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Preventing postnatal depression in new mothers using telephone peer support: protocol for the DAISY (Depression and AnxIety peer Support studY) multi-centre randomised controlled trial

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ABSTRACT

Introduction Postnatal depression affects up to one in six new mothers in Australia each year, with significant impacts on the woman and her family. Prevention strategies can be complicated by a woman's reluctance to seek professional help. Peer support is a promising but inadequately tested early intervention. Very few trials have reported on the efficacy of peer support in the perinatal period and no study has been undertaken in Australia. We will explore if proactive telephone-based peer (mother-to-mother) support, provided to women identified as being at high risk of postnatal depression, impacts on clinically significant depressive symptomatology at 6 months postpartum.

Methods and analysis This is a protocol for a single-blinded, multi-centre, randomised controlled trial conducted in Melbourne, Australia. Eligible women will be recruited from either the postnatal units of two maternity hospitals, or around 4 weeks postpartum at maternal and child health centres within two metropolitan council areas. A total of 1060 (530/group) women will be recruited and randomly allocated (1:1 ratio) to either—usual care, to receive the standard community postpartum services available to them, or the intervention group, to receive proactive telephone-based support from a peer volunteer for 6 months, in addition to standard community services. Primary outcome: clinically significant depressive symptomatology at 6 months postpartum as measured using the Edinburgh Postnatal Depression Scale. Secondary outcomes: symptoms of anxiety and/or stress, health-related quality of life, loneliness, perception of partner support, self-rated parenting, child health and development, infant feeding and health service use. The cost-effectiveness of the intervention relative to standard care will also be assessed.

Ethics and dissemination Ethics approval has been obtained from La Trobe University, St. Vincent's Hospital, the Royal Women's Hospital, Northern Health, Victorian Department of Health and Human Services and Victorian Department of Education and Training. Written informed consent will be obtained from all participants before randomisation. Trial results will be disseminated through peer-reviewed publications, conference presentations and a higher degree thesis.

Trial registration number ACTRN12619000684123; Australian New Zealand Clinical Trials Registry.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study will provide important new knowledge in the effect of proactive telephone-based peer support on postnatal depression and/or anxiety in Australia.
⇒ As a preventative strategy, peer support has the potential to offer a sustainable and scalable intervention that is acceptable to providers and recipients.
⇒ A comprehensive cost-utility analysis of the intervention will be included.
⇒ Recruitment from maternity services and maternal and child health services have been strategically chosen to optimise scale up if the intervention is effective by increasing the likelihood, it will be embedded within existing perinatal depression referral pathways.
⇒ Given this trial will assess the effectiveness of proactive telephone-based peer support, blinding of trial participants and peer support volunteers is not possible.

INTRODUCTION

Postnatal depression is defined as depression occurring within the year following childbirth. It has a period prevalence in the first 12 weeks postnatally of 19.2% for all depression, and 7.1% for major depression.[1] Over 50 000 new mothers in Australia (1 in 6) are affected each year.[2 3] Postnatal depression has significant long-term effects on the woman (including increased risk of future depressive episodes[4 5]), her child and the family.[6 7] In severe cases, left untreated,

maternal depression can lead to suicide.[8–10] Cost implications are considerable; perinatal mental health problems in each 1-year cohort of births in the UK are estimated to have long-term societal costs of around £8.1 billion.[11]

Some prevention efforts have been shown to be effective,[12] but women may be reluctant to seek professional help.[13 14] One in three new mothers in the state of Victoria, Australia who are experiencing depression do not seek help.[15] Barriers include concerns about the stigma of mental illness, being perceived as 'unable to cope',[13] practical challenges (eg, language, transportation, costs),[16] lack of knowledge regarding service availability and access,[13] cultural factors[13] and caregiver attitudes and lack of knowledge.[13] Web-based resources and mobile apps can provide informational support but have limited capacity to address social isolation, and their effectiveness in reaching at-risk populations is unknown.[17]

Proactive telephone-based peer support addresses a well-documented risk factor for postnatal depression—inadequate social support,[18 19] experienced by mothers as lacking a confidante or understanding friend to converse with, not receiving support without having to ask and feeling socially isolated.[20] Social support provides a sense of belonging, self-worth, and normative guidance,[21] and can increase motivation for self-care, enhance help-seeking, lead to more benign appraisal of stressful events and modulate the neuroendocrine response to stress.[21] Women also prefer support from other mothers.[13]

Peer support is a specific type of social support provided by lay people who have experienced a similar health problem or stressor, and encompasses the provision of informational, appraisal and emotional support.[22] A peer has experiential knowledge of the stressor, is not part of the mother's family or immediate social network and may or may not have similar sociodemographic characteristics.[22] The peer is provided with enough training to be supportive while preserving their 'peer-ness', and not creating a para-professional.[22] Peer support has a positive effect on psychological well-being of recipients.[21 22] It reduces loneliness, buffers the impact of stressors, increases self-efficacy[22] and facilitates linking women with referral services.[23] Psychosocial benefits for peers have also been reported.[24 25]

While there is growing evidence of improved health outcomes using telephone-based peer support, very few RCTs have reported on the efficacy of mother-to-mother telephone peer support in the perinatal period. One trial conducted in Canada reduced the onset of postnatal depression among women at high risk.[20] To our knowledge, the Canadian study is the only telephone support trial to date with a perinatal mental health focus,[20] but this single study does not provide sufficient evidence for adopting peer support as a prevention strategy in the Australian context.

We aim to explore the effect of proactive telephone-based peer support for women identified as being at high risk of postnatal depression, compared with women receiving usual care, on clinically significant depressive symptomatology at 6 months postpartum. Secondary outcomes include symptoms of anxiety and/or stress, health-related quality of life, loneliness, partner support, parenting, child health and development, infant feeding, service use and intervention cost-effectiveness. Views and experiences of mothers and peer volunteers will also be explored.

METHODS AND ANALYSIS

Design

A two-arm, multi-site randomised controlled trial (RCT) will be used.

This protocol conforms with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT),[26] and the RCT will conform to the Consolidated Standards of Reporting Trials (CONSORT) statement for reporting RCTs.[27]

Primary hypothesis

Women allocated to peer support, compared with those allocated to usual care, will be less likely to have clinically significant depressive symptoms at 6 months postpartum, defined as scoring >12 on the Edinburgh Postnatal Depression Scale (EPDS).[28]

Setting

Women will be recruited in Melbourne, Australia, but the intervention can be provided by women anywhere in Australia.

Participants

Inclusion criteria: women with a singleton live birth, who can speak and understand English, are accessible by telephone and have one or more pre-defined risk factors that increase their risk of developing postnatal depression (risk factors in table 1).

Exclusion criteria: having had a multiple birth, currently using anti-depressant, anti-anxiety or anti-psychotic medication, and major/serious mental health condition (details in table 1).

Recruitment

We originally aimed to recruit women only from maternal and child health (MCH) clinics, in two purposively selected local government areas (LGAs) in metropolitan Melbourne, but when testing recruitment, it was found to be very complex. There was poor identification and uptake, and too many steps between identification of eligible women and randomisation. We, therefore, modified the original strategy to include postnatal units in two Melbourne hospitals, thus recruitment will be from both sources. Figure 1 outlines the anticipated participant flow.

Recruitment from MCH Centres: in Victoria, universal free community-based support for new parents is provided by the MCH service for families with children from birth to school age[29] and organised by LGAs, which have up to 40 MCH centres. MCH nurses (MCHNs) have qualifications in nursing, midwifery and child and family health.[30] The

Table 1 Eligibility criteria

Inclusion criteria
With a live birth of singleton infant ≥32 weeks gestation, where neither mother nor baby is extremely unwell.
Who have ability to speak and understand English.
Who are ≥16 years of age.
Who are accessible by telephone.
With any of the following risk factors:
History of mental health issues (excluding major mental health issues as explained below under exclusion criteria) (diagnosed or self-reported) previous to pregnancy or during pregnancy.
If EPDS administered in pregnancy or during routine postnatal visit by MCH nurse: A score of between 9 and 20 (inclusive), or if mother scored less than 9, but responded '1', 'Hardly ever' to item 10 (in the last 7 days, the thought of harming myself has occurred to me).
Social isolation (eg, family overseas/interstate, no family support, isolated residence and no transport, etc).
Single mother.
Previous Sudden Infant Death Syndrome (SIDS); previous fetal death in utero (FDIU); previous stillbirth.
Exclusion criteria
Current anti-depressant, anti-anxiety or anti-psychotic medication use or any medication in relation to mental health (the aim of the study is prevention, and these women are receiving treatment).
A score >20 on EPDS either in pregnancy or prior to recruitment postpartum*.
Responding 2 or 3 ('yes, quite often' / 'sometimes') to item 10 of the EPDS (in the last 7 days, the thought of harming myself has occurred to me).
Major or serious mental health conditions that peer support volunteers are not sufficiently trained to deal with (eg, bipolar, psychosis, schizophrenia, personality disorder).
Severe alcohol or illicit drug use (likely to have complex psychosocial issues).
Current experience of family violence (as peer support volunteers not sufficiently trained to deal with complex issues).
Multiple birth.
Intellectual disability to the extent informed consent can not be provided.
Infant not expected to be (or was not) discharged home at time of recruitment (with a life threatening or significant health problem; eg, brain injury; cardiac abnormality).

*Prior self-reported or diagnosed mental illness (eg, depression, postnatal depression, anxiety) is not an exclusion criterion if the woman is currently stable.
EPDS, Edinburgh Postnatal Depression Scale; MCH, maternal and child health.

two included LGAs have high birth rates and multi-ethnic communities that reflect the diversity of the Australian population. There are 46 MCH centres and 111 MCHNs in these LGAs. Women will be recruited by MCHNs at the 4-week postpartum health check (which 95% of all women birthing in Victoria attend).[31]

The MCHNs will receive education about the trial, and on how to identify and refer eligible women and will screen women during a consultation using the EPDS (routinely used at the 4-week postnatal consultation).[29] If a mother is eligible, the study will be briefly explained, and if the woman is interested and consents, her details will be sent to a study midwife. The study midwife will contact the woman, ensure eligibility, then provide a study explanation and participant information and consent form (online supplemental material S1). When consent is received, the mother will be contacted by telephone to collect baseline data and be randomised. MCHNs will not be informed of trial arm allocation, and all women will be managed according to MCHN Practice Guidelines.[29]

Recruitment in hospitals: women will be recruited by study midwives on the postnatal units of participating hospitals from 24 hours post-birth, or before discharge for women staying <24 hours. Study midwives will screen medical records to identify potentially eligible women, who will be provided with a study explanation and consent form (online supplemental material S1). If a woman agrees to participate and provides written consent, baseline data will be collected, then the woman randomised and informed of group allocation. If any woman scores >20 on the EPDS at baseline or scores '2' or '3' on the EPDS self-harm question, she will be excluded before randomisation and offered referral and support via the hospital clinical team providing care.

Usual care (comparison group)

Mothers allocated to usual care will have access to all standard community postnatal services, including ongoing support from their MCHN, a state-wide 24-hour MCH helpline, general practitioners (GPs), Perinatal Anxiety & Depression Australia (PANDA), the Australian Breastfeeding Association (ABA) and ABA 24-hour helpline.

Intervention (telephone-based peer support)

Mothers allocated to the intervention will receive proactive telephone-based support from a peer volunteer in addition to usual care. Where possible, individual preferences will be considered when matching women with peer volunteers (eg, cultural background, number of other children). Telephone contact will proceed until 6 months postpartum. Peer volunteers will provide appraisal support (helping women appraise their situation and make informed decisions) and emotional support by telephone. They will also provide information and suggestions about existing clinical and support services as indicated or if asked. The goal is to encourage and overcome barriers to help-seeking, not provide mental health treatment.

Intervention contact schedule

Peer volunteers will be asked to initiate early telephone contact with the women they are allocated to

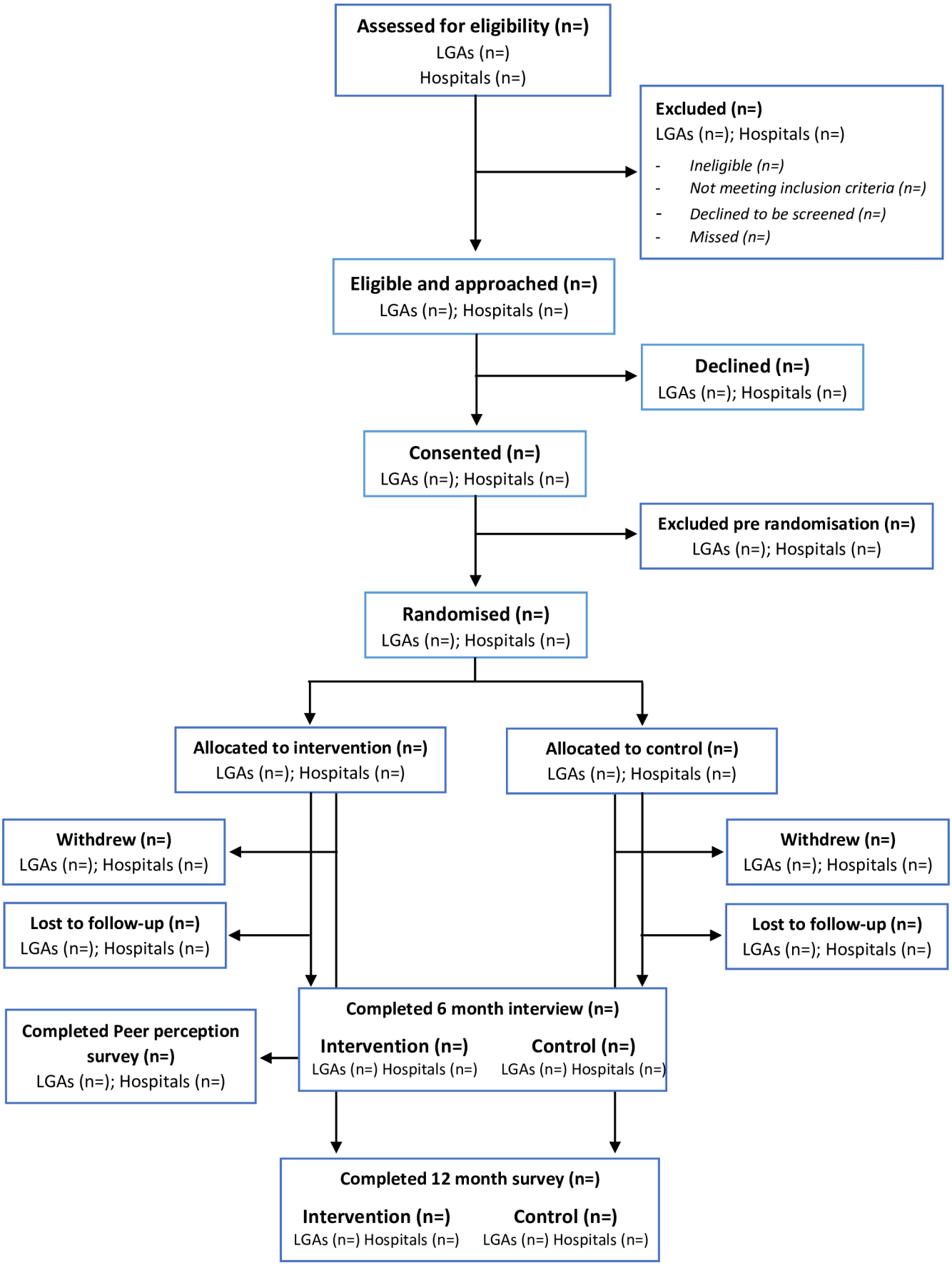

Figure 1 Flow diagram to summarise the DAISY trial design. DAISY, Depression and Anxiety peer Support study; LGA, local government area.

support—within 48 to 72 hours of recruitment if a woman is recruited from an MCH centre, or within 1 to 2 weeks of birth if recruited from a hospital. The contact schedule guides the support, but intervention duration and intensity will be responsive to the mother's needs. Other communication such as text and email can be used if preferred by the new mother. The peer volunteer will send an introductory text and say she will call in a day or two. As well as an 'introduction', the text circumvents the issue of women not answering unknown telephone numbers. The first call will be to establish contact, ask how the woman is feeling and organise a convenient time for the next call. The volunteer will also encourage the mother to make contact when or if she would like someone to talk to, or if she is feeling emotionally unwell.

The planned schedule is telephone calls at weekly intervals for 8 weeks or until 3 months postpartum, whichever is longer for each woman, then 2-weekly to 6 months postpartum, with flexibility. It is likely not all peer relationships will continue to 6 months, and number of calls may not be the key factor affecting outcomes.[20] The focus is to offer support and a listening ear and provision of details of services as needed. Peer volunteers will not make a formal assessment of maternal mental health, but if they concerned a mother's mental health is deteriorating, the volunteer will consult the volunteer coordinator and refer as appropriate.

Peer volunteers—eligibility, recruitment, training, support

Eligibility: peer volunteers must have a history of, and recovery from, postnatal depression and/or anxiety (self-reported or diagnosed), want to support other mothers, be empathetic, have good communication skills and be able to share their own experiences as appropriate. Women with previous mental health issues who meet inclusion criteria but are on medication and stable may be eligible to volunteer depending on medication type and dose, with consultation with the research team perinatal psychiatrist as needed.

Women will be ineligible if they have a severe mental health condition (eg, bipolar disorder, schizophrenia, personality disorder, psychosis). Women likely to have more training in mental health (eg, mental health professionals, obstetricians, midwives, MCHNs) will also be excluded given we are testing 'lay' peer support.

Eligible potential volunteers are required to attend training delivered by a research team member and volunteer coordinator in small group sessions (face-to-face or video). If there are concerns about a volunteer who has attended the training, the principal investigator, peer volunteer coordinator and perinatal psychiatrist will liaise and decide about the volunteer's suitability. The perinatal psychiatrist may undertake further assessment and refer the volunteer as appropriate for support. National Criminal History checks will also be completed.

Recruitment: volunteers will be recruited by advertisements in local newspapers, fliers in MCH centres, word of mouth and social media. The volunteer coordinator will provide information about the study and ask women to complete an online questionnaire about their experience of postnatal depression and/or anxiety, including checks for severe mental health conditions. Further screening by telephone will confirm eligibility and explore women's experiences of and recovery from postnatal depression or anxiety as well as their current mental health state. Eligible women will be asked to attend a training session as a final step.

Training: peer volunteers will undergo a 4-hour group training session[20 32]—face-to-face or by synchronous online delivery—based on the model developed for the Canadian trial,[20] modified slightly for the Australian context. Training will include women sharing their experiences of postnatal depression or anxiety, a presentation on the study and background information on perinatal mental health and peer support. The study aim will be explained, as will the characteristics of women who will be recruited and receive support. The second part will focus on skills required to provide effective telephone-based support and suggested referrals the peer volunteers may make. Topics will include developing a relationship, building trust and rapport and providing a safe non-judgmental space. Peer volunteers will learn how to provide validation support and normalise the experience of motherhood as well as build confidence and self-esteem in the mother/s they will support. Skills and techniques will include active listening, maintaining a positive regard and refraining from advice-giving or problem-solving. How to respond to a mother experiencing a mental health crisis or who discloses intimate partner violence (IPV) will be discussed. Role plays will be conducted in pairs followed by group debriefing. Available support for peer volunteers will be explained, and maintaining personal and professional support networks discussed and encouraged. A handbook including the training content and a list of resources for the mothers they will be supporting and for themselves will be provided.

Peer volunteers will be given activity logs to record details of calls. Reimbursement of AUD$50 per completed period of support to cover the costs of telephone calls and incidentals will be offered. Peers will sign a confidentiality agreement.

The volunteer coordinator will recruit volunteers, coordinate and assist in volunteer training, match mothers with volunteers, monitor implementation, provide support to volunteers and lead monthly peer volunteer support meetings. They will have regular email and telephone contact with the peers, and send a quarterly study newsletter to provide updates and encouragement.

Randomisation

Women will be randomly allocated to intervention or control group, with stratification by recruitment site, parity (first baby or not) and self-reported or diagnosed history of depression and/or anxiety, including postnatal depression. A secure, password-protected, computerised randomisation schedule will be designed and

	STUDY PERIOD				
	Enrolment	Allocation	Post-allocation		Close-out
TIMEPOINT (postpartum)	*Early postpartum period (Postnatal ward prior discharge or 4-week MCH visit)*		*6 months postpartum*	*12 months postpartum*	*15 months*
ENROLMENT:					
Eligibility screen	X				
Informed consent	X				
Allocation	X				
INTERVENTIONS:					
Telephone peer support	◆—	—	—◆		
ASSESSMENTS:					
Baseline data (Maternal and infant characteristics)	X				
Primary and secondary outcomes			X	X	X

Figure 2 Protocol schedule for enrolment, intervention and assessments of DAISY trial. DAISY, Depression and Anxiety peer Support study; MCH, maternal and child health.

administered by the Clinical Trials Centre, University of Sydney, Australia, accessed by telephone using an interactive voice response system. The randomisation ratio will be 1:1 peer support to usual care, with block sizes of 4 or 6 distributed randomly. Blocks will be pre-assigned to strata.

Bias protection

Participants cannot be blinded, but community service providers will be blinded and unaware of whether a woman is participating in the trial. There is no formal peer support programme to prevent postnatal depression in the Victorian community, so no mother in the control group will receive the intervention. Data collection will be conducted blinded to group allocation, and the research team will be blinded to group allocation until the trial is fully recruited and primary analysis complete.

Data collection

Baseline data will be collected at recruitment, by telephone if recruiting from MCH centres, or face-to-face if recruiting in the hospitals. Outcome data will be collected at 6 months by telephone interview, or online if needed (eg, participant requests to do online, woman has moved overseas), and via online survey at 12 months. A summary of study schedule is presented in figure 2.

Primary outcome

The primary outcome is clinically significant depressive symptomatology, defined as an EPDS score >12 at 6 months postpartum (indicating high likelihood of depression and likely need for active management).[28]

The EPDS is a 10-item self-report instrument (4-point ratings, range 0–30), with higher scores indicating greater symptoms of depression.[28] It is the most frequently used tool for assessing postpartum depressive symptoms[7] and has been validated by standardised psychiatric interviews with large samples, with well-documented reliability and validity.[33]

Secondary outcomes include anxiety, stress, health-related quality of life, loneliness, perception of partner support, self-rated parenting, child health and development, infant feeding and health service use (table 2).

Covariates: demographic data, for example, parity, mode of birth, employment, income, alcohol and drug use.

Maternal perceptions of peer support: The Peer Support Evaluation Inventory, a 4-sub-scale self-report tool, 5-point Likert-type scale[23] will assess supportive interactions (15 items), relationship qualities (31 items), perceived benefits (27 items), and satisfaction with peer support (14 items) in the intervention arm. This will be explored *after* outcomes have been assessed by telephone at 6 months, to maintain blinding in the 6-month telephone interview.

Table 2 Secondary outcome measures in detail

Trial outcome	Measurement
Secondary outcomes (measured at 6 months and 12 months postpartum)	
Anxiety: Symptoms of anxiety in the moderate-to-high range	Proportion of women scoring more than 9 on Depression Anxiety Stress Scales-21 (DASS-21) Anxiety Scale (where multiplying the score by 2)[41] Moderate (10–14), severe (15–19) and extremely severe (≥20). DASS–21[41] is a self-report 21-item scale (a set of three 7-item sub-scales, 4-point ratings, range 0–3 Likert type score) designed to measure the negative emotional states of depression, anxiety and stress. Only the sub-scales of anxiety and stress will be included given we are using the EPDS to measure depressive symptomatology. The sub-scales and full DASS-21 have high internal consistency and concurrent validity.[42]
Stress: Symptoms of stress in the moderate-to-high range	Proportion of women scoring more than 18 on DASS-21 Stress Scale (where multiplying the score by 2)[41] Moderate (19–25), severe (26–33) and extremely severe (≥34).
Health-related quality of life	Comparison of self-reported health-related quality of life using the EuroQol 5D-3L (EQ-5D-3L), a preference-based measure of health status and a key component of cost-utility analysis.[43] This includes 5-item descriptive questions and a visual analogue scale (EQ VAS).
Loneliness	Comparison of mean score for self-reported feelings of loneliness and social isolation measured using short version of UCLA Loneliness Scale (V.3), a 10-item scale, each with 4-point ratings, ranging from 1 to 4.[44]
Perception of partner support	Comparison of self-reported assessment of partner support, measured using the Postpartum Partner Support Scale, a 25-item scale, 4-point ratings, ranging from 25 to 100.[45]
Self-rated parenting	Comparison of self-reported: (a) a single item global rating of the *parent's perception of themselves as being a 'good' parent,* ranging from '1' being a 'Not very good' parent to '5' being a 'Very good' parent[46]; (b*) parents' confidence*, measured using four items (scoring from 1 to 10) which are summed and averaged to give a total score ranging from 1 to 10; (c*) parental warmth,* measured using six items (scoring from 1 to 5), assessing parents' expression of warmth, affection and enjoyment with the child and (d*) parental irritability*, measured using five items (scoring from 1 to 5) about frequency of parental anger and irritability toward the child. Items (b), (c) and (d) use the Longitudinal Study of Australian Children (LSAC) brief self-report scales modified and validated for the Australian setting.[47]
Child health and development	Comparison of self-reported: (a) any child health problems and hospital visits/admissions since birth; (b) infant temperament, using four items relating to settling the baby (eg, soothing), and baby behaviour (eg, crying), with scores being averaged across four items.[48]
Infant feeding	Feeding in last 24 hours and since birth, including 'any' and 'only' breast milk feeding for both timepoints.[36 49 50]

Continued

Table 2 Continued

Trial outcome	Measurement
Health service use	Comparison of self-reported health service use using questions adapted from the Patient Cost Questionnaire[51], including the use of community-based services (eg, GP consultations, psychiatric consultations, psychological counselling), routine and additional visits with MCHNs, prescription medication use, ambulance and hospital-provided health service use (eg, hospital admissions, emergency department presentations, ambulance use) since birth. Resources used in intervention delivery, including hours of volunteer input and consultations with the trial psychiatrist, will be recorded by project staff and peer activity logs. Resource and service use will be costed using existing, published unit costs (eg, Medicare Benefits Schedule, National Hospital Cost Data Collection). An economic cost for volunteer time will be imputed based on average wage rates. Training costs will be treated as a capital item with the total cost annuitised over time.
Intervention delivery (measured after 6 months postpartum)	
Maternal perceptions of peer support	Assessment of supportive interactions, relationship qualities, perceived benefits and satisfaction with peer support using the Peer Support Evaluation Inventory.[23]
Peer volunteer perceptions	Assessment of programme training and expectations; interactional characteristics; volunteer role; intrapersonal effects; and recruitment and retention using the Peer Volunteer Experience Questionnaire.[35]
Peer volunteer activities	Peer support activities (number and length of calls; broad content of each discussion), documented by peers using the Peer Volunteer Activity Log.[32]

EPDS, Edinburgh Postnatal Depression Scale; MCHN, maternal and child health nurse.

Peer volunteer perceptions: all volunteers will complete an enrolment form to collect demographic characteristics, reasons for volunteering, willingness to have a criminal check and availability for volunteering, and will include the Kessler 10[34] to check current emotional wellbeing. After the 4-hour training session, volunteers will complete a survey to assess preparedness, if the training was useful and if they needed other information. A final survey adapted from the Peer Volunteer Experience Questionnaire[35] will be administered by postal survey (or online) when a peer completes study participation. Questions assess motivation to volunteer, experience of being a volunteer (including interactional characteristics, challenges, satisfaction, positive or negative effects on them as a person) and questions related to retention and sustainability. Interviews or focus groups will also be conducted with a small group of volunteers after trial conclusion for a more in-depth understanding.

Table 2 describes measures for secondary outcomes and intervention delivery in more detail.

Intervention fidelity

Data collected will include volunteer allocation monitoring and mothers' reports. Peer support activities (eg, number and length of calls, broad content of each discussion) will be documented by the peers using the Peer Volunteer Activity Log.[32] Nature and intensity of the peer support will be assessed using this log.

Sample size considerations

Victorian population-based data show that 17% of women have probable depression at 6 months postpartum.[2] Our sample will be women screened in the early postpartum period who are at increased risk to develop postnatal depression, so likely to have higher than population levels of depression 6 months postpartum. Taking this into account, we estimate that 25% of women in the control group will have probable depression (score >12 on the EPDS) at 6 months postpartum. To detect a decrease of 8% (ie, to the population rate of 17%), based on a more conservative estimate than the decrease found in the Canadian trial,[20] given there is a higher level of primary MCH care offered in Australia, with 80% power, and a two tailed α of 0.05, a sample of 862 (431/group) is required. Allowing 15% loss to follow-up (based on 90% retention for telephone interviews at 6 months postpartum[36]), 1014 (507/group) women are needed. To account for the potential clustering effect of peer volunteers (ie, the possibility that outcomes among women with the same peer volunteer may be correlated), we estimate

an intracluster correlation (ICC) of 0.03, based on our recently completed cluster RCT in the same population,[37] to inflate the sample size to allow for this adjustment in the outcome analysis. The variance inflation factor (IF=1+(m-1)×ICC [where m=average cluster size, that is, average number of women supported by each volunteer]) was calculated as 1.045 =(1+(2.5-1)×0.03). Thus, the final required sample size is 1060 (1014×1.045) (530/group), which also allows detection of clinically meaningful differences in all secondary outcomes.

Timeline

With an estimated study uptake of 30% of eligible women offered participation (based on our previous RCTs and study feasibility work), we expect recruitment to be completed in 24–36 months. To achieve this, we will need an adequate pool of peer volunteers. Based on our current RCT of telephone peer support for increasing breastfeeding,[36] we expect to recruit and train 15 to 20 peer volunteers per month, with recruitment increasing over time. We expect an overall number of approximately 220 volunteers to support 530 women in the intervention group (supporting 2 to 3 women on average).[20 36] Participant recruitment commenced in May 2019 with significant COVID-related delays. The study is expected to conclude by 2026.

Data management and analysis

CONSORT guidelines will be followed. Participant data will be collected by structured interviews, entered directly into REDCap electronic data capture tool,[38] then transferred to Stata V.17[39] for analysis. We will check baseline comparability of the groups, then compare the intervention group with the control group for all trial hypotheses using intention-to-treat analyses.

Primary outcome: the proportion of women scoring >12 on the EPDS at 6 months will be compared for the primary outcome. Relative risks (RR) and 95% confidence intervals will be estimated. Regression analyses will adjust for potential clustering, all stratification variables, and for any differences in key demographic characteristics at baseline. RR will be estimated using log-binomial models (or Poisson regression in the case of non-convergence) and clustering accounted for using cluster-robust standard errors.

Secondary outcomes: comparison of means will be undertaken using t-tests where data are normally distributed, or otherwise medians compared using non-parametric tests. Validated scales will be analysed per published instructions. Pearson's correlations will explore the relationship between frequency of peer volunteer contacts and maternal depressive symptoms.

Cost-effectiveness analyses will report both health funder and social perspectives. A cost-consequences analysis will present the incremental costs of the intervention (costs of intervention and health service use over the period of follow-up, minus costs accrued in the control arm) alongside a profile of all outcomes.[40] A cost-effectiveness analysis will then compare incremental costs per case of probable depression avoided as well as cost per quality-adjusted life year gained, using data from the measure of health-related quality of life. Future costs and benefits will be discounted at 3%. Probabilistic sensitivity analysis will explore consequences of uncertainty.

Risk considerations

Participants: a protocol will guide the support of any mother with a positive response on the EPDS self-harm ideation item (item 10), both at recruitment and at the 6 month data collection point. Likewise for any woman scoring >20 on the EPDS at recruitment or 6 months. In both instances, the woman will be offered assistance to seek support and asked for permission to inform their midwife, MCHNs, GP or suitable health provider. Women who disclose IPV to peer volunteers or whose mental health deteriorates during the telephone support period will be referred to appropriate support services and continue in the study unless they choose not to.

Peer volunteers: training will include information on when to refer mothers to professional services, and clear guidelines regarding responding to disclosure of self-harm thoughts and IPV as well as boundary-setting to protect peer volunteers from participant's potential overdependence. The volunteer coordinator will provide regular support and supervision to peer volunteers, monitor their well-being and institute appropriate referrals if required. The study perinatal psychiatrist will provide clinical supervision for the peer volunteers as needed, and be available for consultation and referral.

Data and Safety Monitoring Committee

A Data Safety and Monitoring Committee (DSMC) will be convened to safeguard the interests of trial participants, monitor statistical aspects and protect the credibility and conduct of the trial. The DSMC will review the progress and accruing data of the study, provide advice on safety and conduct of the trial and review reports of serious adverse events in both trial arms to identify possible contributing factors related to participation in the trial. The DSMC will include at least a statistician, a perinatal psychiatrist and an experienced senior clinician with relevant experience.

Patient and public involvement

Acceptability and feasibility of telephone-based peer support for mothers at risk of postnatal depression were established through interviews with new mothers from proposed recruitment sites, focus groups with MCHNs from three LGAs and from data collected from volunteers who provided peer support as part of a breastfeeding trial. The handbook, training materials and support protocol for volunteers were developed in consultation with PANDA, the peak perinatal consumer body in Australia.

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