) to end of intervention ($Md = 1.00$, $n = 7$), and 6-months follow-up ($Md = .00$, $n = 13$). For the PE group, we observed reductions in depressive symptoms from baseline assessment ($Md = 3.00$, $n = 12$) to end of intervention ($Md = .500$, $n = 6$), and 3 months follow up ($Md = 1.00$, $n = 6$). However, no statistically significant differences were observed between baseline assessment and 6 months follow-up ($Md = 3.00$, $n = 9$). In comparing the trajectories of improvement between the LTP+CaCBT and PE conditions, we find similar degrees of depressive symptoms at baseline, (LTP+CaCBT = [$Md = 3.00$,

TABLE 2 Results of Verona Service Satisfaction survey at 12 sessions end of intervention comparing LTP+CaCBT and PE

S/N	Survey questions	LTP+CaCBT $n = 7\%$					PE $n = 6\%$				
		0	1	2	3	4	0	1	2	3	4
1.	Amount of help received? 0 = extremely bad; 1 = somewhat bad; 2 = neither good nor bad; 3 = somewhat good; 4 = extremely good.	0.0	0.0	0.0	57.1	42.9	0.0	0.0	0.0	66.7	33.3
2.	Kind of services? 0 = not at all useful; 1 = slightly useful; 2 = moderately useful; 3 = very useful; 4 = extremely useful.	0.0	0.0	28.6	42.9	28.6	0.0	0.0	0.0	100.0	0.0
3.	Explanation of specific procedures and approaches used? 0 = never; 1 = sometimes; 2 = about half the time; 3 = Most of the time; 4 = always.	0.0	0.0	0.0	71.4	28.6	0.0	0.0	0.0	83.3	16.7
4.	Information on diagnosis and prognosis? 0 = extremely unclear; 1 = somewhat unclear; 2 = neither clear nor unclear; 3 = somewhat clear; 4 = extremely clear.	0.0	0.0	0.0	71.4	28.6	0.0	0.0	0.0	50.0	50.0
5.	Publicity or information on mental health services, which are offered? 0 = none at all; 1 = A little; 2 = A moderate amount; 3 = A lot; 4 = A great deal.	0.0	0.0	0.0	100.0	0.0	0.0	0.0	16.7	50.0	33.3
6.	Effectiveness of the service in attaining wellbeing and preventing relapses? 0 = not effective at all; 1 = slightly effective; 2 = moderately effective; 3 = very effective; 4 = extremely effective.	0.0	0.0	42.9	28.6	28.6	0.0	0.0	16.7	50.0	33.3
7.	Effectiveness in the service in helping patients deal with problems? 0 = not effective at all; 1 = slightly effective; 2 = moderately effective; 3 = very effective; 4 = extremely effective.	0.0	0.0	0.0	85.7	14.3	0.0	0.0	16.7	83.3	0.0
8.	Effectiveness of the service in helping patient to improve knowledge and understanding of his/her problems? 0 = not effective at all; 1 = slightly effective; 2 = moderately effective; 3 = very effective; 4 = extremely effective.	0.0	0.0	14.3	42.9	42.9	0.0	0.0	0.0	100.0	0.0
9.	Effectiveness of the service to help patient relieve symptoms? 0 = not effective at all; 1 = slightly effective; 2 = moderately effective; 3 = very effective; 4 = extremely effective.	0.0	0.0	0.0	57.1	42.9	0.0	0.0	0.0	83.3	16.7
10.	Effectiveness of the service in improving the relationship between patient and relative? 0 = not effective at all; 1 = slightly effective; 2 = moderately effective; 3 = very effective; 4 = extremely effective.	0.0	0.0	0.0	100.0	0.0	0.0	0.0	16.7	83.3	0.0
11.	Effectiveness of the service in helping patient improve capacity to look after him/herself? 0 = not effective at all; 1 = slightly effective; 2 = moderately effective; 3 = very effective; 4 = extremely effective.	0.0	0.0	28.6	42.9	28.6	0.0	0.0	16.7	83.3	0.0
12.	Effectiveness of the service in helping patient establish good relationships outside family environment? 0 = not effective at all; 1 = slightly effective; 2 = moderately effective; 3 = very effective; 4 = extremely effective.	0.0	0.0	28.6	42.9	28.6	0.0	0.0	0.0	100.0	0.0

(Continues)

TABLE 2 (Continued)

S/N	Survey questions	LTP+CaCBT $n = 7\%$					PE $n = 6\%$				
13.	Effectiveness of the service in helping patient improve abilities to work? 0 = not effective at all; 1 = slightly effective; 2 = moderately effective; 3 = very effective; 4 = extremely effective.	0.0	0.0	0.0	85.7	14.3	0.0	16.7	16.7	66.7	0.0
14.	Overall satisfaction? 0 = extremely dissatisfied; 1 = somewhat dissatisfied; 2 = neither satisfied nor dissatisfied; 3 = somewhat satisfied; 4 = extremely satisfied	0.0	0.0	0.0	85.7	14.3	0.0	0.0	16.7	83.3	0.0

TABLE 3 Results of consumer satisfaction with intervention measure at 12 sessions end of intervention comparing LTP+CaCBT and PE

S/N	Survey instruction: For the following questionnaire, please respond according To your experience of the service provided	LTP+CaCBT $n = 7\%$					PE $n = 6\%$				
		0	1	2	3	4	0	1	2	3	4
1.	Acceptability 0 = not at all useful; 1 = slightly useful; 2 = moderately useful; 3 = very useful; 4 = extremely useful.	0.0	0.0	14.3	71.4	14.3	0.00	0.00	16.7	83.3	0.00
2.	Effectiveness 0 = not effective at all; 1 = slightly effective; 2 = moderately effective; 3 = very effective; 4 = extremely effective.	0.0	0.0	0.0	85.7	14.3	0.00	0.00	33.3	66.7	0.00
3.	Intrusiveness 0 = extremely uncomfortable; 1 = somewhat uncomfortable; 2 = neither comfortable nor uncomfortable; 3 = somewhat comfortable; 4 = extremely comfortable.	0.0	0.0	0.0	85.7	14.3	0.00	0.00	0.00	66.7	33.3
4.	Quality 0 = extremely bad; 1 = somewhat bad; 2 = neither good nor bad; 3 = somewhat good; 4 = extremely good.	0.0	0.0	0.0	57.1	42.9	0.00	0.00	0.00	66.7	33.7
5.	Satisfaction 0 = extremely dissatisfied; 1 = somewhat dissatisfied; 2 = neither satisfied nor dissatisfied; 3 = somewhat satisfied; 4 = extremely satisfied.	0.0	0.0	0.0	57.1	42.9	0.00	0.00	0.00	83.3	16.7
6.	Recommend to others 0 = definitely not; 1 = probably not; 2 = might or might not; 3 = probably yes; 4 = definitely yes.	0.0	0.0	0.0	28.6	71.4	0.00	16.7	0.00	50.0	33.3

TABLE 4 Descriptive table showing medians and categories

	Baseline *Md*	EOI *Md*	3 months *Md*	6 months *Md*
LTP+CaCBT depressive symptoms	3.00	1.00	1.00	.00
PE depressive symptoms	3.00	.500	1.00	3.00
LTP+CaCBT anxiety symptoms	3.00	1.00	1.00	1.00
PE anxiety symptoms	3.00	1.00	1.00	3.00

Note: *Md* Category: *.00* = No depression/anxiety; *1.00* = Minimal depression/anxiety; and *3.00* = Moderate depression/anxiety.

$n = 13$], PE = [$Md = 3.00$, $n = 12$]); however, decrease in depressive symptoms were observed in the treatment group at a 6 months follow-up ($Md = .00$, $n = 13$) when compared to the control group ($Md = 3.00$, $n = 9$).

With regard to anxiety scores, we further observed reductions in anxiety symptoms in the treatment group from baseline ($Md = 3.00$, $n = 13$) to end of intervention ($Md = 1.00$, $n = 7$), 3 months follow-up ($Md = 1.00$, $n = 12$) and 6-months follow-up ($Md = 1.00$, $n = 13$). Similarly, the PE group revealed reductions in anxiety symptoms from baseline assessment ($Md = 3.00$, $n = 12$) to end of intervention ($Md = 1.00$, $n = 6$), and 3 months follow up ($Md = 1.00$, $n = 6$). However, no differences were observed between baseline assessment ($Md = 3.00$, $n = 12$) and 6 months follow-up ($Md = 3.00$, $n = 9$). A similar trajectory of improvement was observed between the LTP+CaCBT and PE groups from baseline assessment (LTP+CaCBT = [$Md = 3.00$, $n = 13$], PE = [$Md = 3.00$, $n = 12$]), to end of intervention (LTP+CaCBT = [$Md = 1.00$, $n = 7$], PE = [$Md = 1.00$, $n = 6$]) and 3 months follow-up (LTP+CaCBT = [$Md = 1.00$, $n = 12$], PE = [$Md = 1.00$, $n = 6$]). However, we found anxiety symptoms to worsen in the PE group at 6 months follow-up when compared to the CaCBT group (LTP+CaCBT = [$Md = 1.00$, $n = 13$], PE = [$Md = 3.00$, $n = 9$]).

3.2 | Feasibility of the intervention

As the results section depicts, there was a high participant retention rate (>95% retention; <5% attrition) across the 12 sessions of LTP+CaCBT with 90% acceptability; thus, the intervention was rated as very useful or extremely useful. Although, of the $n = 13$ participants in the LTP+CaCBT group, only $n = 7$ (55%) completed the 'End of Intervention' survey, which might be impactful in the conclusion drawn from the overall findings based on the survey completed. Of the $n = 13$ participants, $n = 12$ were consistently present in all the 12 sessions of the LTP+CaCBT intervention. However, the control group (PE) recorded high attrition, with less than half of the randomized participants providing data for analysis.

3.3 | Qualitative findings

Thematic analysis was adopted and underpinned by socio-constructionism. The socio-constructionist theoretical lens guided the analytical commentary of data verbatim used to support each of the emerging themes, which include (i) Enlightenment Following Limited Awareness, (ii) Positive learning experience underpinned by culturally-informed content and (iii) Quality training underpinned by e-convenience. These are reported below with supporting extracts:

3.4 | Enlightenment following limited awareness

The dataset highlights a sense of awareness where participants did not have the requisite knowledge concerning the mother–child relationship and its impact. The sense of enlightenment was construed from diverse perspectives spanning from not being aware of varying emotions postpartum and reconciling beliefs they previously held that might be detrimental to the attachment between the mother and child. Concerning the former, one participant in the experimental group who was a first-time mum noted the following:

> For me it was a bit of a sharp learning curve because I'm currently because my baby is currently six months and she's my first child, so it was a sharp learning curve and there were loads of things that I just didn't know about and have never heard about until I had the baby but the parenting training have been able to help […]. because I had a C-section, for instance, and I didn't know what to expect when it comes to the recovery process and another thing as well was postpartum depression […] I think when we were doing the first and second sessions, the other moms were able to throw more light on the issue and that really helped me because it made me feel like, you know, it's quite normal to feel that way (E2).

In a slightly similar vein, another participant in the experimental arm (LTP+CACBT) focus group, while commenting on what might be held and dispelled as a result of enlightenment from the training, said the following:

> In terms of mirror like my own culture say that it is not actually good for children to be staring at the mirror, but through the session I actually knew it was OK for the children and helping them to grow. (E1)

Again, the extracts denote the importance of addressing previously held beliefs that might not be appropriate in child upbringing and well-being. The participant extract also highlights awareness importance given how it mirrors her personal experience.

The control group (PE) participants also indicated useful learning as one participant in the individual interviews stated:

> I am. I've learned quite a lot really. I've learned that you know you have to put as much as you at mom and stuff; you have to put yourself first. And everything else you know, as a mum, everything else does fall on you, but you kinda have to give yourself time and you really have to know that you are human as well (C1).

The participant extract suggests an aspect that was found useful during the intervention. Being able to be enlightened on the importance of looking after herself as a mom despite the busy schedule of parenting was important to the participant. Previous literature has shown that parenting could be hectic (Kalmuss et al., 1992), and some moms could be entangled in it without giving adequate attention to themselves. The implication might negatively affect the mother's

emotions and, by extension, the relationship with the child. Being aware could thus be construed from a positive perspective in enhancing parenting and the mother–child wellbeing, especially as it relates to improving positive thoughts and emotions. As another participant in the control group (PE) mentioned:

> So, in terms of coping, sorry, I'm so one thing that I definitely remember is when we spoke about thinking patterns that aren't helpful? Uh, and. One of the things we spoke about is that when we have some of those thoughts, some of the other things that we should be thinking about, and we should be asking ourselves, rather than focusing on the negative thinking patterns and ways of thinking (C3).

Here, another positive aspect of engaging in the intervention was the ability to understand active processes in dealing with negative thoughts. Previous studies have shown that unhealthy thinking patterns could further impact depression (Ma & Teasdale, 2004). Based on our intervention, the participant highlights a sense of enlightenment on ways of addressing such negative thoughts by imbibing more positive ones.

3.5 | Positive learning experience underpinned by culturally-informed content

The dataset suggests that participants had positive learning experiences throughout the training due to its culturally relevant contents that promote parenting learning and healing from maternal depression, which was indicated especially in the experimental group. For example, A participant commented:

> My experience from the training, is that I actually learnt a lot and to be honest there were some certain things I actually never knew while giving birth to my children and I got to learn more bits from both experiences from other mums and also from the training. And also, I found this so educative and really it was worthwhile, and I feel going forward, and I will be able to apply it to my own home and other children to come. So, I feel the training so far is ok for me (E2).

Similarly, in the focus group of the experimental arm (LTP +CaCBT) another participant with two young children commented the following:

> Yeah! I think the main thing I learned was this eh how to manage their tantrums. What we can do, how we can help them, that they are only trying to express themselves. So how we can help them more so that they can get over the tantrums as soon as possible. (E5)

The extract highlight participant's expression of learning things that they felt will be beneficial in their relationship and the upbringing of their children. Tantrum is one of the features young children express especially during the age ranges that the study focused on. Managing these tantrums based on what was learnt during training represents an invaluable skill considered useful.

In the control arm (PE) focus group. Participants also expressed satisfaction even though areas of improvement were suggested during the training. For example, one participant in the focus group commented:

> In terms of improvements, I already bought it up the other week which was about giving us something to think about, kind of a homework kind of a thing to do during the week and the last few weeks we've been doing it which I think is good (C1).

Another participant in the focus group of the control group (PE) also commented on her satisfaction with the training though with some comments on what she found not too appealing:

> Personally, my experience was good; erm I think the only thing I would bring up erm is the name of it. So, I think there's something about; there's something about the words parent, parenting training or parent training that is quite off-putting for me, erm maybe it's a cultural thing. I don't know. Erm I think something like parenting, parental support or parenting support classes rather than parenting training. It's just off-putting (C2).

While pointing to areas of improvement, the participant extract highlights a positive experience of the delivery. A possible explanation that might have informed the participant's view is the role of culture taken seriously by the participant. The findings resonate with previous literature highlighting the importance of culture in providing mental health care for mothers of African and Caribbean descent (Jidong, Husain, Roche, et al., 2021). Being sensitive to the cultural aspects could improve the experiences further.

3.6 | Quality training underpinned by e-convenience

Overall, participants expressed satisfaction with the training, from the length of time and support given and encouraged engagement to the virtual nature of the intervention delivery. Commenting on this, a mom of two children aged 6 and 34 months respectively in the experimental arm commented:

> Well, I think during the course of the training there was actually sufficient time for me and I know like most of the times I do working so I have to be trying to

> juggling with my work and the session. But so far so good there was sufficient time for me to make my own comment still (E2).

Concerning the delivery online, another mom noted the following:

> And it was quite good that we were doing it through teams because. If it was face-to-face for me personally, it would have been more difficult for me to attend the sessions because I have to consider travelling down with the baby and all of that, or because the sessions were done over teams, it was more convenient for me and because it was only for an hour. Like even though I was busy, I was still able to juggle everything and attend the session. So yeah, I think the time was quite, it was good. It wasn't too long and it wasn't too short. It was just enough to be able to learn from it and also be able to contribute to the sessions as well. (E6)

A similar view was also echoed by another mum in the focus group of the experimental arm (LTP+CACBT) when she noted the following:

> I mean, if it was a physical training to have really been difficult for some of us to participate in it, so the timing was good. The training is OK and I think for me I've really learned a lot from these sessions; thank you (E7)

The preceding extract denotes how the innovative delivery of the intervention virtually was found useful and aided engagement throughout the session. The mothers found it useful, given the enormous burden and cost of child-care on their ability to actively engage in other activities or programmes that could be directly useful to their improvement and well-being. Accessing the programme directly from the comfort of their homes was an invaluable benefit that aided their learning and, by extension, enhanced their parenting knowledge.

However, despite the e-convenience of the virtually parenting training, some participants glamoured face-to-face as the preferable means of LTP+CaCBT intervention. For example, one mum said:

> I will definitely prefer a face-to-face intervention because that way, you not only express yourself you also interact physically with other mums and the facilitator. For me that is therapeutic (E8).

Understandably, potential nuances and explicit features could only be harnessed in a face-to-face intervention. The researchers are aware of other significant non-verbal clues often meaningful in therapeutic interactions, such as physical appearance, body posture and facial expression that were not accounted for due to the virtual nature of the present intervention. However, in the control group, some parents did not mind the type of delivery but also expressed a sense of its usefulness and the need to deliver more of such sessions regardless of the format (e.g., online/face-to-face). As one mum commented:

> Just to do things that can bring people together, whether it's online or not online. When things get better and just have them kind of conferences and just do other stuff, I think that that would be really good for everybody (C5).

The extract thus denotes the sense of improving people despite the format used to deliver such support. Here usefulness is prioritized over format.

4 | DISCUSSION

Ourstudy aimed to examine the feasibility and acceptability of the psychological intervention called 'Learning Through Play plus Culturally adapted Cognitive Behaviour Therapy' (LTP+CaCBT) in comparison with PE for the treatment of maternal depression in British mothers of African and Caribbean origin in the United Kingdom.

The study's quantitative arm showed that LTP+CaCBT is feasible and acceptable to the British mothers of African and Caribbean origin. Similarly, the potential feasibility and acceptability of the LTP+CaCBT psychological intervention in the present study were predicted in a systematic review by Jidong, Husain, Roche, et al. (2021) of $n = 13$ psychological intervention studies for maternal depression among women of African and Caribbean origin in HICs. They found culturally appropriate maternal care (Jesse et al., 2010, 2015) and internet-mediated care (Logsdon et al., 2018) for maternal depression to be effective in enhancing parenting confidence and self-care (Holditch-Davis et al., 2014). The findings from Jidong, Husain, Roche, et al. (2021) depict the core tenets articulated in LTP+CaCBT. However, the feasibility and acceptability of the intervention in the PE group was slightly lower compared with the LTP+CaCBT group.

Similarly, Notiar et al. (2021) conducted a feasibility study on the treatment of maternal depression in low-income women using LTP+CaCBT in the rural community of Kilifi in Kenya. They found that LTP+CaCBT was feasible and acceptable with high satisfaction among the participating mothers. Similar to the present study, the findings of Notiar et al. (2021) also indicated a reduction in scores on PHQ-9 and GAD-7. They also examined and found an increase in perceived social support and health-related quality of life, which was not measured in the present study. Although, Notiar et al. (2021) study was a single arm with no controlled or comparative group. The LTP+CaCBT intervention has been tested widely in Pakistan for depressed mothers (Husain et al., 2017, 2021) and fathers (Husain et al., 2021) of young children.

Furthermore, the qualitative arm of our study showed that participants received valuable parenting skills, self- and child-care enlightenment powered by the parenting training aspects of the psychological intervention articulated in both LTP+CaCBT and PE. Similar findings

were reported in a process evaluation of a qualitative study conducted in Pakistan exploring views of depressed mothers about LTP+CaCBT intervention (Husain et al., 2017). Our finding resonates with previous literature concerning mental health awareness of mothers from the African and Caribbean communities in the United Kingdom (Jidong, Husain, Roche, et al., 2021).

For example, the delivery of LTP+CaCBT stimulated a positive learning experience underpinned by culturally-informed content with interactive sessions that strengthened the core elements of collectivism within the group-integrated intervention. This entails harnessing traditional values and cultural beliefs embedded in daily personal and parenting routines, which gave participants ample opportunities for meaningful practicums on sessions and home activities that were attested to be beneficial in building parenting confidence, relieving anxiety and depressive symptoms. Similar findings were identified by Notiar et al. (2021) that showed significant improvement in mothers' knowledge about child development due to the parenting training embedded in the LTP+CaCBT in rural Kenyan women. Furthermore, Jidong, Husain, Karick, et al. (2021) found in an interpretative phenomenological analysis of maternal health lived experiences of mothers in Jos Nigeria that maternal anxiety increases in mothers due to inadequate knowledge about child-care and parenting skills.

Also, the present study showed qualitative evidence of the quality of parenting training underpinned by e-convenience. It is further depicted in the online ability of participants to multi-task 'on-the-go' such as in transit or doing home chores and simultaneously participate in the training sessions. Thus, the barriers of distance were eliminated in the present study. The e-convenience found in the present study was similar to that of Logsdon et al. (2018) who tested the effectiveness of an internet-based intervention in the USA for maternal depression with $n = 151$ adolescent African American mothers who gave birth in the last 12 months. They found that internet-based intervention for maternal depression is an inexpensive and convenient method of increasing access to treatment for mothers.

4.1 | Strengths, implications, limitations and future directions

To the best of the researchers' knowledge, this is the first culturally relevant psychological intervention study that is specifically well-designed for treating maternal depression for British mothers of African and Caribbean origin in the United Kingdom. The transformational evidence of the study's findings demonstrated a clear-cut impact on the mothers who participated in the study regarding the transformation in their maternal mental health and its impact on their children. Thus, 'a well, happy and confident mother makes a healthy child'.

The study recorded a high level of participants' engagement and retention. In addition, the service-user survey demonstrated that the intervention was feasible, acceptable, useful, and highly appreciated by the participants. The study's impact and rigour were further demonstrated as recorded at baseline, end of intervention at 12-week, 3-month and 6-month follow-up randomized controlled trial with both an experimental (LTP+CaCBT) and comparative (PE) group. The intervention is also proven low-cost and ecologically friendly because it was delivered by minimally trained community health workers who are not heavily trained experts such as clinical psychologists or psychiatrists. The use of non-experts for treating mild to moderate mental health problems in low-recourse settings, also known as the task-shifting mechanism, has been supported in the literature (Gureje et al., 2019; World Health Organization, 2010).

Despite good follow-up and retention rates in the intervention group (LTP+CaCBT), this was poor in the control group (PE) with less than half of the randomized participants providing data for analysis. The high level of attrition in the controlled group has been observed and will be mitigated in a future larger trial.

Ourstudy has a small number of participants of 26 mother–child pairs (LTP+CaCBT $n = 13$; PE $n = 13$). This is limited in terms of a representative sample size adequate for the wider generalizability of findings. However, the study is advantageous in terms of randomization with comparative groups and longer follow-up to 6 months post-intervention, which constitute a significant part of the study's strengths. Considering the economic potential of the present intervention, future studies should examine the cost-effectiveness of the intervention's delivery compared to 'treatment as usual'. Another study's limitation is that the participants' immigration status was not collected. Future studies could collect this data and explore how the findings could address participants' pre-and-post migration experiences and how this might impact their coping strategies against maternal depression.

Furthermore, due to the online nature of the present study's intervention, there were few reports of distractions especially when participants multitasked during intervention sessions, on a few occasions we experienced poor internet connections and were unable to achieve the dynamic nature of face-to-face facilitator-participants interactions. In addition, it is important to acknowledge the study does not have a face-to-face control group with regard to the comparable levels of acceptability or cultural appropriateness as shown in the online groups. Therefore, future studies should consider conducting face-to-face group integrated intervention in a conducive learning environment that provides child-care to enable full mother's concentration in the parenting training. More so, ToC was integrated into the study's process but not evaluated. We recommend the inclusion of the future impact assessment element of ToC to provide valuable evidence that will benefit future trial outcomes.

The present study's findings have methodological and practice implications, which entail an evidence-based process of using non-mental health specialists persons for treating maternal depression to tackle workforce shortage in the care sector. In addition, it is anticipated if the LTP+CaCBT intervention programme is further tested in a fully powered randomized controlled trial, the knowledge to be gained can be further tested and transferred to other Black Asian and Minority Ethnic (BAME) groups in the United Kingdom. For example, LTP+CaCBT can be integrated into existing NHS primary care provision at a minimal extra cost using trained community health workers, facilitators and health volunteers who are more culturally

knowledgeable. This approach is more sustainable, evidence-based and low-cost compared with the limited workforce of mental health experts such as clinical psychologists or psychiatrists (Notiar et al., 2021; World Health Organization, 2010). This will further ease the long waiting lists of service-users in the queue for several months and increase access to maternal mental health services.

5 | CONCLUSION

The present study showed that LTP+CaCBT is feasible and acceptable for treating maternal depression in British mothers of African and Caribbean origin. It is evidence-based, ecologically friendly, co-developed, manualized and can be delivered by non-mental health specialists such as trained community health workers who are more culturally knowledgeable. In future studies, we intend to examine the intervention's cost-effectiveness and clinical efficacy in a fully powered RCT with more participants to maximize the study's impact on a wider population.

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AUTHOR CONTRIBUTIONS

D. E. J., T. J. I. and N. H. designed, planned and developed the study's protocol. D. E. J., M. M., C. F. and S. B. M. contributed to ethics applications and supporting documents such as interview schedules, participants' information sheets, consent forms and questionnaires. D. E. J. and M. M. organized survey tools on Qualtrics. C. F. and S. B. M. led data collection process for surveys, focus groups and individual interviews. T. J. I., M. M., C. F., S. B. M. and J. E. J. transcribed all focus group discussions and interviews. C. F., S. M. B., J. E. J. and P. P. N. carried out qualitative data coding and themes' development. J. B. D., D. E. J., P. B. and T. J. I. performed statistical analysis of quantitative data and interpretation. J. Y. P., M. M. and T. J. I. conducted the literature review for the study. D. E. J., T. J. I. and M. M. performed qualitative data analysis, discussion and write-up. All authors contributed to refining multiple drafts of the research article. D. E. J., N. H., T. K. and T. J. I. reviewed arguments, data analysis, discussion of findings, edits and proofreads the article. D. E. J. finalized all component of the study, thoroughly proofread the manuscript, prepared it for the journal submission and served as a corresponding author. All authors have approved the final manuscript for the journal submission.

DATA AVAILABILITY STATEMENT

Due to the research scope and ethical consideration, there will be no third-party access to this study's raw data.

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APPENDIX A: 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 randomized trial in the title	Identification as a pilot or feasibility randomized 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 randomized pilot trial	
2b	Specific objectives or hypotheses	Specific objectives or research questions for pilot trial	
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 and when they were actually administered		

(Continues)

Section/topic and item no.	Standard checklist item	Extension for pilot trials	Page no. where item is reported
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 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		
Randomization:			
Sequence generation:			
8a	Method used to generate the random allocation sequence		
8b	Type of randomization; details of any restriction (such as blocking and block size)	Type of randomization (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 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 (e.g., 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	
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 randomization, together with reasons		

Section/topic and item no.	Standard checklist item	Extension for pilot trials	Page no. where item is reported
Recruitment:			
14a	Dates defining the periods of recruitment and follow-up		
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 randomized 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 estimates. If relevant, these results should be by randomized 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			
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	
Generalizability:			
21	Generalizability (external validity, applicability) of the trial findings	Generalizability (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 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	

(Continues)

Section/topic and item no.	Standard checklist item	Extension for pilot trials	Page no. where item is reported
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	