INTRODUCTION

Background

Postnatal depression is associated with a range of adverse child outcomes\(^1\)-\(^3\). Furthermore, there is good evidence that caregiving difficulties associated with depressive symptoms play a key role mediating the association between maternal depression and adverse child outcomes\(^4\)-\(^6\). A range of important caregiving practices are adversely affected by postnatal depression including breastfeeding, sleep routines, health check attendances and vaccinations\(^4\). Problems in all of these areas can adversely affect children’s longer-term growth and development. The UK National Institute of Clinical Excellence (NICE) guidelines for ante- and postnatal care highlight that even sub-threshold depressive symptoms can adversely affect mothers’ general functioning and infant development\(^7\). This has led many countries, including Australia, to initiate universal screening programs to identify mothers with depressive symptoms. However, a major ongoing challenge is the very limited availability of support services for mothers who screen positive and difficulty engaging busy new mothers with clinic-based treatment programs.

In 2014, a new NICE guideline specifically advocated for randomised controlled trials (RCTs) focused on mothers experiencing sub-threshold depressive symptoms to test the effectiveness of interventions designed to improve mother-baby relationships in this large group of mothers\(^7\). The aim of this trial is to evaluate a new internet-based intervention that addresses both parenting problems and symptoms of depression, using mobile phone technology to provide easy access for larger numbers of new mothers to both nurse and peer support during the immediate postnatal period.

Two broad approaches have been used to help mothers with symptoms of depression and parenting problems. Commonly these are delivered in separate services and provide supports for either depression or parenting problems. First, community child and family health
services provide help that focuses on: (i) improving maternal parenting skills and self-efficacy, (ii) reducing mother-infant problems, and (iii) supporting maternal health and wellbeing. A significant strength of community services is that they have direct contact with a very high proportion of all mothers during the immediate postnatal period. As such, they are well placed to screen mothers for the presence of problems and to help large numbers of mothers with difficulties in these areas. However, the help provided by these services is limited and largely focuses on caregiving problems rather than maternal depressive symptoms. Additionally, nurse training and confidence needed to manage maternal postnatal depression is often limited. The second approach, which is widely used in mental health services, typically employs psychosocial programs based on cognitive behavioural therapy (CBT) or interpersonal psychotherapy (IPT). However, an important limitation of these programs is that, in contrast to child and family services, they largely focus on maternal depressive symptoms rather than caregiving problems. Furthermore, mental health services often lack the resources to provide help to those with sub-threshold levels of depressive symptoms, reserving treatment for those with serious mental illness. As a result mothers with sub-threshold depressive symptoms can have little or no access to professional services. Postnatal depressive symptoms also have unique triggers, such as the challenges of the transition to a parenting role, time demands required to care for new infants, and the potential for social isolation during this period. Given this, it is not surprising that there is little evidence that current mental health programs have a positive effect on mother-infant problems or longer-term child outcomes.

The intervention tested in this trial is based on evidence that maternal self-efficacy and social support are two key mechanisms influencing the onset, maintenance and impact of maternal postnatal depressive symptoms. Perceptions of self-efficacy influence the extent to which individuals feel that they can cope with demanding life situations and this in turn can shape
affective responses to stressful role changes such as becoming a new mother\textsuperscript{11}. For example, mothers who lack confidence in their ability to settle their distressed infant are more likely to give up quickly, leading to a sense of failure and depressed mood\textsuperscript{10}. They are then more likely to experience persistent infant problems, such as feeding and sleeping difficulties, placing them at greater risk for elevated depressive symptoms. Additionally, social support appears to play a protective function in the postnatal period by reducing stress associated with the transition to motherhood\textsuperscript{10}. However, greater family mobility, changes to female participation in the labour market and increasing time pressures on young families has made access to traditional sources of family and professional support more difficult. This increases the risk that new mothers will become socially isolated and lack daily support\textsuperscript{12}. As such, online interventions that facilitate easy access to social and professional support may be particularly important for new mothers experiencing depressive symptoms and struggling with parenting demands\textsuperscript{13}.

In order to support the large number of women who experience sub-threshold levels of depression new approaches are needed that can help larger numbers of mothers than it is possible using traditional face-to-face programs. Online interventions are one way that this can be achieved. Internet access among women of child-bearing age in Australia is now ubiquitous with new mothers making extensive use of the internet to obtain child-raising information and social support. This has encouraged the development of numerous websites and ‘phone apps’ by commercial, professional and government organisations. However, health-related information on the internet can often be misleading and occasionally, “utterly wrong”\textsuperscript{12}. As well, there is a marked absence of evaluations assessing the extent to which online information and support is utilised by mothers and improves maternal and child outcomes.
The intervention tested in the present trial was based on our previous evaluation of ‘eMums’, an innovative online group-based nurse-led intervention that provided support for common parenting difficulties for the general population of mothers\textsuperscript{14,15}. The intervention tested in the current trial ‘eMums plus’ builds on this work with the addition of integrated support for depression as well as parenting difficulties. The eMums plus intervention was based on four core principles. Firstly, it was designed to provide both peer and professional support as there are a number of online interventions that provide information alone without peer or professional support but when tested have very low usage rates\textsuperscript{16,17}. Second, it was designed as an online intervention to enable easy access very early after birth without requiring travel or attendance at clinics at specific appointment times. Third, it was designed to have the capacity to support larger numbers of mothers than is possible with face-to-face care. Finally, it was designed and tested in a pragmatic RCT in collaboration with a State-wide Child and Family Health Service (CaFHS). This was done to ensure the intervention was readily translatable into standard clinical practice, in contrast to efficacy trials where interventions are generally developed and tested by researchers in academic settings and then have to be adapted to the demands of routine clinical service. To the best of our knowledge, no previous study has evaluated the effectiveness of an online group-based nurse-led intervention delivered through routine services and designed to reduce maternal depressive symptoms and parenting problems.

**Objectives and hypotheses**

The protocol for the study utilised a randomised controlled trial to determine whether a 4-month group-based nurse-led intervention delivered via a mobile phone app when infants were 2-6 months, reduced levels of maternal depressive symptoms and improved the quality of maternal caregiving when infants were aged 8-12 months.

Assessments were completed when infants were aged 1-2 (pre-intervention), 8, and 12
months. The primary outcomes for the trial are level of maternal depressive symptoms and observed quality of maternal caregiving assessed when infants are aged 12 months.

We hypothesised that when their infants are aged 12 months, questionnaire scores and direct observation assessments will indicate that mothers who received the online intervention will be functioning better than comparison mothers with:

(i) lower scores on the Edinburgh Postnatal Depression Scale (EPDS)\(^{18}\), assessing level of maternal depressive symptoms.

(ii) higher scores on the Parenting Sense of Competence Scale (PSCS) score assessing mothers’ perception of their maternal caregiving competence\(^{19} \,^{20}\).

(iii) higher scores on the NCAST Parent-Child Interaction Teaching Total Scale scores\(^{21}\), assessing quality of mother-child interactions.

**METHODS**

**Study design**

The study is a pragmatic RCT of an online group-based nurse-led intervention *versus* ‘standard care’. The trial was embedded into routine service practice in the state-wide CaFHS. This enabled the trial to examine whether the intervention is effective when delivered as a part of routine service delivery\(^{22} \,^{23}\).

**Setting**

Participants were recruited from 14 CaFHS sites located in major urban areas and a large regional centre in South Australia. CaFHS is the key community health service in the State providing a range of services for mothers and infants including infant health checks and home-based maternal support.

**Participants and recruitment**
We aimed to enrol 160 mothers of infants aged 2-8 weeks at the time that they completed their 1-4 week postnatal health check with CaFHS. At the time CaFHS administration staff routinely make contact with mothers to organise their postnatal health check, potential participants were asked whether they were willing to consider participating in the research project should they prove to be eligible for the study. Mothers who indicated that they were willing to consider participation were asked to consent to allow their phone contact details to be passed on to the research team, if they were eligible for the study. During the postnatal health check all mothers completed a questionnaire comprised of a 4-item parenting problems scale and the Edinburgh Postnatal Depression Scale (EPDS)\(^18\). Mothers who scored $\geq 7$ on the EPDS and reported at least one problem on the 4-item parenting problems questionnaire were eligible to participate. Following their postnatal health check, eligible mothers were contacted by telephone by the research team. The research team explained the study to the mother, sought verbal consent for a home visit by a member of the study's field-worker team, and randomised mothers to either the intervention arm or the comparison (‘standard care’) arm of the study. Field-workers contacted mothers who had given their consent and arranged a time to visit them to complete the ‘formal’ consent process and, where written consent was given, complete the baseline research assessment.

Exclusion criteria included mothers: (i) with an EPDS score $\geq 13$ and who were judged by their screening nurse to have a level of depressive symptoms that precluded their participation in the study, (ii) judged by their screening nurse to be experiencing domestic violence, illicit drug use or other major distress that precluded their participation in the study, or (iii) lacking sufficient English skills to complete the self-report questionnaires. Mothers with an EPDS score $\geq 13$ were able to participate provided they also had access to support
from a family doctor or other health professional. All mothers identified as experiencing high levels of depressive symptoms (i.e., $\geq 13$ on the EPDS) were referred to other services, most frequently general practitioners. Such referrals occurred in both the intervention and comparison groups in the present study.

**Figure 1.** Flow chart of participants.
Following randomisation, mothers in the intervention arm were assigned to an online group supported by a CaFHS nurse comprising approximately 20 mothers of similar-aged infants. They were also able to access standard care services as required. The intervention was delivered when infants were aged 2-6 months because this is: (i) a key developmental period for infants; (ii) a time when mothers are most vulnerable to depressive symptoms; and (iii) as previously shown, it is a time when mothers most actively seek information from nurses, and want to share and exchange ideas with each other\textsuperscript{14}.

**Randomisation**

The trial used group randomisation with blocks of 20 eligible mothers consecutively identified and then randomised to either the intervention or comparison arms of the study. A group randomisation sequence was used to determine the arm to which each group was assigned. This approach ensured that mothers’ groups in the intervention arm contained no more than 20 mothers per group. The randomisation schedule was generated by a statistician who was independent of the study team.

The research team were blind to group allocation at the time of recruitment and assignment of mothers to the study groups. However due to the nature of the intervention, after the intervention commenced, it was not possible to keep research staff or field workers blind to the groups to which mothers had been allocated. The exception to this was research staff coding the NCAST Parent-Child Interaction scale, who were blind to group allocation while completing coding.

**Intervention delivery**

The intervention was comprised of a 4-month group-based nurse-led program delivered by community health nurses to mothers via a mobile phone app when infants were 2-6 months. A key premise of the intervention is that to be effective, help for new mothers experiencing
problems with their mood and caregiving role must be closely integrated. To achieve this, the intervention is designed to:

(i) reduce maternal depressive symptoms,

(ii) support mothers to gain competence and self-efficacy in caring for their infants and solving caregiving difficulties, and,

(iii) support mothers to achieve healthy lifestyles for themselves and their infants.

Nurses who delivered the intervention received training in the use and management of the app from the lead nurse who was extensively involved in the delivery of our original eMums program and from the research team. Nurses also received an additional 3 days of training in the delivery of the mental health components of the eMums plus intervention and general training in responding to those experiencing mental health problems (outlined below).

The ‘mother’s view’ of the app: is comprised of four components each of which is explained in an ‘Orientation’ given at the beginning of the program (See figure 2). The components are also highlighted in a ‘site-map’ available with the app. The four components for mothers are:

(i) Chat – contains the chat room where mothers post questions and nurses can reply with posts and comments visible to all group members in a similar format to Facebook. Mothers can also reply and answer each other’s questions. The parenting and emotional health curriculum is posted in the chat room twice a week for mothers. The nurse also posts additional content depending on the needs of her group.
(ii) **Timeline** – provides an interactive list of child development milestones and health reminders that provides guidance to mothers appropriate to their baby’s age during the intervention. Nurses can also view the timeline to assess whether children have completed health checks and are meeting developmental milestones. Mothers can also access a maternal and infant ‘mood-rater’ that allows mothers to monitor their own mood, and nurses to track mothers’ and infants’ moods over time. It also contains an interactive events calendar displaying topics that nurses discuss, and other material relevant to the functioning of the group.

(iii) **Resources** – contains the short articles and activities on parenting and emotional health that make up the eMums plus curriculum, as well as additional information about other topics that may be useful for mothers. This is available for mothers to...
search as required if they are looking for accurate CaFHS endorsed information on a particular topic. Mothers are able to post topics from the resources section into the Chat page if they want to share information with the group.

**(iv) Contacts and Assistance** – contains useful contact numbers and a portal through which mothers can privately message their group’s nurse. Nurses are able to respond to mothers privately, and to send messages and notifications about upcoming discussions to all the mothers in their group.

**The ‘nurses’ view’ of the app:** is comprised of three main elements:

(i) **Group Dashboard** – displays information about individual groups such as group activities, notes maintained by nurses, and responses to mood ratings completed by mothers.

(ii) **Parent Dashboard** – displays information about individual mothers including parent case notes, individual website login activities (e.g., when mothers view material, such as a depression module or the content of the chat room, mothers’ latest ratings of their mood and their babies’ mood), and notifications that mothers have added information about children’s milestones.

(iii) **Nurse Home Group** – enables nurses to access their group’s chat room but also contains additional resources that nurses utilise (e.g., information inserted into the group chat room such as messages, reminders, and curriculum topics). In addition to accessing the program on their computer, nurses also have a nurse-app installed on their mobile phones. This app contains all the features of the mothers’ app, with additional capabilities which allow them to send messages and notifications about upcoming discussions to all the mothers in their group.

At the beginning of the program, nurses welcome mothers to their group and outline the goals of the program. They explain how to make the best use of the app and its various features.
(e.g., the use of notifications to mothers about when the nurse will be online, and topics scheduled for discussion).

**Intervention content**

The intervention has two main curriculum components and a training component for nurses delivering the intervention. The curriculum consists of information provided to support mothers with parenting problems, and a modulised program designed to reduce symptoms of depression.

**Maternal Parenting problems** - For the purpose of the eMums plus program we have adapted existing CaFHS parenting resources to create an online intervention designed to help mothers with parenting during their infants’ first months of life. The curriculum focuses on improving maternal caregiving through anticipatory guidance about infant development, problem-solving, common parenting difficulties, promoting maternal sensitivity and responsiveness, and providing social support. The parenting content includes steps that mothers can take: (i) to resolve common practical problems experienced by mothers of young children (e.g., feeding, sleeping and ‘settling’), and (ii) to look after their own health and well-being. It also shows mothers activities that they can use to promote the health and development of their infants (e.g., improving parent-infant attachment, stimulating infant language development). The curriculum is comprised of weekly modules containing information and links to further information in the “Resources” section of the website. This section can be accessed independently by mothers. While the curriculum has a schedule for delivery, nurses use their experience of child development and maternal psychosocial role adjustment, as well as the content of mothers’ online discussions and questions, to tailor the curriculum to each group’s particular needs. This ‘just in time’ approach is used
because clinical experience suggests that new mothers primarily want information relevant to their specific situation and the age of their infant, rather than more broadly-based anticipatory advice about what might occur in the future.

(ii) **Maternal Depressive Symptoms** – The curriculum addressing maternal depressive symptoms is adapted from the *Mothers and Babies Course*, a manualised group treatment program for postnatal depression. The *Mothers and Babies Course* is an evidenced-based program that has been demonstrated to reduce maternal depressive symptoms in efficacy trials. Our adaptation of the *Mothers and Babies Course* makes it appropriate for delivery in combination with the online parenting intervention content. The program is based on Cognitive Behavioural Theory and Attachment Theory, and targets the unique needs and stressors mothers face during the postnatal period. It has achieved promising results in initial trials delivered alone and in combination with a home-visiting program provided to low-income mothers. In the app, module content is presented in the form of text and video/audio messages. Each module provides mothers with a task to complete (e.g., Behavioural Activation), with the aim of prompting group discussion and problem-solving around the task, and engaging mothers in managing mood and the stressors of parenthood. The timing of the presentation of the depression modules is based on children’s ages and they are largely ‘self-help’ rather than requiring nurse assistance for their completion. The primary role of the nurses is to encourage use of the modules. Nurses receive training in the use of their content from a clinical psychologist trained in the delivery of the *Mothers and Babies Course*.

(iii) All nurses delivering the intervention complete the *Mental Health First Aid* training program with the aim of improving their ability to identify depressive symptoms and provide support for mothers experiencing symptoms of postnatal
depression. This training program was designed to help lay individuals and professionals develop skills in working with individuals developing mental health problems or in a mental health crisis. A meta-analysis of trials evaluating *Mental Health First Aid* has shown that this training increases participants’ knowledge regarding mental health, decreases their negative attitudes, and increases supportive behaviours for individuals with mental health problems\(^2\).

The use of these curriculum and training components ensures that the intervention appropriately addresses both maternal depressive symptoms and problems with parenting.

**Standard Care**

Only mothers in the intervention arm had access to the internet intervention. However, mothers in both intervention and comparison groups had access to standard care arrangements.

For the vast majority of mothers, standard care is comprised of a single home-visit by a CaFHS nurse who checks the health of mothers and infants, provides advice about issues relevant to infant care, and offers information about other relevant community services available for mothers and infants.

**Outcome Measures**

All measures, were completed when infants were aged 1-2 months (pre-intervention), 8 months, and 12 months. Measures were completed during home-visits conducted by trained field workers to ensure high quality data.

**1. Maternal Depressive Symptoms**

The Edinburgh Postnatal Depression Scale (EPDS): is a 10-item self-report questionnaire that
assesses the level of depressive symptoms experienced by mothers during the postnatal period\textsuperscript{18}. Questions assess symptomatology during the previous 7 days and utilise a 4-point response scale. Scores on all items are summed and recommended cut-points are available to identify mothers who would benefit from additional support\textsuperscript{29}.

2. Maternal Caregiving

(i) The Parenting Sense of Competence Scale (PSCS): is a 16-item self-report questionnaire designed to measure parental efficacy and satisfaction in the parenting role. Items are rated on a 6-point response scale. The scale has been successfully used with Australian mothers and has satisfactory psychometric properties\textsuperscript{19,20}.

(ii) NCAST Scales: The NCAST scales are designed to assess the quality of mother-child interactions including sensitivity to cues, response to distress, fostering social-emotional functioning and fostering cognitive growth\textsuperscript{21}. For the purpose of this study we used the Teaching Scale suitable for use with 0-36 month olds. The scale utilises a 3-5 minute video-recording of mothers teaching their child a skill appropriate to the age of their child, selected from a list in the NCAST training manual. Field workers recorded mothers completing the teaching interaction during home visits. Subsequently, research assistants who have completed the NCAST training program coded the video-recordings to generate a total score and subscale scores\textsuperscript{21}.

(iii) Parenting Stress Index (PSI): The PSI is a widely used self-report questionnaire designed to assess parent and child characteristics relevant to ‘parent-child systems’\textsuperscript{30}. Items consist of statements with a five-point response scale, and relevant subscales assess maternal perceptions of parenting competence, the quality of parent-child relationships, and the impact of parenting responsibilities on autonomy and self-identity.

3. Other Measures
(i) Service Utilisation: was included as a secondary outcome for the present study as it is possible that mothers who received eMums plus required less support from other services. This information is routinely recorded by CaFHS including number of clinic visits, and number of health checks. Maternal self-report questionnaires identified other services (e.g., general practitioners) used by mothers and infants.

(ii) Intervention Quality: Mothers’ perceptions about the quality of the support provided by the intervention was assessed using a 40-item questionnaire which we have developed for this purpose. Items ask about intervention effectiveness and usability of the mobile phone app.

(iii) App Usage: The extent to which mothers use the app was recorded. Data will be automatically collected on a number of indices including the number of log-ins, comments and replies that mothers post, as well as the amount of time spent in different sections of the app.

**Analysis plan**

Analyses will be by Intention-to-Treat and focus on intervention effects on maternal depression (EPDS)\textsuperscript{18}, mother-child interactions (NCAST)\textsuperscript{21}, and maternal caregiving competence (PSI and PSCS)\textsuperscript{19,30} at 8 and 12 months. General linear modelling techniques will be used when the scores are continuous outcomes, including log-binomial regression for dichotomous outcomes (e.g., the percentage of mothers scoring above recommended EPDS cut-off scores). Data collected at baseline will be used to control for any imbalances between the trial arms.

**Sample size**

The sample size target for this study was 160 (80 in each trial arm). This sample size would provide .80 power to detect an effect size of 0.4SD at $\alpha=0.05$. 
**Ethics**

Ethics approval was received from the Women’s and Children’s Health Network Human Research Ethics Committee (approval numbers SSA/16/WCHN/016, HREC/16/WCHN/014).

**RESULTS**

Participant recruitment was carried out from March to July 2017. Follow-up data collection was completed in mid-2018.

**DISCUSSION**

The broad aim of this study was to assess whether a 4-month group-based nurse-led intervention delivered via a mobile phone app when infants were 2-6 months, reduced levels of maternal depressive symptoms and improved the quality of maternal caregiving when infants were aged 8-12 months. The intervention was assessed in a pragmatic RCT with the intervention delivered as part of routine service practice by community child health nurses. The advantage of this methodology is that when an intervention is found to improve child and maternal outcomes services are more readily able to take up the intervention and continue providing this service using staff already experienced in delivering the intervention. It has been widely recognized in the medical and public health literature that results from such trials are more likely to be translated into practice than results from trials conducted in academic or research settings\(^\text{22 23}\).

If the results from the trial demonstrate a positive effect, it will have established the basis for a new online approach that can help large numbers of mothers experiencing depressive symptoms and caregiving difficulties early in their infant’s life, including mothers in rural communities who frequently have limited access to clinic-based services.
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CONFLICTS OF INTEREST

The authors have no conflicts of interest to declare.

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