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Effectiveness of Kushal Maa, a group-based mhealth interactive education and social support intervention for maternal and neonatal health outcomes: study protocol for a multisite randomised controlled trial in India

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ABSTRACT

Introduction Perinatal care continuity across the full continuum is essential for optimising maternal and infant health; however, a stark gap occurs post partum, with less than one half of Indian mothers receiving postpartum care due to significant logistical and sociocultural barriers, particularly for periurban and rural residents. To overcome these barriers and reduce women's postpartum isolation, our international team of maternal and infant health clinicians and researchers developed and pilot-tested a culturally-tailored mobile interactive education and support group intervention, *Kushal Maa ('informed-mother')*, confirming feasibility and acceptability and preliminary effectiveness. The current study seeks to estimate the effectiveness of the *Kushal Maa* intervention compared with standard care on maternal and neonatal health-related behaviours and health, characterise the mechanisms of intervention impact and evaluate the cost-effectiveness of the *Kushal Maa* intervention in improving postpartum maternal and neonatal health compared with the standard of care.

Methods and analysis We will conduct a prospective, parallel block-randomised controlled trial with a 1:1 allocation ratio among 2100 pregnant women across three geographically diverse Indian states. Inclusion criteria for women: aged 18+years of age at enrolment, in the last trimester of pregnancy (30–33 weeks of gestation), with any parity, carrying single or multiple gestation (1-2), with knowledge of site-specific local language and had access to a mobile phone. Participants will be block-randomised in groups of 15. Intervention participants will receive 28 tailored education and support sessions weekly via audio/video conference facilitated by trained moderators (four prenatal and 24 weekly postpartum sessions through 6 months) and will be engaged in WhatsApp groups for health education videos and peer discussion via text chat. Control participants receive the standard of care. Data will be collected at four points: 30–33 weeks of pregnancy (enrolment), 6 weeks, 3 months and 6 months postpartum (endline). Investigators, outcome assessors and data analysts will be blinded to group allocation. Primary outcomes will be measured at 6 weeks, 3 months and 6 months post partum and include: postpartum depression (using Edinburgh Postnatal

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ We seek to engage diverse study participants (eg, geographies, languages, sociocultural practices, caste, religion, cultural and sociodemographic characteristics) to increase generalisability of our study findings, yet are limited per feasibility to three sites in Punjab, Madhya Pradesh and Maharashtra which may influence the generalisability of our results.

⇒ Our primary outcomes focus on a diverse range of key indicators of postpartum depression, exclusive breastfeeding and met need for postpartum family planning, and we capture a variety of secondary health knowledge, behaviour and outcome data to fully inform potential intervention impact and mechanism.

⇒ Data collection employs validated measures across four time points to inform our understanding of knowledge and behaviour across critical periods of pregnancy, childbirth and through 6 months postpartum.

⇒ Our data analysis strategy engages natural language processing tools using specialised domain-specific retrieval augmented generation enabled solutions.

⇒ Estimates of intervention effectiveness from this study will represent the intervention as delivered through trained moderators appointed by collaborating institutions instead of community-based health professionals, who would be engaged as intervention moderators if the intervention were to be scaled.

Depression Scale), exclusive breastfeeding and met need for postpartum family planning. Secondary outcomes include other maternal and child health knowledge, outcomes and maternal and newborn healthcare use indicators. We will use intention-to-treat analysis. Mixed-effects models will account for clustering due to the group-oriented delivery of the intervention and repeated measures.

Ethics and dissemination This study has been approved by the Health Ministry Screening Committee, Government of India and approved by ethics boards at the Post-Graduate Institute for Medical Education and Research, Chandigarh (Ref:001208, IEC-06/2022–2471), Maharashtra University of Health Sciences (Ref: MUHS/EC/06/2024), Sangath (Ref: AB_2022_81) and the University of California, San Francisco (Ref: 21–35730). All research activities will be performed in accordance with the Declaration of Helsinki. On completion, findings will be disseminated to stakeholders through diverse strategies. Results will be published in academic journals and presented at conferences.

Trial registration number ClinicalTrials.gov: NCT05268588 Clinical Trials Registry – India: CTRI/2022/07/043889.

INTRODUCTION

Despite India's significant achievements in the prenatal period and during childbirth, maternal and infant mortality remain relatively high, at 97 per 100 000 live births and 35 per 1000 live births, respectively.[1 2] While perinatal care access is increasing, quality shortfalls persist, with notable drops in the postpartum period, only 78% of mothers and 79.1% of newborns receive postpartum care within 2 days of delivery.[2 3] Interventions and maternal health schemes such as Janani Suraksha Yojana and Janani Shishu Suraksha Karyakram have reduced mortality rates, but they have not adequately addressed non-economic determinants of adverse maternal and neonatal health outcomes.[4 5] Ensuring continuous, high-quality perinatal care through the postpartum period is crucial for maternal and neonatal health, especially given the significant barriers many Indian women face and large disparities within and across states.[6] This includes attention to perinatal mental health which, despite its significant prevalence and impact, has remained understudied and underaddressed in the maternal, newborn and child programme, research and policy space.[7 8]

Postpartum care and support have received less focus than other perinatal continuum of care indicators, yet ensuring continuity of high-quality perinatal care into the postpartum period is key for optimising maternal and neonatal health and well-being,[9 10] particularly given the significant logistical, sociodemographic and sociocultural barriers that some Indian women experience.[11] Increasing access to and use of postnatal care and improving health behaviours responsible for key postpartum health behaviours, such as breastfeeding, family planning and immunisation have proven to be challenging in India. Common logistical challenges, such as transportation and low autonomy or mobility, are exacerbated by rural geographic distances, cultural and linguistic barriers to care and postnatal seclusion practices.[11–15] Other barriers to perinatal care include poverty, low education, lack of male involvement, lack of health insurance, costs and perceptions of poor quality or lack of benefit of services.[16–18] Most interventions targeting this period have been limited in scope, for example, targeting postpartum family planning uptake or maternal postpartum depression alone,[19 20] with fewer addressing postpartum health needs comprehensively. Critical barriers to perinatal care access include sociodemographic characteristics (wealth, education, parity, young age at marriage or childbirth), sociocultural factors (gender norms, women's mobility), geography (rural) and household responsibilities (caring for children, preparing meals, cleaning).[21–23] Similar factors influence the social support available to a woman, which may subsequently influence perinatal care access.

Group-based mHealth interventions are an innovative approach that have led to improved health and social support outcomes for other health topics[24 25] and are promising for overcoming persistent challenges to postpartum care in this setting. Group participatory learning and action models for perinatal care have been found to be successful at increasing antenatal care and infant vaccination and at increasing social support, critical for mental health.[26–34] mHealth approaches have been transformative for the practice and reach of medical care and research, particularly in low- and middle-income country (LMIC) settings, through expediting patients and provider connections, facilitating remote patient monitoring and improving treatment adherence, patient medication safety and provider communication and coordination. Compared with conventional care, mHealth has a wider market reach and economic advantages, and it empowers users. A systematic review of broad mHealth interventions found three-quarters to be cost-effective, economically beneficial or cost-saving. mHealth approaches to perinatal care challenges suggest high acceptability, promising results and high cost-effectiveness[35 36]; however, reviews of the literature emphasise the need for more robust cost assessments of such mHealth approaches.[37]

Social support, facilitated through postnatal care and women's individual social resources, is critical for navigating the substantial physiological and psychological adjustments of the postnatal period, conferring protection against postpartum depression and improving care access.[38 39] A recent systematic review and meta-analysis of studies in India on postpartum depression reported a pooled estimate of 22% and identified lack of support as a primary risk factor.[40] Beyond the individual importance of maternal mental health, it is linked to relationship challenges with partners, parenting self-confidence and increased risks of impaired emotional and cognitive development and worse physical health among children.[7] Thus, ensuring that new mothers have the social support that they need, particularly during the postpartum period, has the potential for broad and long-lasting impact on women and families. Providing targeted education and support to women in the postnatal period through a mobile social network holds potential to improve knowledge, social support

and behaviours, including care seeking, positively impacting maternal and child health.

Combining mHealth with group care for postpartum health and in LMICs is understudied but has great potential for expanding reach. Nearly all households (over 90%) in Punjab, Madhya Pradesh and Maharashtra have a mobile phone, and 61.2%, 38.5% and 54.8% of women in reproductive age have their own phones.[6] Our intervention comprehensively targets a variety of postpartum behaviours and outcomes (table 1); from these, we have selected three outcomes: exclusive breastfeeding, met need for postpartum contraception and mental health, because they represent key domains of postpartum maternal and infant care and health. Other research has shown that these factors are broadly protective in reducing maternal and infant morbidity and mortality.[41–43] An intensive, multipronged series of interventions trialled in Bihar state that included community health worker (CHW) training, women's self-help groups, facility care quality improvement and demand-creation through media had some success in increasing postnatal visits, breastfeeding practices, immunisation and family planning information provision.[44] However, this complex intervention required significant facilitation and implementation support by external organisations and women's participation in the intervention was challenged by persistent logistical and sociocultural challenges. Our group mobile approach is designed to overcome barriers faced by the previous approaches and engrained in the social and health system more broadly. Our conceptual framework (figure 1) outlines a summary model of the factors influencing perinatal care access and subsequent impact on knowledge, health behaviours and health outcomes.

Study objectives and hypotheses

We will conduct a block randomised controlled trial (RCT) among 2100 postpartum Indian women living in three geographically diverse Indian states to estimate the impact of *Kushal Maa* on maternal and neonatal health-related knowledge, health-related behaviours and health outcomes. Specifically, we seek to estimate the effectiveness of *Kushal Maa* on postpartum behaviours for optimising maternal and neonatal health (Aim 1), characterise the mechanisms of impact of *Kushal Maa* on maternal and neonatal health (Aim 2), and anticipating the determination of intervention effectiveness, we will evaluate the cost-effectiveness of *Kushal Maa* on improving postpartum maternal and neonatal health as compared with the standard of care (Aim 3). We hypothesise that, compared with participants who receive the standard of care, participants in the intervention group will have reduced onset of postpartum depression, increased exclusive breastfeeding and greater uptake of needed postpartum family planning after completing the intervention.

METHODS AND ANALYSIS

Study Setting

Study participants will be recruited from three diverse sites within the states of Punjab, Madhya Pradesh and Maharashtra states. Perinatal care indicators are presented for the states overall (table 2) and specific focal districts (table 3). Due to an incentive scheme to encourage facility deliveries, most women in India (~90% in all three states) now deliver in a health facility.[4 6] In the focal Indian states of this study, although maternal and infant healthcare indicators have increased over time, many remain suboptimal or information is limited, particularly in the postnatal period.[6] The Indian Ministry of Health and Family Welfare (MOHFW) recommends a maternal postnatal health check within 24 hours of birth for facility-based births and referral to a facility within 12 hours of birth for home births. Under MOHFW's Home-based Care of Newborn and Young Child Programme, six infant postnatal visits are recommended at 3rd, 7th, 14th, 21st, 28th, and 42nd days after birth for facility-based births with an additional visit within 24 hours of birth for home births. However, full postnatal care is infrequently achieved, and evidence on postnatal healthcare following the initial hospital-based check for facility deliveries and for women who deliver outside of the facility is sparse.[45] Postnatal care received at the facility or within the community impacts subsequent maternal and neonatal health behaviours such as maternal breastfeeding initiation and continuation and improves infant immunisation and met need for postpartum contraceptives.[46] High-quality postnatal care can optimise maternal and infant health by improving knowledge and social support and through ensuring that medical needs are met.

Study Participants

Inclusion and exclusion criteria

Women eligible for study enrolment must meet the following inclusion criteria: 18+years of age at the time of enrolment, in the last trimester of pregnancy (30–33 weeks of gestation), any parity, single or multiple gestation (1–2), knowledge of site-specific local language, access to own phone (either feature phone with WhatsApp ability or smartphone) and if the potential participant does not have their own smartphone, access to household-level smartphone for participating in both her marital and natal home.

Women who meet any of the following exclusion criteria will be excluded from participation in this study: incapable of providing informed consent and any impairment that prevents participation in the study intervention (eg, hearing or speech impairment).

Kushal Maa intervention

The *Kushal Maa* intervention seeks to overcome prevalent barriers to postnatal maternal and neonatal healthcare

Table 1 Kushal Maa study measures and data collection time points

Category	Measure	Pregnancy	Post partum		
		Baseline	6w	3m	6m
Primary outcome					
Exclusive breastfeeding	Current breastfeeding status and exclusivity		●	●	●
Met need for contraceptives	Current contraceptive use, desire for contraception		●	●	●
Postpartum depression	Edinburgh Postnatal Depression Scale		●	●	●
Secondary outcomes					
Maternal and child health knowledge	Knowledge on maternal and neonatal danger signs, infant care, family planning.	●	●	●	●
Postpartum complications	Morbidities (eg, hypertension, infection), recovery, functional mobility		●	●	●
Postpartum healthcare use	Number of maternal visits, concerns		●	●	●
Maternal nutrition	Adequate and diverse diet	●	●	●	●
Infant feeding and care seeking/practices	Number of infant visits, vaccination, appropriate management of early childhood illnesses. Breastfeeding initiation, duration, introduction of water, solids, type of solids/frequency		●	●	●
Maternal and infant morbidity and mortality	Major health concerns, death.		●	●	●
Covariates					
Participant characteristic covariates					
Sociodemographic characteristics	Age, age at marriage, educational attainment, caste, language, religion	●			
	Employment status, income, assets, food security	●			●
Obstetric history	Parity, past pregnancy complications, delivery complications, infant complications	●	●		
General health status	Nutritional status (body mass index, anaemia)	●	●	●	●
Pregnancy-related health	Chronic and pregnancy-related comorbidities (diabetes, hypertension, pre-eclampsia, malaria, infection, etc)	●			
Antenatal care	ANC initiation, timing, frequency and location.	●			
Delivery care	Gestational age at delivery, delivery mode (vaginal, elective caesarean, emergency caesarean), type of birth attendant and length of labour		●		
Contraceptive/fertility intent	Intent to use family planning, previous use of family planning, fertility desires and timing	●	●	●	●
Women's status	Behavioural intention, self-efficacy, decision-making, gender norms	●	●	●	●
Mobile phone access/use	Mobile phone use (text, WhatsApp, social media, etc), type, ownership status.	●	●	●	●
Psychosocial health covariates					
Psychosocial health	Quality of life, self-esteem	●	●	●	●
Social support	Social support, couples' relationship quality	●	●	●	●
Intimate partner violence	Exposure to physical, emotional or sexual violence (type and intensity)	●	●	●	●
Support group network characteristics					
Social Connectedness	Centrality and connectedness of participants, median duration of each communication, estimated total time spent communicating, frequency of communication (eg, number of messages/calls exchanged) and topic	●	●	●	●
Time use/costing					
Individual participant costs to intervention engagement					

Continued

Table 1 Continued

Category	Measure	Pregnancy	Post partum		
		Baseline	6w	3m	6m
Direct costs	Individual/household out-of-pocket expenditures (eg, treatment and phone)	●	●	●	●
Indirect costs, including opportunity costs	Treatment-seeking resources including transportation, opportunity costs (eg, time, intervention participation and activities foregone (time fungibility))	●	●	●	●
Health system and programme costs					
Start-up costs	Infrastructure cost (eg, clinic room), materials (eg, desk for CHWs) and human resources (eg, consultants to inform pilot survey) required to initiate intervention. These costs are non-recurrent.	Ongoing, supplemented by programme budget and accounting records			
Implementation costs - Personnel	Comprehensive cost (or opportunity cost) of intervention personnel time (eg, supervisors, programme coordinators, moderators, community health workers) including level of education, salary and benefits (including performance and incentive pay).	Ongoing, supplemented by programme budget and accounting records			
Implementation costs - Other recurrent costs	Recurrent expenses on any relevant and integral elements to study implementation (eg, travel/transportation, mobile phone app, goods, training and supervision), capital expenses, including rental cost and annualised capital items (eg, office building) and any above-programme costs incurred at the programme level.[59]	Ongoing			

ANC, antenatal care; CHWs, community health workers.

through delivering culturally-tailored educational programming via a provider-moderated group approach to increase women's health-related communication with providers, referring women in a timely and appropriate manner and connecting them with a virtual social support group of other new mothers. *Kushal Maa*'s mobile support and education groups are based on the capabilities, opportunities, motivation and behaviour framework[30 47] and have positively impacted health outcomes in varied settings.[47 48]

Interventions targeting informational and emotional social support have previously resulted in improved maternal and neonatal health, including reduced postnatal depression[49 50]; facilitated and free verbal and text chat discussion directly targets these domains. Perinatal care access increases knowledge of health-promoting behaviours and parental self-efficacy and empowerment, which jointly influence a woman's engagement in health-promoting behaviours that directly influence maternal and child health outcomes. *Kushal Maa* has

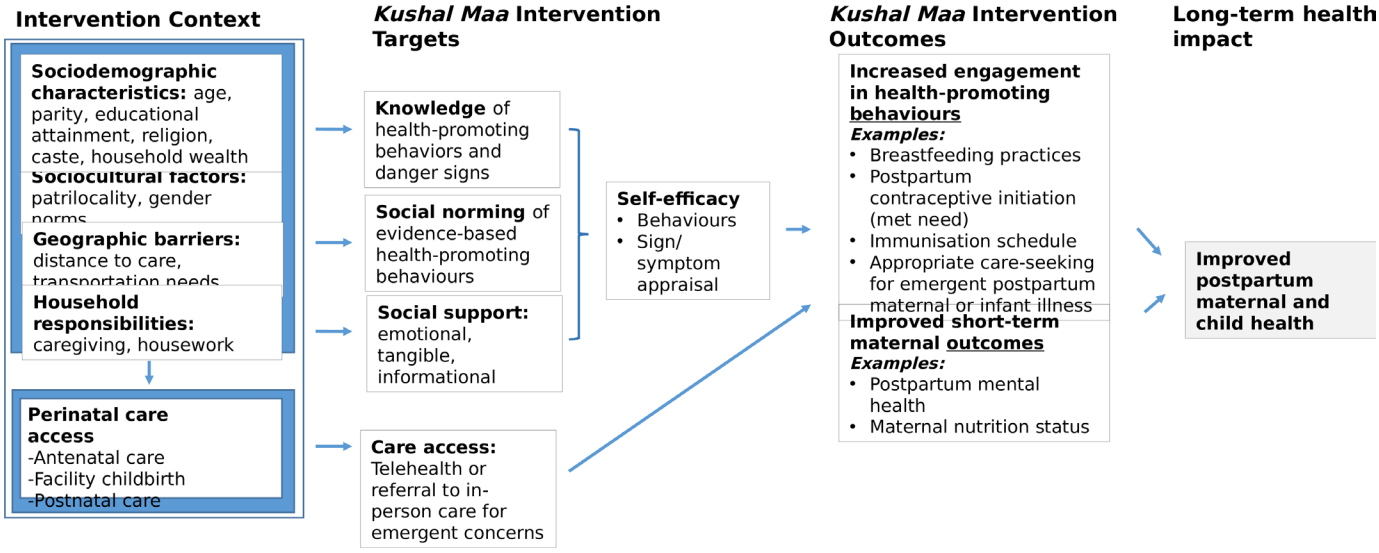

Figure 1 Conceptual framework of intervention context, Kushal Maa intervention targets, outcomes and anticipated long-term impacts. Kushal Maa intervention targets include knowledge, social support and postnatal care. Primary behavioural and health outcomes are postpartum depression, exclusive breastfeeding and needed postpartum contraceptive uptake.

Table 2 Perinatal care, breastfeeding and contraceptive indicators overall and by rurality, across study states

	Punjab	Maharashtra	Madhya Pradesh
	%	%	%
4+ANC			
Urban	60.8	72.2	63.3
Rural	58.4	68.7	55.6
Total	59.3	70.3	57.5
Maternal PNC <2 days			
Urban	82.4	87.2	87.6
Rural	88.3	84.8	82.2
Total	86.2	85.9	83.5
Infant PNC <2 days			
Urban	79.2	91.4	89.0
Rural	87.8	87.9	82.3
Total	84.7	89.5	83.9
Breastfeeding (<1 hour)			
Urban	52.3	51.1	36.2
Rural	53.5	54.2	42.8
Total	53.1	52.9	41.3
Exclusive breastfeeding (<6 months)			
Urban	52.6	66.9	68.8
Rural	57	74.1	75.2
Total	55.5	71.0	74.0
Modern contraceptive use			
Urban	49.4	62.7	63.8
Rural	51.1	64.7	66.1
Total	50.5	63.8	65.5
Total unmet need for contraception			
Urban	8.8	9.9	8.4
Rural	10.5	9.3	7.4
Total	9.9	9.6	7.7

Source: NHFS-5.
ANC, antenatal care; NFHS-5, National Family Health Survey-5; PNC, postnatal care.

Table 3 Study site characteristics

	Punjab	Maharashtra	Madhya Pradesh
	%	%	%
District	Mohali	Nashik	Sehore
Population*	994 628	1 646 177	1 311 332
Literacy*	83.8	82.3	70.1
4+ANC†	69.0	66.4	45.0
Facility birth†	97.4	90.5	94.7
PNC†	88.7	76.5	74.4
Mobile phone ownership†			
Household	97.0	91.9	91.6
Women	71.0	56.0	44.0
SMS literacy†	81.0	77.0	53.0

*IndiaGraphy.
†NHFS-5.
ANC, antenatal care; NFHS-5, National Family Health Survey-5; PNC, postnatal care; SMS, short message service/text message.

been designed to overcome challenges to postpartum care access that result from sociodemographic characteristics, sociocultural factors, geography and household responsibilities through its mobile approach that allows the woman to participate in the intervention from her home.[51] Furthermore, it directly increases knowledge of health-promoting behaviours through its educational content and social support through emphasis on group dynamics.

Women are enrolled in our group intervention (n~15 per group) in late pregnancy (30–33 weeks gestational age). They participate in approximately four weekly intervention sessions, including an orientation session where the participants are guided through the functionality of WhatsApp and Zoom meeting platforms, including how to use them in the weekly calls, receive updates, access helpline support in an emergency, etc, in the prenatal period and then have weekly intervention sessions through 6 months postpartum for a total of 28 potential sessions (figure 2). Each week, women receive educational material tailored to their pregnancy or postpartum stage through engaging in a video or audio-based (Zoom) virtual group discussion moderated by a trained female intervention moderator, through educational videos relevant to their life stage shared via text chat and have access to a facilitated chat (WhatsApp) group for further group contact outside of the meetings (figures 2–3). Group rules will be established to respect member privacy and confidentiality. Moderators will undergo a 3-day training plus monthly 1-day refreshers and ongoing weekly supportive supervision. Women in the intervention group will also receive the standard of care.

Our control group will receive the standard of care for postpartum women in this setting, which includes postpartum health visits to women's homes by accredited social health activists (ASHA) or anganwadi workers (referred to as CHW). Women in both groups will also have access to the standard of care supplemental foods for pregnant and postpartum women, community vaccination and other healthcare events and access to CHWs at the local community healthcare centre.

Study measures

Study measures are detailed in table 3 by category: primary outcomes, secondary outcomes, participant characteristic covariates, psychosocial health covariates, support group network characteristics, individual participant costs to intervention engagement and health system and programme costs.

Kushal Maa intervention timeline

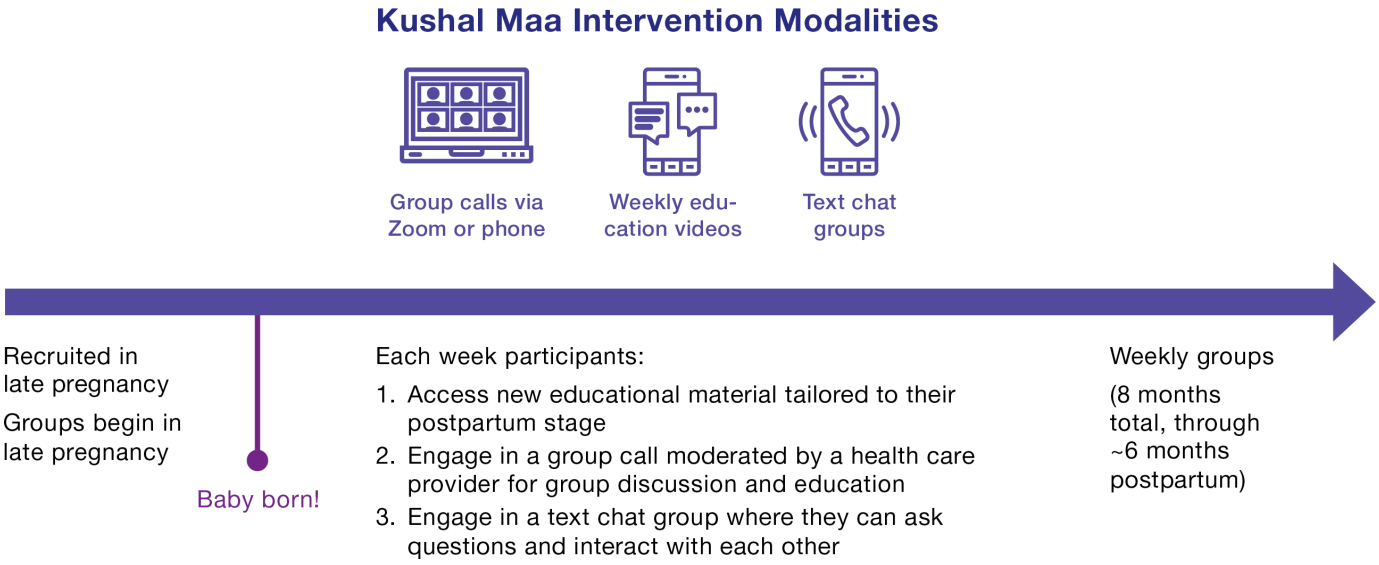

Figure 2 Kushal Maa intervention modalities.

Primary effectiveness outcomes (Aim 1) are exclusive breastfeeding, unmet need for postpartum contraceptives and postpartum depression at 6 months postpartum (ie, the end of the intervention). Exclusive breastfeeding is defined as the practice of providing the infant only breastmilk for nutrition for the first 6 months of life, as per WHO recommendations, without provision of any other liquids or solids except oral rehydration solution as needed or drops of vitamins, minerals or medicines.[52] Unmet needs for postpartum contraceptives are defined as sexually active, not using any form of contraception and reporting not wanting any more children or wanting to

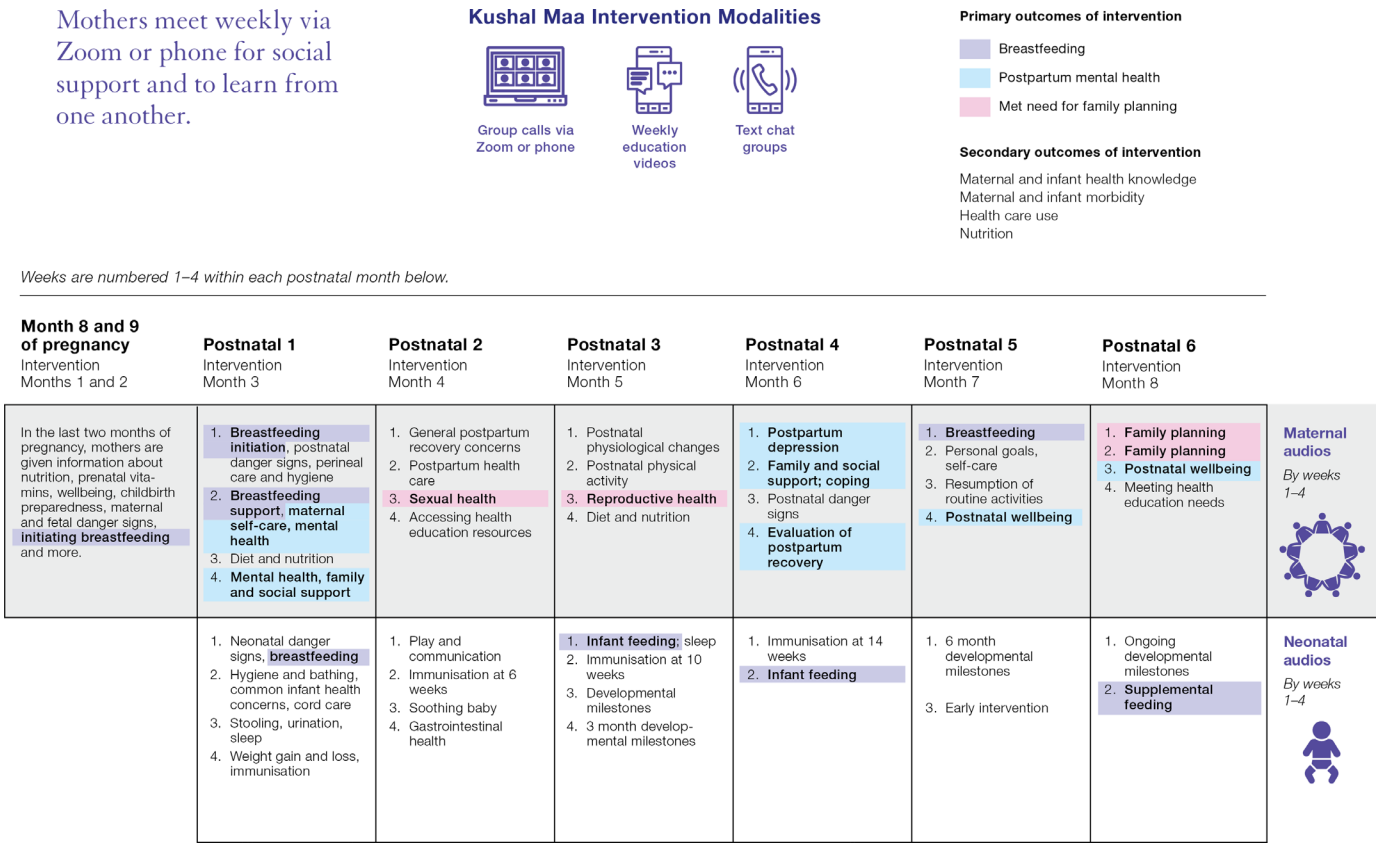

Figure 3 Summary of Kushal Maa intervention content. Note: Not all audios are listed above. This figure gives an overview.

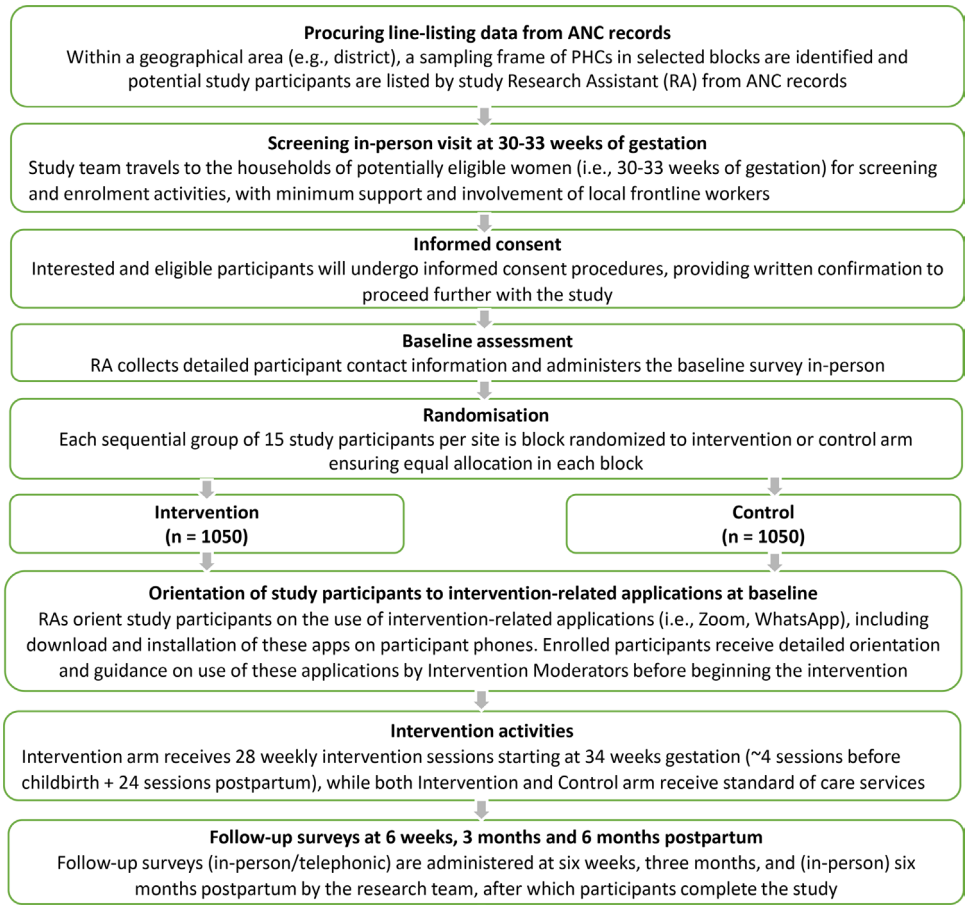

Figure 4 Study participant flow. ANC, antenatal care; PHC, primary health centre.

delay the next child.[53] Postpartum depression is defined as a score of 13 or higher on the Edinburgh Postnatal Depression Scale.[8 54]

Intervention mechanisms to be investigated as mediators of impact (Aim 2) include changes in maternal and child health-related knowledge and social support.

Study procedures

Participant recruitment and enrolment

Participant flow through the study is detailed in figure 4 and online supplemental table S1. Recruitment will be carried out simultaneously across study sites following the same protocol. First, within one geographical area, we will select a sampling frame of primary health centres, where we will be recruiting from. With the assistance of the community health providers, auxiliary nurse midwives, ASHAs, Community Health Officers and any other administrative staff, study research assistants (RAs) will review antenatal care registration data and list potential study participants.

As soon as the listed women meet the gestational age eligibility criteria (ie, 30–33 weeks of gestation), the study team will travel to the household, preferably accompanied by the relevant ASHA worker for screening and enrolment activities. If a woman is identified as eligible for the study, the RA will carry out an informed consent process including a detailed description of study procedures, possible risks and benefits to participation and participant rights in research. The potential participant and their family members will have the opportunity to ask questions. Concurrence will be requested from household heads as appropriate (eg, mothers-in-law and husbands) for women's participation in the study, and each woman will be requested to provide written (or thumbprint with witness, if illiterate) confirmation of informed consent per Indian guidelines.[55] A copy of the informed consent form and the study information sheet will be provided to the women for their records (see example under online supplemental material).

Randomisation

Informed by the group nature of the intervention, limited gestational age range eligibility criteria and site-specific birth rates, each sequential group of 15 study participants per site will be block randomised to intervention or control arm using fixed-size blocking to ensure equal number of blocks for each arm and consistent intervention group sizes. Randomisation is conducted within REDCap's randomisation module that is programmed to provide fixed-sized blocks (n=15 participants each) to ensure equal allocation in each block. Blocks thus formed are then randomly assigned to either intervention or control arms.

Blinding

Due to the nature of the behavioural intervention delivered at a group level, it is not possible to blind study participants or intervention moderators. However, to increase study robustness, our study will maintain blinding for study investigators, research coordinators, RAs conducting outcome assessments and data analysts.

Data collection and management

On participant enrolment, the RAs will collect detailed participant contact information and administer the baseline survey (table 1) in person in a private location at the participant's residence or another convenient location. Follow-up surveys will be administered at 6 weeks, 3 months and 6 months post partum by the research team. Follow-up surveys at 6 weeks and 3 months post partum may be conducted over the phone, only if the participant is out of reach and has gone to natal home after delivery, whereas the 6-month endline survey will be conducted in person (table 1). For consistency, follow-up data collection points are defined by estimated due date due date with a window period of ±2 weeks from the scheduled date. At roughly 6 months post partum, participants will have had the opportunity to participate in 28 weekly Kushal Maa sessions. Self-reported health outcome data will be validated as possible against women's health cards and CHW-maintained registers. Reasons for study withdrawal will be captured for all participants. All participant data will be collected on encrypted and password-protected tablets using REDCap secure data collection software, uploaded to project servers and regularly checked for quality. However, data will be gathered using paper-based forms as a backup in the event that tablets are not working or REDCap is experiencing technical difficulties. The site principal investigators are in charge of the safe storage of these paper forms. The data are transcribed into the REDCap secure data collecting programme, checked for accuracy and uploaded to the project server.

Backend data on intervention engagement will include weekly moderator tracking of each participant's attendance and level of participation in group interactive sessions and use of the chat platform (posts, frequency, topic). Deidentified transcripts of group interactive sessions and text chats will be used to further understand health educational needs and interests for postnatal women.

Orientation to intervention digital platforms: Zoom and WhatsApp

Once participant eligibility for study participation is confirmed through screening and informed consent received, RAs will briefly orient all study participants on the use of the intervention-related applications (ie, Zoom, WhatsApp), confirming participants that they could or could not be assigned to the intervention arm, including facilitating their download on participant phones and providing them with an instructional information sheet. Further orientation on intervention-related applications will be conducted by intervention moderators for study participants randomised to the intervention group.

Participant retention

To maximise participant retention, data collection and intervention implementation activities will be closely tracked. Loss to follow-up will be reduced through collecting complete participant contact information at study recruitment, including contact information of two family members or friends (one each from marital and natal homes), at two inperson data collection points and following up in person with participants who were unable to be reached via phone. For intervention participants, loss to follow-up will be reduced through use of local moderators for intervention activities, follow-up to understand any non-attendance and inperson enrolment and early data collection activities.

A participant will be considered lost to follow-up if she fails to attend at least four group call sessions in sequence and study staff are unable to reach the participant after at least four contact attempts. End-of-study is defined as when the last participant collects the endline data collection.

Data analysis

Effectiveness and intervention mechanism analyses

Primary analyses will be conducted first as intention-to-treat including all randomised participants, regardless of their level of engagement in the intervention. Secondary analyses will be done per-protocol, with intervention participants categorised into high (75% of group calls), medium (50% of group calls) or low attendance who attended a medium level of calls (at least four group calls defined as per-protocol). The quantitative analysis will be done using the Consolidated Standards of Reporting Trials guidelines for individual RCTs.[56]

Study participant sociodemographic characteristics and obstetric history will be described overall and by intervention group using appropriate distributional statistics (means, SD, medians, IQRs). Baseline equivalence of sociodemographic characteristics across the final analytic sample will be assessed using χ^2 or t-tests, as per variable distribution.

We will estimate the effectiveness (Aim 1) of the *Kushal Maa* intervention following an intent-to-treat approach using mixed-effects logistic regression analyses to accommodate for any clustering induced by the group-oriented delivery of our intervention for primary outcomes at 6 months: exclusive breastfeeding, unmet need for postpartum contraceptives and postpartum depression. Secondary analyses of other maternal and child health behaviours and outcomes will follow a similar approach, employing logistic or linear mixed-effects regression for binary and continuous outcomes and survival analysis for time-to-event outcomes (eg, length of exclusive breastfeeding). Perprotocol analyses will be conducted as secondary.

Analyses of the intervention mechanism (Aim 2) will evaluate whether maternal and child health knowledge and social support mediate the relationship between intervention participation and the primary outcomes. To maximise rigour, these analyses will be conducted using modern principles of structural equation modelling (SEM) and causal inference methods. SEM readily allows for the inclusion of multiple mediators simultaneously and the creation of latent variables which represent shared variation among similar measures that are likely to be correlated. As part of our analyses, we will investigate whether the various candidate mediators are sufficiently correlated to be treated as measures of one or more latent variables. The resulting latent variables may be used as mediators, reducing the effects of measurement error and improving statistical power for tests of mediation. Causal inference methods extend SEM-based mediation approaches to yield optimal estimates of indirect effects for non-continuous outcomes and/or mediator, an important benefit for this study given that its outcomes are binary. We will use Mplus (Los Angeles, California, USA) to perform analyses for Aim 2 because it unites SEM and latent variables with causal inference-based mediation methods in the same software platform and because it can adjust SEs for the clustering of participants within intervention groups. To extend the rigour of these analyses, we will prespecify and control for the covariates that could influence the mediator-outcome relationship (eg, age, region) and perform sensitivity analyses to investigate the robustness of the results to potential confounding of mediator-outcome relationships by any remaining unobserved confounders. Technology assessment analysis (backend data) will contribute to this aim. We will analyse quantitative backend data to gain more insight into women's intervention participation and engagement, including attendance and level of participation in group interactive sessions and use of the chat platform (posts, frequency, topic, etc) using frequencies and means/medians. WhatsApp group discussion data will be translated and analysed qualitatively for content to further understand educational needs and interests for postnatal women.

Process evaluation activities will explore study implementation through review of monitoring indicators collected from back-end data sources such as women's weekly attendance and engagement in group calls, interactions in the text chat group, etc, as well as from descriptive analysis of weekly reports submitted by intervention moderators regarding their perspectives of the group. Further evaluation will occur through review of monitoring data, study documents and interviews with study personnel.

Cost and cost-effectiveness analyses

Hypothesising and anticipating that the intervention will yield effectiveness, we will conduct cost analysis and cost-effectiveness analyses (Aim 3) from the individual, health system (inclusive of programme and health system costs) and societal perspectives (inclusive of participant, programme and health system costs) (table 3). We will value and calculate costs from the individual perspective and health system perspective, following published guidelines on costing approaches performed in LMICs. The health system costs will be derived from the study budget and accounting records and relevant estimations. Start-up costs, which include office furniture and equipment, employee recruitment costs and other resource costs incurred for the purpose of initiating implementation, will be calculated and presented separately from the implementation cost. We will annualise the start-up cost but not discount the value of the start-up capital items.

The implementation costs include personnel salaries (eg, administrative staff, CHWs), training, CHW travel costs, supplies (eg, office supplies), equipment and buildings (eg, rent, utilities) and other recurrent costs (eg, telephone and internet). The costs will be collected during the trial period in Indian rupees and will be inflated to the year of analysis and presented in both Indian rupees and US$.

Costs from the individual perspective include healthcare-related out-of-pocket payments and will be measured through repeated individual surveys, asking participants the time it took them to seek care (opportunity cost) and the amount they paid for travel, medications, food and accommodation and other expenses. One central objective to the cost analysis and cost-effectiveness analysis for this study is to evaluate the value of the support group. We hypothesise that time spent in the programme, specifically engaging with a support group, will increase a sense of connectedness and lead to the formation of community, both of which will contribute to better maternal health in general and mental health in particular. Each participant's social connectedness assessment will be represented as a social network indicator building from betweenness, degree and eigenvector centrality of individual communication to generate a measure of centrality.

We will estimate the incremental cost-effectiveness ration (ICER) of Kushal Maa as compared with the standard of care. Incremental costs will be divided by incremental health effects to generate a deterministic estimate of ICERs, expressed as a cost per: (1) exclusive breastfeeding added, (2) postpartum depression averted and (3) met need for postpartum contraceptives. Time horizons of 1 year and 10 years will both be considered to cover all costs and effects of the intervention on postpartum depression. To understand the short-term cost-effectiveness of Kushal Maa, a 1-year time horizon that encompasses the trial period will be used. In the analysis for short-term cost-effectiveness, no modelling or simulation will be employed. We will use the data collected from this RCT to calculate ICER using the following equation:

$$ICER = \frac{Cost\ of\ Kushal\ Maa - Cost\ of\ SoC}{Effect\ of\ Kushal\ Maa - Effect\ of\ SoC}$$

To evaluate the long-term cost-effectiveness of Kushal Ma, we will use a 10-year time horizon with a cycle length of 1 year. We will use TreeAge Pro V.2023 to construct a decision tree and conduct the analysis. We will test for uncertainty by conducting one-way and probabilistic sensitivity analyses.

We will use the calculated social network indicator to stratify the cost-effectiveness analysis (CEA) and examine the ICER of Kushal Maa under varying levels of social connectedness. This study will measure social connectedness and associated opportunity cost to gain the connectedness through capturing the frequency, duration and sum of unique contacts with whom each participant engaged during the trial period. We will ask participants to report their contacts (table 3). The information will be used to construct matrices, enabling us to calculate degree centrality and betweenness centrality for each participant. The information will enable us to evaluate how the cost-effectiveness of Kushal Maa in improving maternal and neonatal health outcomes may vary by social connectedness. The findings will be critical to informing potential replication and programme expansion costs as well as scaling and implementation.

Sample size

Our study is powered on our effectiveness aim (Aim 1). Within Stata's power procedure using α=0.05, 1-β=0.8, interclass correlation coefficient of 0.05 and baseline postpartum depression prevalence estimates among Indian women of 24% (95% CI 20% to 28%),[40] we calculated a randomised sample size of 70 intervention groups incorporating a minimum of 1050 intervention participants and 1050 control participants in order to detect a minimum 8% difference in postpartum depression between the intervention and control groups. This difference has been selected as it represents a clinically significant reduction and is consistent with reductions in postpartum depression associated with other educational and social support interventions (range 6–31%) and findings of group-delivered perinatal interventions.[57]

Our target sample size of 1050 each for intervention and control arms is sufficient to meet the sample size needed for the CEA (1-year time horizon: n=1652, 826 per arm; 10 year: n=1990, 995 per arm). We calculated the sample size for the CEA following the value of information theory.[58]

Data and safety risks: monitoring and reporting

Study participation is expected to confer minimal risk to study participants due to the content and digital delivery of the intervention and may result in both individual and societal benefits through education, social support and referral as well as demonstrating the effectiveness of an intervention that could be scaled up within lower-resource settings to improve women's postnatal health outcomes. This protocol uses the definition of adverse event from 21 Code of Federal Regulations (CFR) 312.32 (a): any untoward medical occurrence associated with the use of an intervention in humans, whether or not considered intervention related. The safety of participants will be prioritised throughout the trial, and data on adverse events will be collected through ongoing study data collection activities and monitoring by intervention moderators. All adverse events and serious adverse events will be tracked, participants reporting concerning symptoms will be referred per protocol, and these events will be reported to the relevant institutional review boards following established protocols and as per Indian national ethics guidance.

A three-member Data and Safety Monitoring Board with expertise in behavioural RCTs, mHealth and perinatal health will be implemented for the current project in order to review study data for participant safety, study conduct, progress and effectiveness and make recommendations on study continuation, modification or termination of the trial. The DSMB will meet once prior to study start and every 6 months until study termination.

ETHICS AND DISSEMINATION

Research ethics approval

The study protocol has been reviewed and approved by the Health Ministry Screening Committee, Government of India and human subjects research ethics review committees at the University of California, San Francisco (REF# 21–35730), Maharashtra University of Health Sciences (REF# MUHS/EC/06/2024), Post-Graduate Institute of Medical Education and Research, Chandigarh (PGI/IEC/2022) and Sangath (REF # AB_2022_81). Appropriate clearances have been obtained from the MOHFW at both central and state levels. All study participants will undergo a thorough informed consent process, and written confirmation of informed consent will be obtained (see sample form under online supplemental materials).

Dissemination plan

On study completion, the findings of the study will be shared with community members of the populations in which we are conducting the study, other scientific and governmental stakeholders and will be published in the scientific literature. These activities will include community dissemination meetings to be attended by community leaders, health providers and village members; in-person seminars or webinars; and publication in peer-reviewed publications and presentation at scientific conferences. We plan to develop a policy brief to concisely summarise our findings and share this with stakeholders, including policymakers who can use our evidence to shape relevant maternal and infant health programming and policy. Study interpretation and dissemination activities will be supported by a ~10-member technical advisory group of individuals with relevant scientific and policy experience across India. This study is registered with ClinicalTrials.gov (NCT05268588) and Clinical Trials Registry – India (CTRI/2022/07/043889), and study findings will be

shared online at these sites. Study data will be deidentified and made publicly available after conclusion of the trial and all primary analyses.

Current status

Participant enrolment for this study began on 20 January 2025 and is currently ongoing. Our anticipated study completion date is October 2027.

Plan for patient and public involvement

Patients were not involved in the design of this research and will not be involved in conducting or reporting on the research; however, they were involved in the development of the intervention.[51]

Protocol version and date

This article represents protocol V.1.1, dated 4 January 2025. Protocol amendments will be reported to relevant parties as they are made available.

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