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Title:

Engaging the whole family to support expectant mothers: A family-based mHealth intervention to reduce maternal postnatal depression and promote family health

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Research Proposal

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(a) Title:

Engaging the whole family to support expectant mothers: A family-based mHealth intervention to reduce maternal postnatal depression and promote family health

(b) Justification for conducting the project:

(i) **Health Needs of Expectant Mothers**

Globally, about 10% of pregnant women and 13% of postpartum women experience a mental disorder, primarily depression.[1] Findings from meta-analyses show that 11% of pregnant women in Asia have experienced pregnancy depression,[2] and 26% have shown symptoms of postnatal depression (PND).[3] In Hong Kong, a cohort study conducted by our research team revealed a 26% rate of pregnancy depression and a 9% rate of PND.[4]

In response to the issue, the Hong Kong government and the Hospital Authority (HA) have been making an effort to promote maternal and infant health, for example, through providing antenatal classes and health advice for pregnant women. Although empirical evidence has proven the effectiveness of face-to-face education and advising services for expectant mothers and fathers,[5] the availability of such support is often limited and is insufficient to benefit all parents who need it.[6] Our team found that 39% of first-time mothers were unable to join face-to-face antenatal classes in Hong Kong due to the limited seats available.[7] Clearly, there is a need for more effective measures that could deliver support to a wider population of expectant mothers.

Another challenge in pregnancy support in Hong Kong is the failure to engage family members in providing support for expectant mothers. In some previous studies, our team highlighted the importance of involving fathers in pregnancy and childcare to promote family health,[4,8] while other researchers have suggested the potential benefits of grandparental support and care in reducing maternal PND.[9] Unfortunately, there has been a lack of empirically supported programmes to engage family members in supporting pregnant women in Hong Kong, indicating a need for development and implementation of a family-based approach in providing pregnancy support in the community.

(ii) **Existing Strategies and Work Done by the Research Team to Address Health Needs**

To address the limitations of traditional face-to-face services, mobile health (mHealth) technologies have been widely employed in healthcare services in recent years.[10] mHealth is defined as the use of mobile technologies for medical and public health practices.[11] Some major strengths of mHealth over traditional approaches include the accessibility to service without time and location constraints, the opportunity for instant interaction with professionals and peers, and the relatively low running costs.[10,12] A meta-analysis conducted by the research team revealed moderate to large effect sizes of pregnancy related mHealth apps in promoting maternal physical health ($d = 0.72$), mental health ($d = 0.84$), and improving knowledge about pregnancy ($d = 0.80$).[12]

In Hong Kong, there have been similar attempts to adopt mHealth technologies in pregnancy care. In 2015, a telephone-based cognitive behavioural therapy for PND was demonstrated to be effective in reducing PND when compared to standard care.[13] In 2017, the HA developed a smartphone app called "HApi Journey" to provide support for expectant mothers. In 2019, the research team developed and evaluated an mHealth intervention for expectant mothers

using a randomized controlled trial (RCT).[7] The intervention was designed to deliver psycho-education on antenatal care, postnatal care, and infant care. The study revealed positive benefits of the mHealth intervention (a smartphone app) for expectant mothers in reducing maternal PND at four weeks postpartum.[7]

(iii) **Scientific Evidence Supporting the Strategies to Address the Needs Proposed in This Project**

The success of the mHealth intervention for expectant mothers has warranted the development of other mHealth interventions to engage more family members to support expectant mothers. In this project, we propose to develop a mHealth intervention that engages not only expectant mothers but also expectant fathers and grandparents in supporting pregnancy and infant care.

The literature shows that involving fathers in different stages of pregnancy and childbirth may have positive impacts on promoting family health and improving marital relationships.[14] In a local study, an intervention programme called Positive Fathering was successfully in improving physical health, mental health, and marital relationship of expectant fathers.[15] These positive outcomes in fathers may have potential benefits to expectant mothers, which may in turn, improving overall family health.

Engaging and educating expectant grandparents is equally essential to enhance pregnancy support, especially in Hong Kong households.[16] In Hong Kong, approximately 30% of grandparents were living with young children more than five days a week, and more than 25% were responsible for providing primary childcare during the daytime.[17] Grandparental involvement in pregnancy and childcare has been demonstrated to improve family health and reduce PND by increasing the levels of perceived social support among mothers,[8] and promoting a healthy and non-violent family environment.[18]

Possible mechanisms underlying the positive impacts of father and grandparent involvement may include increased social support, improved knowledge on pregnancy, and enhanced family communication and relationships. In a study on social capital during pregnancy, it was shown that close family was one of the most important sources of social capital that significantly influences maternal health other than medical professionals.[19] As the immediate environment that expectant mothers primarily inhabit, the family could provide valuable psychosocial resources through strong family cohesion.[19]

In the proposed study, we aim to develop and test a new mHealth intervention by including a smartphone app with different versions specifically designed for expectant mother, father, and grandparents who are part of the same household. To our best knowledge, there has been no empirically evaluated family-based mHealth intervention for pregnancy support.

(c) Aim and Objectives:

Aim

To develop a cultural-specific, family-based mHealth intervention to reduce PND and promote health among expectant mothers in Hong Kong by engaging all family members, including expectant fathers and grandparents, in giving support. Additionally, the family-based mHealth intervention aims to promote health of expectant fathers and grandparents, as well as cohesion of families. In alignment with World Health Organization's definition of health as a state of physical, mental, and social well-being[20], in this study we assess participants' health in multiple dimensions, including symptoms of depression, anxiety, and stress, health-related quality of life, and social support.

Objectives

(i) To develop a family-based mHealth intervention to engage family members in supporting expectant mothers during pregnancy;

(ii) To evaluate the effectiveness of the family-based mHealth intervention in reducing PND and promoting health (symptoms of depression, anxiety, and stress, health-related quality of life, and social support) among expectant mothers; and

(iii) To evaluate the effectiveness of the family-based mHealth intervention in promoting the health (symptoms of anxiety and stress, and health-related quality of life) of the expectant fathers and grandparents and promoting family cohesion.

Hypotheses

(i) The family-based mHealth intervention is more effective in reducing PND and promoting health among expectant mothers than the previously developed mHealth intervention for expectant mothers (mother-only mHealth intervention) and the control; and

(ii) The family-based mHealth intervention is more effective in improving promoting health of the expectant fathers and grandparents and promoting family cohesion than the mother-only mHealth intervention and the control.

(d) Project Plan:

(i) Target Group

1,578 families with expectant mothers will be recruited in Kwong Wah Hospital (KWH) and Tsan Yuk Hospital (TYH), two public hospitals that are managed by the Hospital Authority in Hong Kong, on a 1:1 basis.

Sample size calculation

Assuming a Cohen's d effect size of 0.20, an effective sample of 1,182 would be required to achieve 80% statistical power in detecting the effect in pairwise comparison. Assuming a retention rate of 75% for the current sample, a total of 1,578 families will be recruited.

(ii) Implementation Plan

This project will involve development, implementation and evaluation of the family-based mHealth intervention. Details of the development and implementation of the intervention are elaborated below, and the evaluation of the intervention is detailed in Section (v).

Development of family-based mHealth intervention

Mother-only mHealth intervention (previously developed by the research team)

The mother-only mHealth intervention contains all psycho-educational materials from routine education practice promoting healthy pregnancy, guides for antenatal care, postnatal care, and infant care that are available at the hospital.[7] Most of the information is re-organised into small topics to increase readability and accessibility and is presented in the form of short videos, illustrations, and brief messages. There is also a platform for users to ask questions, and our affiliate member, who is an obstetrician, will answer these questions. Answers will be provided via private messages in the App, or by publicly posted on the FAQ section of the app at users' choice after removing personal identifiable information. In the FAQ section of the app, there will be a message reminding participants that the purpose of the FAQ is for them to ask questions on pregnancy care that do not require professional's immediate attention or care. For emergency medical issues, they are advised to seek medical treatment from their doctors or go to the Accident and Emergency Department at hospitals. Also, there will be information about social services and 24-hour hotlines.

Family-based mHealth intervention (to be developed in this project)

We will develop a new smartphone app on the basis of the previous mother-only mHealth intervention. There will be three versions of the app to meet different needs of family members:

The mother version will contain all psycho-educational materials in the mother-only mHealth intervention app.

The father version will include all materials of the mother version and additional information tailored for fathers. Psychoeducational materials on family

communication, father's involvement in pregnancy and child care are delivered in a format of a quiz game.

The grandparent version will include all materials of the mother version and additional information on physical and mental health, and family communication tailored for grandparents to enhance their health awareness. Specifically, the information includes educating grandparents to identify sources of stress and the effect of stress on their well-being and interpersonal relationship, introducing ways to reduce stress, including eight videos demonstrating the Eight Section Qigong exercises (one video for each Section) and a series of yoga exercises suitable for older adults. Regarding family communication, there will be materials to enhance grandparents' awareness of their own intergenerational communication pattern and competence in effective communication with family members. All of the materials were previously developed by the research team and successfully delivered to local grandparents.

Similar to the mother-only mHealth intervention, users of all versions will be granted access to a platform to raise questions related to pregnancy care, which will be answered by our affiliate member who is an obstetrician. In addition to questions related to pregnancy care, users of the family-based mHealth intervention can ask questions related to family communication, which will be answered by a social worker. Answers will be provided via private messages in the app, or publicly posted on the FAQ section of the app, at users' discretion, after removing personal identifiable information.

Additionally, the app will utilize the family approach of intervention and incorporate several new functions to enhance family cohesion. There will be a platform for members within the same family to send and share texts and photos

using the app. Besides, the app will provide a shared calendar for users to set reminders for all family members on important dates related to pregnancy and other family activities. The messages and photos shared via the app will not be used for data analysis. All messages will be deleted upon completion of the study.

Implementation of intervention

The interventions will be implemented at antenatal clinics at KWH and TYH. The interventions will be provided to participants free-of-charge. Families with expectant mothers attending the two clinics will be recruited. For the purpose of intervention evaluation, participants in the intervention groups will receive the intervention. As the interventions will be delivered via smartphone apps, research staff will be stationed at the clinics to assist participants in downloading and installing the apps.

(iii) **Contingency/Alternative Plan if any Problems are Encountered During Implementation**

A potential challenge may come from the non-100% penetration rate of smartphone usage, particularly among older adults. According to the census statistics in Hong Kong, the penetration rate was about 95% in general and 58%-70% among elderly people over 60 years of age.[21] We will encourage the use of smartphones among eligible participants; however, if participants refuse, they will be excluded from our study, before randomisation is performed.

Possible cross-contamination between groups may also be a challenge in this project. To ensure that only participants in the intervention groups can get access to the app, we will provide unique login credentials for each of them. We will also

ask all participants to report their use of the family-based app or other similar parenting apps during the study period.

(iv) **Indicators and Targets**

Corresponding to Objective (i)

The coverage and usage of the app among expectant mothers, expectant fathers and grandparents, as well as their feedback on the app will be used as preliminary indicators of the success of the smartphone intervention. We expect high coverage and high usage, and positive user feedback.

Corresponding to Objective (ii)

Findings of the RCT will provide empirical evidence for the effectiveness of the family-based mHealth intervention in reducing maternal PND and promoting health among mothers. We expect to see a greater effect of the new family-based mHealth intervention in reducing maternal PND and promoting health among mothers than in the mother-only mHealth intervention and the control group.

Corresponding to Objective (iii)

Findings of the RCT will also provide empirical evidence for the effectiveness of the family-based mHealth intervention in promoting health among fathers and grandparents and promoting family cohesion. We expect to see a greater effect of the family-based mHealth intervention in promoting health and cohesion of the family than in the mother-only mHealth intervention app and the control group.

(v) **Evaluation Plan**

Corresponding to Objective (i)

The coverage and usage of the family-based mHealth intervention will be recorded automatically within the app, while feedback will be elicited from all users during the follow-up survey.

Corresponding to Objectives (ii) and (iii)

Study design

We will conduct a three-arm RCT to evaluate the effectiveness of the family-based mHealth intervention, and the three arms include two intervention groups: (i) the mother-only mHealth intervention, and (ii) the new family-based mHealth intervention, and (iii) the control group: basic health information. A three-arm RCT in this project allows evaluation of additional benefits of the family-based mHealth intervention over the mother-only intervention and of the control group.

Subject recruitment

The subject recruitment and baseline survey will be conducted when eligible expectant mothers show up for their first visit to the antenatal clinics of TYH and KWH. Given that there are approximately 231 births per month at each hospital and a response rate of 82.2% achieved in the previous study,[7] a 5-month recruitment period will achieve the required sample size.

Inclusion criteria:

Eligible families are those with an expectant mother who is 18 years old or above and is attending the antenatal clinics at the two selected public hospitals, Kwong Wah Hospital and Tsan Yuk Hospital in Hong Kong. Other inclusion criteria will be the possession of a smartphone and a personal email address for receiving and sending information relevant to the study of each of the participating family members, and the willingness to accept our study arrangements. Whether or not the family members co-reside with the mother is not an eligibility criteria.

Exclusion criteria:

Families will be excluded if the expectant mother scores 10 or higher on the EPDS. Participants will be excluded if the expectant mothers, fathers, or grandparents are not able to understand written or spoken Chinese or are unable/not willing to give informed consent.

Randomization

The RCT will require recruitment of three groups, on a 1:1:1 basis, for comparison: (i) mother-only mHealth intervention; (ii) family-based mHealth intervention; and (iii) health information control. A computerized blocked randomisation programme will be used to generate a series of random numbers to determine the group to which the family is assigned.

Baseline survey

Participants will be briefed by a trained research assistant about the purpose and the details of the study, and will be asked to provide written consent. Blocked randomisation will be performed using a centralised online website upon participation. Depending on their group assignment, expectant mothers will be asked to download the respective smartphone app, log in to the app with a unique username and password that they will be assigned. The expectant mothers will also be asked to complete the baseline survey via online, which will take about 15-20 minutes to complete. After that, the participants will be asked about their expected delivery date, and their preferred contact method for the follow-up survey.

Eligible expectant fathers and grandparents who are not present at the clinics will be contacted by the research assistant using the contact methods given by the participating mothers, study details will be explained to them, and they will be asked to provide informed consent. They will be instructed to complete a structured questionnaire, which will take about 15 minutes. Fathers and grandparents who are

allocated to the family-based intervention group will then be provided with a link to download the father or grandparent version of the app, and a unique login information.

Intervention arms

Participants in the two intervention groups (family-based mHealth intervention and mother-only mHealth intervention) will be granted free and unlimited access to the respective smartphone app from the time of recruitment up to four weeks after childbirth. Their usage of the app will be recorded in terms of the time spent on the app (in minutes). For ethical reasons, the participants in the intervention groups will not be deprived from usual face-to-face antenatal classes at the hospitals; instead, they will be provided something more than they can obtain in existing service.

Control arm

The control group will receive routine services provided by KWH and TYH, i.e., they will be provided with information and videos about all the essential information for expectant parents via a smartphone app. They can be enrolled to nurse-led face-to-face antenatal classes, although 39% of first-time mothers previously reported that they were unable to join the face-to-face antenatal classes due to the limited seats available.[7] For those who are not offered a place for the antenatal classes, they will not have the opportunity to ask questions about their pregnancy until their antenatal visits.

Follow up survey

Participants will be contacted for the follow-up survey around four weeks after childbirth via their preferred contact method indicated in the baseline survey.

Measurements

Specific outcome indicators and the target respondents are listed both in Table 2 and as follows:

Primary outcome:

Symptoms of Maternal Pregnancy depression and PND at four weeks postpartum will be assessed with the validated Chinese version of the 10-item Edinburgh Postnatal Depression Scale (EPDS).[22]

Secondary outcomes:

Perceived social support levels of expectant mothers will be assessed with the Chinese version of the 12-item Multidimensional Scale of Perceived Social Support (MSPSS). [23]

Anxiety and stress levels of all participants (including the expectant mother, father, and grandparents) will be assessed with the Anxiety and Stress subscales of the Chinese version of the Depression Anxiety Stress Scale (DASS21). [24]

Health-related quality of life (QoL) of all participants will be measured with the validated Chinese version of the Short-form-12 Health survey (SF-12 v2),[25] which consists of 12 items to be computed as two composite scores: physical component score and mental component score.

Perceived family cohesion levels of all participants will be assessed using the nine-item Family Cohesion subscale of the Chinese version of the Family Environment Scale.[26] Sample questions include: “Family members really help and support one another”, “We put a lot of energy into what we do at home”, and “We often seem to be killing time at home”. Each item is rated on a 6-point scale, ranging from 1 = strongly agree to 6 =strongly disagree. The scale showed adequate reliability and validity in a previous study in a Chinese sample.[27]

Covariates

Demographic information including age, education level, marital status, family monthly income adjusted for household size, number of children, and family living arrangement will be collected.

Service utilisation: App users' feedback and engagement data will be obtained via: 1) participants' self-reported usage of the app and 2) the app itself which will capture users' usage of the app, in terms of frequencies and duration of access. For all participants, information about their utilisation of services, such as participation in face-to-face antenatal classes, usage of other similar app and resources on pregnancy care, etc. will be collected via the self-report questionnaire.

Ethical consideration

Approval for the ethics of this study has been obtained from the institutional review boards of the respective institutions. Participation in the study will be completely voluntary. Participants will be reminded that they have the right to terminate their participation at any time during the study, and this will not affect the standard of care they receive at the hospital. All personally identifiable information will be removed before data analysis. In this study, we will obtain information about participants' symptoms of pregnancy depression and PND via the self-reported EPDS at baseline and follow-up. For mothers whose EPDS score is equal to or higher than the cut-off score of 10, we will encourage them to seek help from health and social services. All mothers will receive regular health services and treatments in the hospital as usual. The only difference between the intervention groups and the others will be the use of the mother-only mHealth intervention app or the family-based mHealth intervention app. We will remind mothers that there are relevant services (e.g., the Comprehensive Child Development Service) in the routine hospital care that they can approach when in need.

(vi) **Results analysis**

With regards to **Objective (i)**, we will conduct descriptive analyses to obtain the usage and the coverage of the intervention.

To fulfil **Objectives (ii) and (iii)**, we will conduct general linear model (GLM) to analyse the data. In each GLM, we will use one outcome indicator measured in the follow-up survey as the dependent variable, the corresponding outcome indicator in the baseline survey as the covariate, and the group (family-based mHealth intervention, mother-only mHealth intervention, control [referent group]) as independent variable. We will also conduct sub-group analyses to explore whether the effectiveness of the family-based intervention is affected by various demographic or family factors.

All statistical analyses will be conducted with the intention-to-treat principle. All missing data will be treated with multiple imputation method or full information maximum likelihood depending on the analysis model. Nonetheless, analysis will be performed to compare any baseline differences between dropouts and retained participants. The baseline difference will also be examined by descriptive statistics. SPSS 20.0 will be used, and two-tailed p-values $< .05$ will be regarded as statistical significance.

Impact and Sustainability:

This proposed project entails the development and evaluation of a family-based mHealth intervention programme for families with pregnant women to promote family health. The evaluated intervention will be the first attempt to provide pregnancy support to expectant mothers using a family approach, by engaging and

educating expectant mothers, fathers, and grandparents, with a low-cost, user-friendly smartphone app. Importantly, the app comes in three versions that involve a continuously accessible, constraint-free platform for different family members to receive all the essential information about how to better support expectant mothers during and after pregnancy, and for members to build strong family cohesion.

Compared with traditional pregnancy support services, our new family-based mHealth intervention programme is believed to be a more effective way to reach out to a larger population and engage family members to provide proper pregnancy support to expectant women and to maintain a good relationship among family members. With less manpower required for the smartphone app than traditional face-to-face training, the former could provide longer-term support at lower costs. The non-face-to-face basis of the app may also encourage those parents and grandparents who are too shy to ask questions to discuss their issues with health professionals via the platform provided by the app.

Our mHealth intervention requires minimal manpower: a few IT staff for app maintenance and a few medical or health professionals to occasionally answer questions. Due to its low running cost, it has the potential to be promoted as a routine practice for every family with an expectant mother. We believe that the mHealth intervention will shed light favouring the reform of pregnancy support services.

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