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[Intervention Protocol]

Mobile health (m-health) technological support for women during pregnancy or the first six weeks postpartum, or both

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ABSTRACT

Objectives

This is a protocol for a Cochrane Review (intervention). The objectives are as follows:

To assess maternal and newborn clinical and psychological outcomes where mobile health (m-health) technological support was given during pregnancy or the first six weeks post birth, or both, compared with different methods of m-health or no health support (usual care).

BACKGROUND

This Cochrane Protocol supersedes a published Cochrane Review 'Telephone support for women during pregnancy and the first six weeks postpartum' (Lavender 2013). The previous review focused exclusively on the effects of telephone support during pregnancy and the first six weeks post birth. Given the rapid developments in digital health technology (WHO 2019), this current review plans to broaden its focus and will include client-targeted mobile health (m-health) interventions in addition to telephone support.

Digital technologies, including electronic devices, tools, and systems, for health delivery are now making a significant contribution to addressing health needs across the globe. As such, the growing importance of digital health has been recognised throughout medical and public health settings. In particular, the widespread potential for digital health in low- and middle-income countries has been noted, where mobile technologies are able to overcome the geographical inaccessibility of health care (WHO 2019).

M-health, a subset of digital health, is the use of mobile wireless technologies (WHO 2021). M-health technology is a fast-developing communication system used in consumer and health-professional interactions (Gagnon 2016; Kumar 2013). Though m-health is still relatively new, it is already transforming healthcare delivery (Mbuthia 2019; Sondaal 2016). Mobile devices used in health care offer new means of communication between healthcare providers and users (Afarikumah 2014; Modi 2013; Noordam 2011). Health care delivered in this way offers potential advantages over face-to-face, as support can be delivered wherever the person is located, and whenever it is needed (Davey 2014; Lee 2016; Smith 2015). Consequently, the use of the smartphone is increasingly being integrated and accepted in health care, and used to complement other more traditional delivery of interventions (Mosa 2012; Roland 2019), including those improving maternal outcomes in the antenatal, intrapartum, and postnatal period (Benski 2020; Schiffman 2010). As a consequence, we have seen the growing emergence of m-health (Bradway 2017; Steinhubl 2015), recognising its potential to transform the face of health service delivery globally (WHO 2011; WHO 2019).

Description of the condition

Pregnancy and childbirth is a significant life event, which involves physical and psychosocial changes that often require additional support from routinely-offered care. This support can be provided to address different needs, including information for decision-making, adaptation to parenting, and behaviour change. Increasingly, m-health (smart-phones, tablets, and other mobile devices) have been used to provide this support with the aim of improving clinical and psychological outcomes.

Description of the intervention

Technologies used in m-health include mobile devices, such as different types of mobile and smartphones, portable computers (tablets), personal digital assistants, and other wireless handheld devices (Free 2010; Free 2013; WHO 2011). M-health involves the use of the mobile and smartphones functionality of voice and short messaging service (SMS), as well as more complex applications including Bluetooth technology, global positioning system (GPS), third- and fourth- generation mobile telecommunications (3G and 4G systems), and general packet radio service (GPRS) (WHO 2011). M-health presents itself in different ways. The most common digital health applications for m-health include: educational information, medication adherence, health promotion, alerts/reminders for clinical care attendance, disease diagnosis, and treatment support (Osei 2020). M-health support may be passive, whereby support is only available when requested, or it may be proactively offered. The medium for the support may be text messaging (Jareethum 2008; Lee 2016), or verbal communication (Oyeyemi 2014). Scheduled and unscheduled voice and SMS interactions have also been frequently reported (Gallegos 2014; Knight 2015; Tahir 2013; Wagnew 2018). Furthermore, support may be offered by a healthcare professional or a lay person (Gavine 2022; Jennings 2013). M-health may target a particular sample population with the commonality of a particular medical condition, for example diabetes (Johnson 2018), or it may be used in health promotion in the antenatal period (Lau 2014).

How the intervention might work

Within maternity care, m-health support has been provided in the antenatal and postnatal periods. In the antenatal period, m-health has been used to support women in different ways including: to assist pregnant women with smoking cessation (Rodgers 2005; Sloan 2017; Solomon 2005); to support women at risk of preterm birth (Moore 2004); improve the quality of antenatal care (Benski 2020); and as a means of conducting maternity triage (Kennedy 2007). The potential psychosocial benefits of m-health for pregnant women have also been explored (Bullock 1995; Jareethum 2008), offering some confirmation of benefit.

In the postnatal period, telephone 'hotlines' and text messaging have grown in popularity, partly in response to early hospital discharge policies, in an attempt to provide continuity and support to parents (Cormick 2012; Rush 1991; Siegel 1992). These 'hotlines' appear to be valued by women, particularly for advice on breastfeeding and newborn care (Alam 2017; Gallegos 2014; Osman 2010). Some of these services included other aspects of m-health and were established exclusively as means of providing infant feeding support (Chamberlain 2005; Jiang 2014; Wang 2008), while others focused on mothers who were considered to be at risk of complications, for example, following caesarean birth (David 2010).

Why it is important to do this review

There is a growing body of work presenting the use of m-health and its potential to revolutionise healthcare provision (WHO 2011; WHO 2019). Evidence has demonstrated m-health is fast becoming an integral tool in mother and health worker communication (Kabongo 2021; Sakamoto 2022). Given the global increase in mobile network coverage and Internet use (ITU 2020), this trend is likely to continue. However, with this rapid expansion comes the need to evaluate their contribution to health care to ensure that such interventions do not either cause harm or inappropriately divert resources from non-digital approaches (WHO 2019).

Of importance is the profound impact that the COVID-19 pandemic has had on the digital landscape worldwide (Adepoju 2020; Whitelaw 2020). With lockdown measures disrupting the traditional pathways for care, including restricting in-person clinical consultations, the COVID-19 pandemic has brought about new challenges for healthcare workers and service users (Iyengar

2020). Furthermore, we have seen a substantial increase in the likelihood of depression and anxiety in pregnant and postpartum women during the COVID-19 pandemic (Davenport 2020). As a consequence, alternative information technologies, such as m-health and the use of the smartphone, have become critical to identify beneficial, safe, remotely-delivered health care (Wu 2020).

The evidence from Cochrane Reviews related to the topic of this Cochrane Review can be summarised as follows: Dennis 2013 evaluated psychosocial and psychological interventions for preventing postpartum depression. They found a limited number of studies evaluating telephone support and concluded telephone-based support provided by a peer amongst new mothers with beginning depressive symptomatology early in the postpartum period appears to be a promising secondary preventative intervention and concluded that further research was needed (Dennis 2013).

A more recent Cochrane Review assessed the effects of programmes offering additional social support compared with routine care, for pregnant women at high risk of giving birth to babies that are either preterm (less than 37 weeks' gestation) or weigh less than 2500 g, or both (East 2019). Examples of the additional social support included information, home visits, telephone calls, and stress management. The review authors concluded that while programmes offering additional social support during pregnancy are unlikely to have a large impact on the proportion of low birthweight babies or birth before 37 weeks' gestation and no impact on stillbirth or neonatal death, they may be helpful in reducing the likelihood of caesarean birth and antenatal hospital admission. However, disaggregated data for telephone use only were not presented.

In the same year, a qualitative evidence synthesis on perceptions and experiences of targeted digital communication, accessible via mobile devices, provided a summary of participants' views on acceptability and preferences, technical access, content preferences, confidentiality, and programme impact (Ames 2019).

Our published 2013 Cochrane Review focused on telephone support exclusively (Lavender 2013). The review included 27 trials and concluded that despite some encouraging findings, there was insufficient evidence to recommend routine telephone support for women accessing maternity services, as the evidence from included trials was neither strong nor consistent. Although benefits were found in terms of reduced depression scores, breastfeeding duration, and increased overall satisfaction, the included trials did not provide strong enough evidence to warrant investment in resources. Reviewing the evidence of m-health technological support on maternal and newborn clinical and psychological outcomes will not only complement the evidence from previous reviews, but also enhance our understanding of the broader scope on client targeted m-health interventions.

OBJECTIVES

To assess maternal and newborn clinical and psychological outcomes where mobile health (m-health) technological support was given during pregnancy or the first six weeks post birth, or both, compared with different methods of m-health or no health support (usual care).

METHODS

Criteria for considering studies for this review

Types of studies

Eligible study types are randomised controlled trials (RCTs) and cluster-RCTs. We will include studies published in abstract form only, as well as eligible unpublished data obtained directly from trial investigators. We will exclude trials of cross-over study design and quasi-randomised trials.

Types of participants

Pregnant women, or postnatal women in the first six weeks post birth, or both.

Types of interventions

We will include studies that use client-targeted m-health interventions, whereby the client receives the intervention directly, as opposed to interventions targeted at the healthcare provider, health systems, or data services (WHO 2019). Interventions specific to clients are classified as those relating to targeted communication and client-to-client communication. Targeted client communication includes the transmission of health event alerts and health information by the healthcare provider at the individual level. In contrast, client-to-client communication comprises communication between clients as peers within an organised network/group (WHO 2019).

As such, interventions aimed at supporting women (at the individual level) by using either targeted communication and client-to-client communication m-health, whether for general pregnancy support/information or for a specific medical/social reason (e.g. diabetes, smoking, breastfeeding) will be included in the review. Additionally, we will include studies where the intervention is introduced in pregnancy, or in the first six weeks post birth, or both. The intervention may, or may not, have extended from the antenatal to postnatal period. Interventions may be in any setting and delivered by healthcare staff, peer supporters, or using automated messaging.

We will not include studies presenting m-health interventions targeted at healthcare providers, health system or resource managers, or for data services (WHO 2019).

Comparisons will include:

- Different methods of m-health support versus usual care (no intervention).
- Comparison of different methods of m-health support.
- Different methods of m-health support versus any other active intervention (e.g. peer support).
- Same m-health support versus different intensity (dosage).

Types of outcome measures

We will examine the effect of m-health technological support on maternal and newborn clinical and psychological outcome measures.

All outcomes will be measured during pregnancy and within the first six months postpartum (as defined by trial authors).

Primary outcomes

- Serious morbidity (as defined by trial authors, e.g. haemorrhage, hypertension, obstructed labour).
- Maternal anxiety during pregnancy or the first six months postpartum, or both, using a validated scale, e.g. Hospital Anxiety and Depression Scale, Generalised Anxiety Disorder 7-item (GAD-7), Generalised Anxiety Disorder 2-item (GAD-2).
- Maternal depression during pregnancy or the first six months postpartum, or both, using a validated scale, e.g. Hospital Anxiety and Depression Scale, the Edinburgh Postnatal Depression Scale (EPDS).

Maternal outcomes

- Mother-infant attachment (e.g. The Mother-Infant Bonding Questionnaire (MIBQ), Maternal Postnatal Attachment Scale (MPAS)).
- General health (e.g. as defined by standardised measures, such as EQ 5-D general health status questionnaire).
- Fear of birth (e.g. Wijma Delivery Expectancy/Experience Questionnaire (W-DEQ), Fear of Birth Scale (FOBS) a two-item visual analogue scale).
- Maternal death.
- Maternal satisfaction with m-health support during pregnancy and the first six months postpartum (e.g. scale for measure maternal satisfaction in normal birth).
- Health service utilisation (presentation/attendance at clinics, accident and emergency departments, or general practices).
- Positive behaviour change (e.g. smoking reduction).

Infant outcomes

- Preterm birth/low birthweight.
- Proportion of women exclusively/any breastfeeding up to six weeks postpartum.
- Infant developmental measures (physical and cognitive).
- Neonatal/infant mortality.
- Major neonatal/infant morbidity (e.g. prolonged admission to special care baby unit).

Service

- Intervention cost.

Search methods for identification of studies

Electronic searches

We will search the current version of Cochrane Pregnancy and Childbirth's Trials Register in collaboration with their Information Specialist.

The Register is a database containing over 34,000 reports of controlled trials in the field of pregnancy and childbirth. It represents over 30 years of searching. For full current search methods used to populate Cochrane Pregnancy and Childbirth's Trials Register including the detailed search strategies for CENTRAL, MEDLINE, Embase, and CINAHL; the list of handsearched journals and conference proceedings; and the list of journals reviewed via the current awareness service, please follow this link.

Briefly, Cochrane Pregnancy and Childbirth's Trials Register is maintained by their Information Specialist and contains trials identified from the following.

1. Monthly searches of the Cochrane Central Register of Controlled Trials (CENTRAL).
2. Weekly searches of MEDLINE (Ovid).
3. Weekly searches of Embase (Ovid).
4. Monthly searches of CINAHL (EBSCO).
5. Handsearches of 30 journals and the proceedings of major conferences.
6. Weekly current awareness alerts for a further 44 journals plus monthly BioMed Central email alerts.

Two people screen the search results, and the full text of all relevant trial reports identified through the searching activities described above is reviewed. Based on the intervention described, each trial report is assigned a number that corresponds to a specific Pregnancy and Childbirth review topic (or topics), and is then added to the Register. The Information Specialist will search the Register for this review using this topic number rather than keywords. This results in a more specific search set that will be fully accounted for in the relevant review sections (Included, Excluded, Awaiting Classification, or Ongoing).

In addition, we will search ClinicalTrials.gov and the World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) for unpublished, planned, and ongoing trial reports. The search methods we plan to use are in Appendix 1.

Searching other resources

We will search the reference lists of retrieved studies.

We will not apply any language or date restrictions.

Data collection and analysis

Selection of studies

At least two review authors will independently assess for inclusion all the potential studies we identify as a result of the search strategy. We will resolve any disagreement through discussion or, if required, we will consult a third review author.

We will create a PRISMA flow diagram to map out the number of records identified, included, excluded, or awaiting classification.

Two review authors will evaluate all studies that meet our inclusion criteria against predefined criteria to select studies that, based on available information, are deemed to be sufficiently trustworthy to be included in the analysis. Cochrane Pregnancy and Childbirth has developed a Trustworthiness Screening Tool (CPC-TST) which includes the following criteria.

Research governance

- Are there any retraction notices or expressions of concern listed on the Retratction Watch Database relating to this study?
- Was the study prospectively registered (for those studies published after 2010)? If not, was there a plausible reason?
- When requested, did the trial authors provide/share the protocol or ethics approval letter, or both?

- Did the trial authors engage in communication with the Cochrane Review authors within the agreed timelines?
- Did the trial authors provide individual participant data (IPD) upon request? If not, was there a plausible reason?

Baseline characteristics

- Is the study free from characteristics of the study participants that appear too similar (e.g. distribution of the mean (standard deviation (SD)) excessively narrow or excessively wide, as noted by Carlisle 2017)?

Feasibility

- Is the study free from characteristics that could be implausible (e.g. large numbers of women with a rare condition (such as severe cholestasis in pregnancy) recruited within 12 months)?
- In cases with (close to) zero losses to follow-up, is there a plausible explanation?

Results

- Is the study free from results that could be implausible (e.g. massive risk reduction for main outcomes with small sample size)?
- Do the numbers randomised to each group suggest that adequate randomisation methods were used (e.g. is the study free from issues such as unexpectedly even numbers of women 'randomised' including a mismatch between the numbers and the methods, if the authors say 'no blocking was used' but still end up with equal numbers, or if the authors say they used 'blocks of 4' but the final numbers differ by 6)?

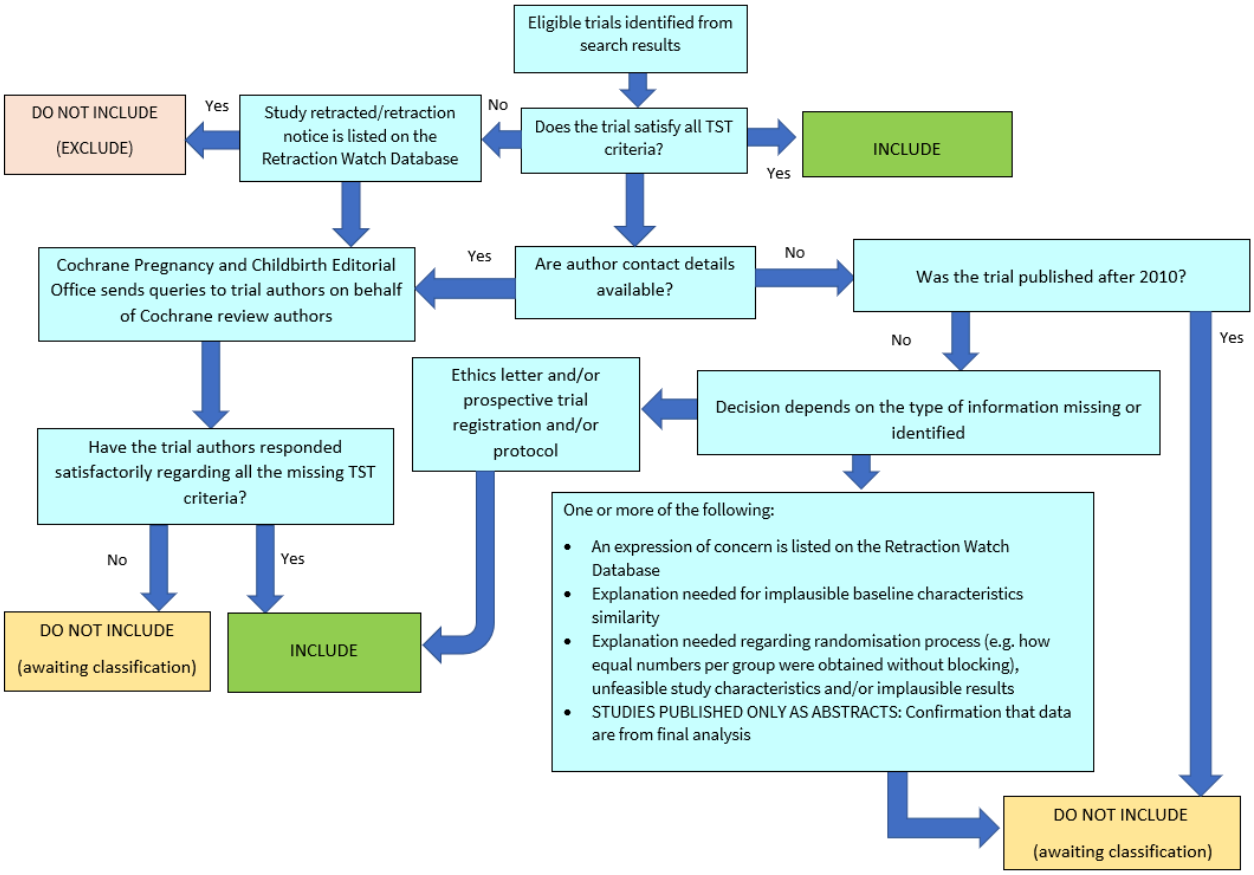
We will exclude studies assessed as being potentially 'high risk' from the review. Where we classify a study as 'high risk', we will attempt to contact the study authors to address any possible lack of information/concerns. In cases where we do not obtain contact details for the study authors or where adequate information remains unavailable, the study will remain in the 'awaiting classification' section, and we will describe in detail the reasons and communications with the trial author (or lack of).

Abstracts

We will only include data from abstracts if, in addition to the trustworthiness assessment, the study authors have confirmed in writing that the data to be included in the review have come from the final analysis and will not change. If such information is not available/provided, the study will remain in 'awaiting classification' (as above).

See Figure 1 for details of how to apply the trustworthiness screening criteria.

Figure 1. Applying the Cochrane Pregnancy and Childbirth Trustworthiness Screening Tool



Data extraction and management

We will design a form to extract data. For eligible studies, at least two review authors will independently extract the data using the agreed form. We will resolve discrepancies through discussion, or, if required, through consultation with a third review author. We will enter data into Review Manager 5 software (RevMan 5) and check for accuracy (RevMan 2020). When information regarding any of the above is unclear, we will attempt to contact authors of the original reports to provide further details.

Assessment of risk of bias in included studies

At least two review authors will independently assess risk of bias for each outcome specified below using version 2 of the Cochrane 'Risk of bias' tool for randomised trials (RoB 2), outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2020). We will resolve any disagreement by discussion or by involving other review authors in case of disagreement. This review will assess the effect of assignment. We will use the RoB 2 Excel tool to manage the assessment of bias.

All outcomes will be measured during pregnancy or within the first six months postpartum, or both.

- Serious morbidity (e.g. haemorrhage, hypertension, obstructed labour).
- Maternal anxiety during pregnancy or the first six months postpartum, or both (e.g. Hospital Anxiety and Depression Scale, GAD-7, GAD-2).
- Maternal depression during pregnancy or the first six months postpartum, or both (e.g. Hospital Anxiety and Depression Scale, the EPDS).
- Mother-infant attachment (e.g. MIBQ, MPAS).
- General health (e.g. as defined by standardised measures, such as the EQ 5-D general health status questionnaires).
- Preterm birth/low birthweight.
- Infant developmental measures (physical and cognitive).
- Proportion of women exclusively/any breastfeeding up to six weeks postpartum.

In response to a series of signalling questions, and facilitated by the RoB 2 algorithm, we will make a judgement about risk of bias for the domains of bias arising from the randomisation process, bias due to deviations from the intended intervention, bias due to missing outcome data, bias in measurement of the outcome, bias in selection of the reported result, classified as:

- low risk of bias;
- some concerns; or
- high risk of bias.

The overall risk of bias for the study will be determined as:

- low risk of bias (the trial is judged to be at low risk of bias for all domains);
- some concerns (the trial is judged to raise some concerns in at least one domain, but not to be at high risk of bias for any domain); or
- high risk of bias (the trial is judged to be at high risk of bias in at least one domain, or the trial is judged to have some concerns for multiple domains in a way that substantially lowers confidence in the result).

For cluster-RCTs, we will use the extension of the RoB 2 tool to cluster trials, which includes the additional domain bias arising from the timing of identification or recruitment of participants in a cluster-RCT (Sterne 2019).

Measures of treatment effect

Dichotomous data

For dichotomous data, we will present results as summary risk ratio with 95% confidence intervals (CIs).

Continuous data

For continuous data, we will use the mean difference if outcomes are measured in the same way between trials. We will use the standardised mean difference to combine trials that measure the same outcome, but use different methods and then convert this to a common scale following guidance in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2019).

Cluster-randomised trials

Cluster-randomised trials are eligible for inclusion in the analyses along with individually-randomised trials. The adapted RoB 2 tool for cluster-randomised trials will be used. We will adjust their standard errors using the methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011), using an estimate of the intracluster correlation coefficient (ICC) derived from the trial (if possible), from a similar trial or from a study of a similar population.

If we use ICCs from other sources, we will report this and conduct sensitivity analyses to investigate the effect of variation in the ICC. If we identify both cluster-randomised trials and individually-randomised trials, we plan to synthesise the relevant information. We will consider it reasonable to combine the results from both if there is little heterogeneity between the study designs and the interaction between the effect of intervention and the choice of randomisation unit is considered to be unlikely.

We will also acknowledge heterogeneity in the randomisation unit and perform a sensitivity analysis to investigate the effects of the randomisation unit.

Cross-over trials

Cross-over trials are not eligible for inclusion.

Other unit of analysis issues

Trials in pregnancy and childbirth may include outcomes for multiple pregnancies. For studies including multiple pregnancies, we will treat the infants as independent and will note the effects of estimates on CIs. If we identify trials with more than two treatment groups, we will only report on the arms relevant to this Cochrane Review. Where there are multiple arms that are relevant to the review, we will combine groups to create a single pairwise comparison. This will be noted in the 'Characteristics of included studies' table.

Dealing with missing data

For included studies, we will note levels of attrition. We will explore the impact of including studies with high levels of missing data in the overall assessment of treatment effect by using sensitivity analysis following guidance for RoB 2 (Higgins 2019).

For all outcomes, we will carry out analyses, as far as possible, on an intention-to-treat basis, i.e. we will attempt to include all participants randomised to each group in the analyses, and we will analyse all participants in the group to which they were allocated, regardless of whether they received the allocated intervention or not. The denominator for each outcome in each trial will be the number randomised minus any participants whose outcomes are known to be missing.

Assessment of heterogeneity

We will assess statistical heterogeneity in each meta-analysis by visual inspection of the forest plot and by using the Tau^2, I^2, and Chi^2 statistics. We will regard heterogeneity as substantial if I^2 is greater than 30% and either Tau^2 is greater than zero, or there is a low P value (less than 0.10) in the Chi^2 test for heterogeneity.

Assessment of reporting biases

If there are 10 or more studies included in the meta-analysis, we will investigate reporting biases (such as publication bias) using funnel plots. We will assess funnel plot asymmetry visually. If asymmetry is suggested by a visual assessment, we will perform exploratory analyses to investigate it.

Data synthesis

We will carry out statistical analysis using RevMan 2020 software. We will use fixed-effect meta-analysis for combining data where it is reasonable to assume that studies are estimating the same underlying treatment effect, i.e. where trials are examining the same intervention, and the trials' populations and methods are judged sufficiently similar. If there is clinical heterogeneity sufficient to expect that the underlying treatment effects differ between trials, we will use random-effects meta-analysis to produce an overall summary if an average treatment effect across trials is considered clinically meaningful. The random-effects summary will be treated as the average of the range of possible treatment effects, and we will discuss the clinical implications of treatment effects differing between trials. If the average treatment effect is not clinically meaningful, we will not combine trials.

The results will be presented as the average treatment effect with 95% CIs, and the estimates of Tau^2 and I^2.

Subgroup analysis and investigation of heterogeneity

If we identify substantial heterogeneity, we will investigate it using subgroup analyses. We will consider whether an overall summary is meaningful, and if it is, use random-effects analysis to produce it.

We plan to carry out the following subgroup analyses.

- Health professional support versus lay support.
- Low-resource versus high-resource settings.
- M-health used to provide general support versus m-health for a specific medical/social reason (e.g. diabetes, smoking, breastfeeding).

The following outcomes will be used in subgroup analysis. All outcomes will be measured during pregnancy or within the first six months postpartum, or both.

- Serious morbidity, maternal anxiety, and maternal depression.

We will assess subgroup differences by interaction tests available within RevMan 2020. We will report the results of subgroup analyses quoting the Chi^2 statistic and P value, and the interaction test I^2 value.

Sensitivity analysis

The following outcomes will be subject to sensitivity analysis. All outcomes will be measured during pregnancy or within the first six months postpartum, or both.

- Serious morbidity (e.g. haemorrhage, hypertension, obstructed labour)
- Maternal anxiety during pregnancy or the first six months postpartum, or both, and maternal depression during pregnancy or the first six months postpartum, or both

We will undertake sensitivity analyses to explore the effects of fixed-effect versus random-effects analyses for outcomes with statistical heterogeneity, as well as the effects of exclusion of studies with a determined overall higher risk of bias (high risk of bias in at least one domain for this result, or some concerns for multiple domains in a way that substantially lowers confidence in the result) and the effects of varying assumptions regarding the ICC of cluster-randomised trials.

Summary of findings and assessment of the certainty of the evidence

We will assess the certainty of the evidence using the GRADE approach, as outlined in the GRADE handbook (Schünemann 2013), in order to assess the certainty of the body of evidence relating to the following outcomes.

All outcomes will be measured during pregnancy or within the first six months postpartum, or both.

- Serious morbidity (as defined by trial authors, e.g. haemorrhage, hypertension, obstructed labour).
- Maternal anxiety during pregnancy or the first six months postpartum, or both (e.g. Hospital Anxiety and Depression Scale, GAD-7, GAD-2).
- Maternal depression during pregnancy or the first six months postpartum, or both (e.g. Hospital Anxiety and Depression Scale, the EPDS).
- Mother-infant attachment (e.g. MIBQ, MPAS).
- Preterm birth/low birthweight.
- Proportion of women exclusively/any breastfeeding up to six weeks postpartum.
- Infant developmental measures (physical and cognitive).

Where data are available, we plan to use GRADE to assess the overall certainty of the evidence for our main comparisons.

- Different methods of m-health support versus usual care (no intervention).
- Comparison of different methods of m-health support.

- Different methods of m-health support versus any other active intervention (e.g. peer support).
- Same m-health support versus different intensity (dosage).

We will use the GRADEpro Guideline Development Tool (GRADEpro GDT) to import data from RevMan 2020 in order to create summary of findings tables. A summary of the intervention effect and a measure of quality for each of the above outcomes will be produced using the GRADE approach. The GRADE approach uses five considerations (overall risk of bias, consistency of effect, imprecision, indirectness, and publication bias) to assess the certainty of the body of evidence for each outcome. The evidence can be downgraded from 'high certainty' by one level for serious (or by two levels for very serious) limitations, depending on assessments for risk of bias, indirectness of evidence, serious inconsistency, imprecision of effect estimates, or potential publication bias.

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As part of the peer review process, this protocol has been peer reviewed by two content peer reviewers (an editor and a referee external to the editorial team), a member of Cochrane Pregnancy and Childbirth's international panel of consumers, and the Group's Statistical Adviser. The authors are grateful to the peer reviewers for their time and comments.

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APPENDICES

Appendix 1. Draft search strategy for ClinicalTrials.gov and WHO ICTRP

ClinicalTrials.gov

Advanced search

Interventional Studies | Pregnancy | mhealth (searches mobile health)

Interventional Studies | Pregnancy | telephone (searches phone)

Interventional Studies | Pregnancy | ehealth (searches telehealth)

Interventional Studies | Pregnancy | messaging

Interventional Studies | Pregnancy | sms

Interventional Studies | Pregnancy | computer

Each line will be run separately and will be re-run substituting the term 'pregnancy' with each of the five terms below:

prenatal

antenatal

postnatal

postpartum

pregnant

WHO ICTRP

(set to search all synonyms)

pregnancy AND mhealth

pregnancy AND ehealth

pregnancy AND e-learning

pregnancy AND computer

pregnancy AND messaging

pregnancy AND phone

Each line will be run separately and will be re-run substituting the term 'pregnancy' with each of the five terms below:

prenatal

antenatal

postnatal

postpartum

pregnant

CONTRIBUTIONS OF AUTHORS

Tina Lavender contributed to and approved the final protocol version.

Rebecca MD Smyth contributed to and approved the final protocol version.

Angela F Chimwaza contributed to and approved the final protocol version.

Tracey A Mills contributed to and approved the final protocol version.

Kerry Dwan contributed to and approved the final protocol version.

DECLARATIONS OF INTEREST

Tina Lavender: supervisor of a PhD student who received donor funding to test a postnatal telephone intervention for adolescents carried out at The University of Manchester. Principal Investigator (PI) of an ongoing NIHR-funded study (PANDA App), an antenatal mobile technology to support antenatal care in Tanzania. The preliminary research, which commenced January 2022, is being carried out at Liverpool School of Tropical Medicine (LSTM), to inform a cluster-RCT.

Rebecca MD Smyth: investigator of a pilot RCT that is eligible for inclusion in this review (Pilot randomised controlled trial on telephone support intervention among young mothers (teenage mothers) during the immediate postnatal period; Kirop, Campbell, Smyth, Lavender), and therefore will not be involved in evaluating this study. No other relevant conflict of interests.

Angela F Chimwaza: none known.

Tracey A Mills: Co-Investigator of an ongoing NIHR-funded study (PANDA App), an antenatal mobile technology to support antenatal care in Tanzania. The preliminary research, which commenced January 2022, is being carried out at LSTM to inform a cluster-RCT.

Kerry Dwan: is an Editor with Cochrane but has not been involved in the editorial process for this protocol.

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Internal sources

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External sources

- National Institute for Health and Care Research (NIHR), UK

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