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Dietitian-led cluster randomised controlled trial on the effectiveness of mHealth education on health outcomes among pregnant women: a protocol paper

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ABSTRACT

Introduction Nutrition education is the cornerstone to maintain optimal pregnancy outcomes including gestational weight gain (GWG). Nevertheless, default for appointments is common and often lead to suboptimal achievement of GWG, accompanied with unfavourable maternal and child health outcomes. While mobile health (mHealth) usage is increasing and helps minimising barriers to clinic appointments among pregnant mothers, its effectiveness on health outcomes has been inconclusive. Therefore, this study aimed to address the gap between current knowledge and clinical care, by exploring the effectiveness of mHealth on GWG as the primary outcome, hoping to serve as a fundamental work to achieve optimal health outcomes with the improvement of secondary outcomes such as physical activity, psychosocial well-being, dietary intake, quality of life and sleep quality among pregnant mothers.

Methods and analysis A total of 294 eligible participants will be recruited and allocated into 3 groups comprising of mHealth intervention alone, mHealth intervention integrated with personal medical nutrition therapy and a control group. Pretested structured questionnaires are used to obtain the respondents' personal information, anthropometry data, prenatal knowledge, physical activity, psychosocial well-being, dietary intake, quality of life, sleep quality and GWG. There will be at least three time points of data collection, with all participants recruited during their first or second trimester will be followed up prospectively (after 3 months or/and after 6 months) until delivery. Generalised linear mixed models will be used to compare the mean changes of outcome measures over the entire study period between the three groups.

Ethics and dissemination Ethical approvals were obtained from the ethics committee of human subjects research of Universiti Putra Malaysia (JKEUPM-2022-072) and medical research & ethics committee, Ministry of Health Malaysia: NMRR ID-22-00622-EPU(IIR). The results will be disseminated through journals and conferences targeting stakeholders involved in nutrition research.

Trial registration number Clinicaltrial.gov ID: NCT05377151.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Large sample with adequate study power.
⇒ The messages and health terminology used in the mobile health (mHealth) apps is simple, not complicated, user-friendly, able to reduce the boundaries among health illiterate communities.
⇒ The study will inform healthcare professionals about the effectiveness and practicality of mHealth in managing gestational weight gain and other pregnancy outcomes.
⇒ The mHealth app holds potential for increasing the relevance, practically, effective and sustainability of digital health technologies.
⇒ The study results will not be generalisable to pregnant mothers who have no smartphone or internet coverage at home.

INTRODUCTION

Gestational weight gain (GWG) is a unique and complex biological phenomenon,[1] with inappropriate rate and magnitude of GWG (either below or above recommendations) were associated with higher risk of adverse maternal and infant outcomes.[2–4] Despite the importance of achieving appropriate GWG for optimal pregnancy outcomes, excessive GWG[5–7] and inadequate GWG[8–11] were both evident.

Excessive GWG can affect both mothers and infants. Frequently reported maternal outcomes linked to excessive GWG are gestational diabetes mellitus,[5 12] caesarean section,[5 12] hypertensive disorders of pregnancy,[12] increased rates of miscarriage[13 14] and increased postpartum weight retention.[12 13 15] Excessive GWG may also lead to large-for-gestational-age neonates,[12 16] fetal macrosomia,[12 17] increased rates of childhood obesity[12 18 19] and asthma.[12] On the other hand, inadequate GWG was found

to be related with a higher risk of low birth weight,[5 20] preterm birth,[21 22] infant no catch-up growth pattern and increased risk of regression after 4 months.[23] Additionally, there is well-proven evidence between insufficient weight increase and perinatal death.[24 25]

Determinants contributing to GWG are multifactorial, which include prenatal knowledge,[26 27] dietary intake,[28–30] physical activity level,[30–32] sleep quality[33–37] and psychosocial well-being.[38–41] However, evidence had been inconclusive on the factors influencing the GWG.[37 42–46] In Asia, available studies showed inadequate fruits intake was associated with insufficient GWG, while lack of exercise was associated with excessive GWG among the Chinese.[47] In Japan, psychological factors including low body esteem and high depression score were associated with low GWG.[48] Such information is scarce or limited among Malaysia pregnant women. Limited previous study in Malaysia showed higher diet quality reduced the risk of inadequate GWG among normal weight pregnant women. On the other hand, higher diet quality was associated with an increased higher risk of excessive GWG among normal weight and overweight/obese women.[49] However, there was no published study on the effectiveness of mobile health (mHealth) on GWG among pregnant women at the time of study conception.

Dietary intake during pregnancy is among the widely investigated environmental exposures, postulated to affect the rate and total GWG.[50] Henceforth, a healthy, nutrient-rich as well as energy-appropriate diet during pregnancy is crucial for optimal development and growth of the fetus.[4] Nutrient requirement is considerably increased along the progression of pregnancy status.[4] Among all, intake of total calories,[51 52] macronutrients that included carbohydrates, fat and saturated fat,[52] sugar and sucrose[52] and micronutrients intake[53] such as vitamin C[51] were associated with GWG. Earlier systematic review and meta-analysis of 90 dietary studies shown that dietary intakes among pregnant women in developed countries were unsatisfactory.[54] Recent studies had consistently reported that only a small proportion of pregnant mothers achieved adequate nutrients intake during pregnancy,[55–58] while most of them were either excessive[59–63] or inadequate in nutrients intake.[51 54 64–67]

Furthermore, the prevalence of lack of exercise is high in pregnant women[68] as women generally tend to have lower level of physical activity as they become pregnant.[69–72] This may due to the perceived barriers to physical activity during pregnancy, which can often be classified as physical (back/leg pain, nausea, fatigue and body size), environmental or lifestyle (lack of time, responsibilities on work and family, lack of activity resources and weather restrictions) or psychosocial (lack of support, conflicting advice, concern for baby, lack of motivation, body image and lack of confidence).[73] A recent study showed that there was a significant association among high sedentary behaviour of pregnant women with excessive GWG, especially when they were in the second trimester, regardless of their physical activity levels.[74] Considering the possible complications associated with inappropriate GWG, evidence-based strategies or interventions are of utmost important. To the best of knowledge, lifestyle interventions, namely diet, exercise or the combination of diet and exercise, are promising interventions to mitigate excessive GWG.[75] It is worth mentioning that available evidence is limited to intervention to mitigate excessive GWG, while inadequate GWG are often neglected. The current practice relies on face-to-face and paper-based delivery methods, with heavy reliance on intensive support from clinical healthcare team, which limits the scalability of the interventions. Innovative techniques are needed to help women manage weight increment during pregnancy because current maternity services may not be able to sustain resource-intensive interventions due to the severity of the maternal weight gain issue.[76]

Pregnant women are now progressively turning to mHealth for health information and support.[77 78] The use of mHealth apps during pregnancy offers a unique window of opportunity which is a teachable moment whereby pregnant women are often more motivated to healthier lifestyle changes,[79] especially among first-time mothers.[80] There was one systematic review found that most studies on mHealth apps that aimed to support lifestyle and medical care for high-income countries stated that these apps were effective in reducing GWG, increased intake of vegetables and fruit and promote smoking cessation.[81] Nonetheless, structured mHealth interventions in promoting a healthy lifestyle and GWG in pregnant women were limited and had yielded inconsistency findings,[82–85] with data are scarce in developing countries, as it is difficult to collect the information throughout the pregnancy period. Whether such findings can be extrapolated to pregnancy in women of a multiethnic community such as Malaysia is yet to be elucidated.

On the other hand, studies available showed mHealth application alone produced better health outcomes than routine standard care.[86–91] Similarly, mHealth apps integrating with healthcare professional's guidance promoted better health outcome compared with routine care alone.[92 93] Meanwhile, it is evident that mHealth application among community dwellers have limited use without the interaction with healthcare team.[94 95] However, to our best knowledge, there is no available data or research available that mHealth with integration of healthcare professionals' interaction supersedes mHealth alone or whether mHealth alone is sufficient to promote health outcomes among pregnant mothers is yet to be elucidated. Thus, in this study, we aim to compare the effectiveness of mHealth apps alone, and mHealth apps in integration of medical nutrition therapy led by dietitian with standard care on GWG and other health outcomes. The theory of planned behaviour (TPB) will be applied to facilitate behavioural change that promotes the pregnant mothers to adhere to the recommended GWG, dietary intake and physical activity. There are three constructs of TPB which consist of attitude, subjective norm and perceived behavioural

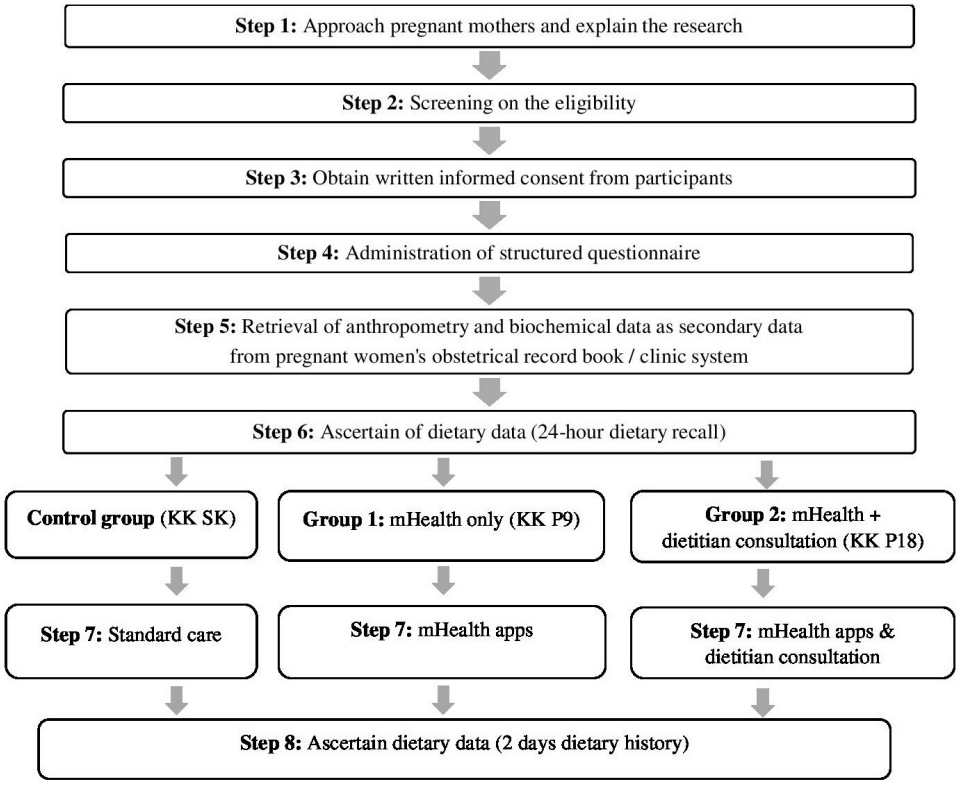

Figure 1 Flows of recruitment process. KK SK – *Klinik Kesihatan* Seri Kembangan (Seri Kembangan Health Clinic); KK P9 – *Klinik Kesihatan* Presint 9 (Presint 9 Health Clinic, Putrajaya); KK P18 – *Klinik Kesihatan* Presint 18 (Presint 18 Health Clinic, Putrajaya).

control, and it has successfully predicted and explained a wide range of health behaviours and intentions.[96–98]

METHODS AND ANALYSIS

This cluster randomised controlled trial aims to determine the effectiveness of a mHealth intervention with its primary outcome on GWG and secondary outcomes are prenatal knowledge, physical activity, psychosocial well-being, nutritional status, quality of life, sleep quality and pregnancy outcomes among pregnant women. This study involves the nutrition intervention delivered either via mHealth or conventional methods (standard usual care) as shown in figure 1. In this study, the effectiveness of mHealth on health outcomes will be ascertained as shown in table 1, which summarises the study variables in the present study. Specifically, mean changes in health outcomes (GWG for example) will be compared between mHealth and control groups, mHealth+personal medical nutrition therapy group and control group, and mHealth and mHealth+personal medical nutrition therapy groups.

The specific objectives of the study are as follows:

Specific objectives

1. To determine the pattern of GWG among pregnant women.
2. To determine the factors contributing to GWG among pregnant women.
3. To compare the mean differences in GWG and other health outcomes between pregnant women receiving intervention groups and conventional health education (control group).
4. To determine the maternal and neonatal outcomes among pregnant women.

Study design

A cluster randomised controlled trial study will be performed among the pregnant women who received antenatal care at government health clinics in Klang Valley as shown in figure 2. The research study periods started in April 2023 and estimated to be completed in June 2024. As this is an intervention study, thus blinding is not applicable for data collection personnel and participants.

Study location

Geographically, Malaysia consists of two regions, which are East Malaysia and West (or peninsular) Malaysia with approximately 400 miles (640 km) apart, separated by the South China Sea. The study location is at the Klang Valley, an urban conglomeration in Malaysia that is centred in the Federal Territories of Kuala Lumpur and Putrajaya, includes its adjoining towns and cities in the state of Selangor as shown in online supplemental appendix 1. There is a total of 109 health clinics in Klang Valley, comprises of 81, 24 and 4 health clinics located in Selangor, the Federal Territories of Kuala Lumpur and

Table 1 Summary of study variables assessed at different study points

	Study period					
	Enrolment	Allocation	Post allocation			Close-out
Time point	$-t_1$	0	t_1	t_2	t_3	t_4
Enrolment						
Eligibility screen	X					
Informed consent	X					
Allocation		X				
Interventions						
Intervention group 1			◆—	—	—◆	
Intervention group 2			◆—	—	—◆	
Control group			◆—	—	—◆	
Assessments						
Sociodemographic data			X			
Anthropometry data (gestational weight gain)			X	X	X	
Biochemical data			X	X	X	
Prenatal knowledge			X			
Dietary intake			X	X	X	
Physical activity			X	X	X	
Psychosocial well-being			X	X	X	
Quality of life			X	X	X	
Sleep quality			X	X	X	
Pregnancy outcome						X

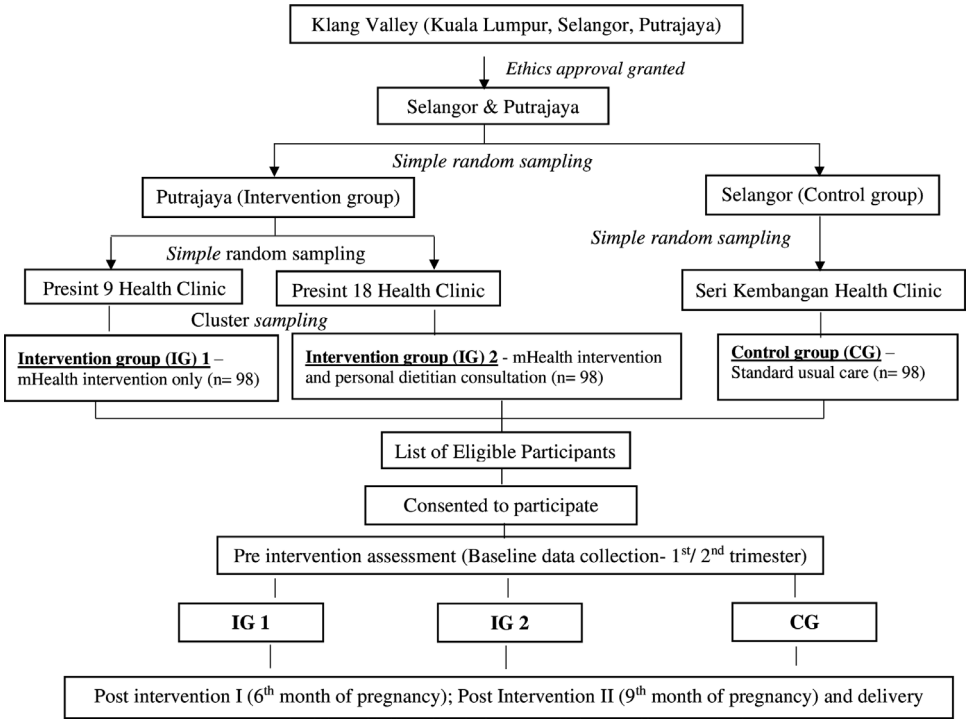

Figure 2 The consort flow diagram.

Putrajaya, respectively. Ethical approvals were obtained to conduct the study in Selangor and Putrajaya from the respective ethics authorities (JKEUPM-2022-072, NMRR-22-00622-EPU(IIR)).

There are nine districts in Selangor, namely Gombak, Hulu Langat, Hulu Selangor, Klang, Kuala Langat, Kuala Selangor, Petaling, Sabak Bernam and Sepang. We stratified the maternal and child health clinics within the 25 km radius from the faculty of medicine and health sciences, Universiti Putra Malaysia due to the geographical proximity and financial constraints, with a total of 15 health clinics are within this radius. This was followed by simple random sampling whereby Health Clinic of Seri Kembangan in the Petaling District was selected as one of the study locations. A similar approach was used to select the two health clinics (Presint 9 Health Clinic and Presint 18 Health Clinic) in Putrajaya. To prevent cross contamination between the respondents, a cluster simple random sampling was employed to allocate the three health clinics into mHealth intervention (Health Clinic of Presint 9 Putrajaya), mHealth intervention+personal dietitian consultation (Health Clinic of Presint 18 Putrajaya) and control (Health Clinic of Seri Kembangan). Pregnant women who agreed to participate in the study will be assigned as intervention or control, depending on the respective health clinics they attended.

Patient and public involvement

Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research.

Study participants

A total of 294 eligible pregnant women will be recruited and allocated into three groups, which are mHealth intervention group and mHealth intervention group+personal medical nutrition therapy group and control group. The target population in this study are pregnant women who have routine antenatal check-up at government sector clinics. Pregnant women are approached by researchers for their eligibility according to the preset inclusion and exclusion criteria as shown in table 2 below. Eligible participants are provided with clear instructions on the nature of the study. An informed consent sheet is given to all eligible pregnant women, and written consent will be obtained prior to their enrolment.

Sample size

The study done by Weeks *et al*,[99] among pregnant mothers and health care providers found that the mean (SD) for the intervention group baseline (n=50) was 11.19 (22.04) and mean (SD) for intervention group post intervention (n=50) was 22.66 (29.39). The sample size was calculated by using the formula difference between groups or between the sample of the population[100] by using 95% interval, $Z_{1-\alpha}$= 1.96 and power of 80%, $Z_{1-\beta}$ = 0.84. To consider the possibility of drop off, a 20% is added which gives a total of 294 participants, with 98 participants needed in control, mHealth intervention alone and mHealth intervention group+personal medical nutrition therapy group, respectively.

Measurements

A set of pretested structure questionnaires (bilingual: English version and Malay version) will be used to obtain information on personal information, prenatal knowledge, physical activity, psychosocial well-being, dietary intake, quality of life, sleep quality, GWG and pregnancy outcomes among the participants comprising of mHealth intervention group, mHealth intervention+personal medical nutrition therapy group and a control group. Other than 24-hour dietary intake (2 weekdays and 1 weekend) will be obtained by face-to-face interview.

Pretesting was performed at the department of obstetrics and gynaecology, *Hospital Sultan Abdul Aziz Shah* to ensure the validity and reliability of the tools. A total of 30 mothers were recruited for instrument pretesting, which met the recommendation of sample sizes for pretesting questionnaires and minimum sample size of reliability test.[101 102] The instruments used for primary (GWG) and secondary outcome determination (prenatal knowledge, dietary intake, physical activity, psychosocial well-being, quality of life, sleep quality, pregnancy outcomes) are shown as below.

The maternal health literacy inventory in pregnancy (MHELIP)

Mothers' prenatal knowledge will be assessed using MHELIP questionnaire. It is a comprehensive, accurate

Table 2 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Malaysian women (all ethnicities) 18–40 years old	Diagnosed with major psychiatric problems (bipolar depression, schizophrenia, suicidal risk)
Single pregnancy	Multiple pregnancies
At the first trimester or second trimester	On other intervention programme
Own smartphone with internet access	Grand multipara
Met or have not meet with a dietitian before	Severe comorbidities (cardiac diseases, severe anaemia)
With or without diseases (diabetes mellitus without/with low dose insulin, hypertension, hyperlipidaemia, overweight/obese)	Type 1 diabetes or type 2 diabetes with high-dose insulin

and validated questionnaire for assessing maternal health literacy during pregnancy.[100] According to a recent study, this tool is valid and reliable and can be used in future studies to assess the health literacy of pregnant women.[103] The Cronbach's alpha was 0.94 and test–retest with 2-week intervals confirmed the tool's reliability, demonstrating that the scale is stable (intraclass correlation coefficient (ICC)=0.96).[103] The Cronbach's alpha values for the MHELIP was 0.961 for this study.

24-hour dietary intake (2 weekdays and 1 weekend)

Dietary intake of participants is examined by using multiple day dietary recalls that include 2 weekdays and 1 weekend 24-hour dietary intake. Mothers will be interviewed by researchers with dietetics background for the 3 days dietary recall. Furthermore, Nutritionist Pro software V.3.1.0 (Axxa Systems, Stafford, Texas, USA) will be used for nutrient analysis, means and SD for energy, macronutrient and micronutrient intakes will be presented. The contribution of carbohydrates, fat and proteins to total energy intake will be calculated too.

Pregnancy Physical Activity Questionnaire (PPAQ)

PPAQ is used to track the pregnant mothers' physical activity levels. PPAQ is a reliable instrument that can be used to assess a wide range of physical activities during pregnancy.[104] A validation study of PPAQ conducted in the local setting recruited a total of 23 pregnant women from two health clinics in Terengganu, aged between 22 and 41 years old showed that the Cronbach's alpha of 0.733 and an ICC value ranging from 0.537 to 0.869 in the reliability test, showing acceptable internal consistency.[105] The Cronbach's alpha values for the PPAQ was 0.709 in this study.

Depression Anxiety and Stress Scale—21 items (DASS-21)

Psychosocial well-being of the pregnant women is ascertained by using DASS-21. The DASS-21 is a series of three self-report scales meant to assess the emotional states of depression, anxiety and stress.[106] According to Bright *et al*,[107] DASS-21 is well validated in pregnant women and has a reliability of 0.82 for anxiety and 0.90 for stress.[106] The Bahasa Malaysia (BM) version of DASS-21 had a very good reliability with Cronbach's alpha of 0.75, 0.74 and 0.79, for depression, anxiety and stress subscales, respectively.[108] These reflect BM DASS-21 had exceptional psychometric properties and is suitable to be used for the Malaysian clinical population.[109] The Cronbach's alpha values for the DASS-21 was 0.940, denoting its good reliability.

WHO-5 Well-being Index

Quality of life of respondents is assessed by using WHO-5 Well-Being Index Questionnaire.[109] The WHO-5 has portrayed good psychometric properties with acceptable validity and internal consistency.[110] It consists of five statements, which respondents' rate according to the scale below (in relation to the past 2 weeks): all of the time=5; most of the time=4; more than half of the time=3; less than half of the time=2; some of the time=1 and at no time=0. The total raw score, ranging from 0 to 25, is multiplied by 4 to give the final score, with 0 represents the worst imaginable well-being while 100 represents the best imaginable well-being. Generally, scores below 13 may indicate poor well-being. The Cronbach's alpha for the WHO-5 Well-being Index was 0.870 in this study.

Pittsburgh Sleep Quality Index (PSQI)

Sleep quality of respondents is ascertained by using a universal sleep tool, PSQI.[111] This tool could be used in clinical settings to provide early assessments for sleep disruption.[112] The PSQI is a self-rated questionnaire consisting of 19 items, of which 18 items are used in score calculation. It comprises of seven components: subjective sleep quality, sleep latency, sleep duration, sleep efficiency, sleep disturbances, use of sleep medication and daytime dysfunction, with a scale factor that varies from 0 to 3 for each question and a global score ranges between 0 and 21. The higher the score, the lower quality of sleep. A global PSQI Score of greater than 5 indicates poor sleep quality. The PSQI used in the present study had been validated extensively among the population in Malaysia,[113] with acceptable reliability.[113] For this study, the Cronbach's alpha values for the PSQI was 0.836.

Pregnancy outcomes

Type of delivery, Apgar score, born term, infant weight, infant length, infant head circumference, infant gender, maternal complications and infant complications will be assessed after the mother delivers the baby.

Data collection

At baseline (first trimester or second trimester), assessment on personal information, anthropometry data, biochemical data (oral glucose tolerance test, blood sugar profile monitoring, urine albumin, urine glucose and haemoglobin), prenatal knowledge, dietary intake, physical activity, psychosocial well-being, sleep quality and quality of life will be performed. All participants will be followed up prospectively until delivery. Reassessments will be performed after 3 months (6th month of pregnancy) or/and 6 months (9th month of pregnancy) and after delivery. Date of data collection for the follow-up will be matched with the prenatal visit of the pregnant mothers to maximise their visit to the health clinic.

Interventions

Wait list control group

Pregnant women in the control group will continue to receive standard antenatal care from the health clinic and be ensured that they will receive the mHealth intervention on study completion (wait list control). Such arrangement will empower the pregnant women on the important aspects of GWG, for example, dietary intake and physical activity recommendation for the future pregnancies.

Intervention group 1: mHealth intervention group

Pregnant women who are attending Health Clinic of Presint 9 Putrajaya will receive mHealth intervention, while pregnant women who are attending Health Clinic of Presint 18 Putrajaya will receive mHealth+personal medical nutrition therapy intervention, in addition to the standard usual care. For pregnant women in the mHealth intervention alone, they will be given a QR code to scan and download the mobile application through the Play Store. By using the mobile apps, participants are able to monitor GWG throughout the pregnancy, assess information on dietary recommendation based on their physical activity level and monitor their dietary intake. Other than that, participants will be able to assess the information regarding psychosocial health, physical activity, dietary intake and GWG during pregnancy via apps which is link to a website. The content of the website is also accessible in the apps format with pertinent information is shown in online supplemental appendix 2.

Intervention group 2: mHealth intervention group+personal medical nutrition therapy group

Pregnant women who are attending Health Clinic of Presint 18 Putrajaya will receive mobile application as the source of education and personal monitoring. In addition, this group of pregnant women will have extra intervention in which they will receive one-to-one personal medical nutrition therapy by a certified dietitian by using the TPB. We anticipate that by using TPB will enhance respondent's behaviour to achieve the recommended weight gain, physical activity level and healthier dietary pattern. According to TPB, pregnant mother will be motivated to engage in good behaviour such as managing GWG, dietary intake and physical activity if she has a positive attitude and feels if her loved one wants her to do it (subjective norm) as well as herself believes she can engage in the behaviour (perceived behavioural control). Self-regulation indicates that actions are motivated by goals and subjected to feedback strategies (one-to-one dietitian consultation). Pregnant mother participates in tasks in which she can succeed, and her perception of her behavioural control will be influenced by her confidence in performance success (self-efficacy). Thus, self-monitoring such as self-monitoring blood glucose (SMBG), monitor frequency of physical activity per week, daily dietary pattern and GWG are essential behaviour modification method as well as a crucial component use to control GWG, practice healthier dietary pattern and be physically active.

Intervention delivery

All intervention participants in this study will undergo a study comprising of mHealth application, whereas for intervention group 2 will receive individual personal medical nutrition therapy, at baseline and during follow-ups. At the first visit, an individual dietary counselling will be conducted. It emphasises on the importance of having adequate macronutrient and micronutrient intake according to the participant's pregnancy trimester. Pregnant women with anaemia or presented with diseases such as diabetes mellitus, hypertension and hyperlipidaemia will be given with pamphlet as personal reference. Other than dietary advice, pregnant mothers are empowered with the recommended weight gain and appropriate physical activity to be performed during pregnancy. During the 6th month (first follow-up) or/and 9th month (second follow-up), recommendation especially on energy and protein requirement will be re-emphasised based on participant's requirement. In addition, reinforcement of individual goals, follow-up on their adherence to GWG, nutrition advice, physical activity and discuss on the possible barriers or challenges they encountered will be performed throughout the intervention journey.

During the personal medical nutrition therapy session, counselling will be given to participants according to dietary assessment based on the analysis of 3 days dietary recall (2 weekdays and 1 weekend), whereby participants will be informed on the macronutrient and micronutrient requirement based on their prepregnancy body mass index, stage of pregnancy and individual health status. Furthermore, participants are informed on the appropriate weight gain rate per week and the frequency, duration as well as intensity of physical activity to be carried out per week. During follow-up visit, participants are encouraged to share the obstacles or challenges faced and appropriate coping strategies will be discussed to ensure participants have perceived behavioural control to overcome the barriers. Throughout the consultation session, motivation will be given in order to ensure respondents have a good attitude to practice the intervention given. Additionally, psychological and emotional support will be given by dietitian to the participants with the reminder of their loved one definately wish they to do the best for better pregnancy outcome. Questionnaire on anthropometry, biochemical data, dietary intake, physical activity, sleep pattern, psychology and quality of life will be administered on the 3 monthly basis and pregnancy outcome will be obtained after mother delivers the baby. Table 3 depicts the gantt chart for main activities for this study.

DISCUSSION

There is growing literature on the use of digital or technological innovations such as mHealth intervention as novel approaches to improve the healthcare of people with diseases and the public, including pregnant mothers. The use of mHealth apps during pregnancy provides an exceptional window of opportunity as women are often more inspired to optimise health and change their lifestyle during pregnancy.[114] One of the important components of mHealth is that these tools inspire people to take responsibility for their health.[115] Earlier studies showed that the medical health app is perceived as a trustworthy source of information that matches the advice given by

Table 3 Gantt chart

Year	2023									2024					
Project activities	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J
Pre intervention assessment (Baseline)															
First follow-up (sixth month)															
Second follow-up (ninth month)															
Third follow-up (after Delivery of baby)															

medical specialists,[115] with increased satisfaction and patient engagement.[116] Thus, appropriate use of technology may assist pregnant women in achieving clinical outcomes, including GWG recommendations. Besides, such apps can be considered a useful tool for healthcare providers as an information management platform for their patients.[117]

There is plausible of data on the effectiveness of mHealth on pregnancy outcomes. Previous randomised control trial reported mobile app led to more engaged and motivated patients to attend prenatal consultations and better compliance on recommendations than conventional method (printed booklet).[118] Self-management among the patients is vital and mobile application will be helpful, this could be applied to populations such as pregnant mothers who are receiving periodic care and mobile apps can be one of the best methods for pregnant mothers who are using mobile phone in their daily life.

Exclusively, digital health interventions targeting diet, physical activity or both to encourage healthier lifestyles during pregnancy and reduce rates of excessive GWG have been shown to be effective.[33 78] However, more evidence is needed to delineate the effectiveness of mHealth apps, considering inconsistency of findings.[82 83 119 120] The creation of high-quality apps may have the potential to enhance prenatal outcomes by improving access to health information, lowering the need for in-person health services and enabling the provision of individualised care as more women use apps during pregnancy.[121]

However, there is a scarcity of information on factors associated with GWG among pregnant mothers in Malaysia by using the incorporation of mobile application into the health management, thus a holistic approach comprising all the above factors and a newly developed mHealth is essential to optimise GWG among pregnant women in Malaysia. Our study adds to the literature by determining whether an application providing information on dietary intake, physical activity level and psychosocial well-being can promote optimum GWG and other health outcomes among pregnant women.

Other than monitor gestational weight gain by weekly, task to do SMBG will be given for those with diabetes mellitus or gestational diabetes as this will encourage mother to monitor and encourage respondents to control diet and increase exercise if the blood glucose level does not achieve the optimum value which the task of doing SMBG will be an enforcement to continue with good behaviour. Eventually, the participants will have perceived power to overcome the barriers as throughout the intervention, education and knowledge they obtain through the dietitian consultation and mHealth usage will facilitate them to change their behaviour as the demonstration and skills given will increase their self-efficacy. Besides, as pregnant mothers will meet with dietitian regularly, the counselling and feedback sessions will reinforce their behaviours and facilitate them to overcome any barriers as well as have intention to perform good behaviour throughout the pregnancy period.

Furthermore, we aim to ascertain whether the mHealth application alone can produce similar outcomes to mHealth together with dietitian interventions. If mHealth alone can improve the GWG and overall maternal health outcomes, it will reduce the reliance on clinical team, which will lead to time and cost-effectiveness for both healthcare professional and pregnant mothers. Additionally, using mHealth can improve the quality of pregnancy care by expanding access to care for individuals who are unable to attend clinic visits so frequently and those who live in geographic areas where clinical care is limited. We expect that there will be an improvement in the GWG and other health outcomes for pregnant mothers in the mHealth intervention groups. Besides, GWG and health outcomes are comparable between the two intervention groups, whereby additional of individual dietary counselling is not required if mHealth information is sufficient to promote optimal pregnancy outcomes.

Data analysis plan

Data will be processed and analysed using SPSS V.29.0 by using descriptive and inferential statistics. All the variables will be run with statistical tests of normality to determine whether the data is normally distributed. Continuous data will be presented in mean and SD while categorical data will be presented in frequency and percentage. For the GWG of the pregnant women will be presented in continuous data (mean and standard deviation) and categorical data which the pregnant women will be classified into three categories which are below, within or above weight gain recommendation. In addition, personal information of the pregnant women will be classified as discrete data (date of birth, age, number of pregnancies, estimated date of delivery, number of kids of current pregnancy and current week), nominal data (ethnicity, working

sector, location of delivery and medical history) and ordinal data (highest educational level and total monthly household income). For anthropometry parameters, biochemical data, level of physical activity, sleep quality and quality of life will be presented as continuous data. However, prenatal scores, psychosocial well-being, nutritional status will be presented as both continuous and categorical data. A generalised linear mixed model test will be performed to determine the mean differences in GWG and other health outcomes between pregnant women receiving intervention groups and conventional health education (control group) over time and group by time interaction. Pregnancy outcomes namely type of delivery, born term, gender, maternal complications and infant complications will be presented as categorical data. Furthermore, Apgar score, infant weight, infant length and head circumference will be presented as continuous data. In addition, multivariate analysis of variance (MANOVA test) will be performed for GWG (categorical data) and pregnancy outcomes (continuous data) while Pearson's correlation test will be run for GWG (categorical data) and pregnancy outcomes (categorical data).

Ethics and dissemination

The study was performed in accordance with all relevant guidelines and regulations. Ethical approvals were obtained from the ethics committee of human subjects research of Universiti Putra Malaysia (JKEUPM-2022-072) and medical research & ethics committee, Ministry of Health Malaysia: NMRR ID-22-00622-EPU (IIR). Permission to conduct this study at each participating site had been obtained from the respective district health offices (Jabatan Kesihatan Negeri Selangor (JKNS/KA/Q-712/04-01 Jld 19 (14) and Jabatan Kesihatan Wilayah Persekutuan Kuala Lumpur dan Putrajaya (Bil.41 dlm.JKWPKL/203/4 Bhg.13). Participants will be provided with a study information sheet that included all information typically included in a consent form and could contact the study team to discuss the study. All participants are required to provide written informed consent prior to data collection. All information obtained in this research will be kept and handled confidentially, in accordance with applicable regulations and/or laws. We plan to disseminate the study findings at various scientific meetings and conferences as well as publication in appropriate peer-reviewed journals targeting stakeholders involved in nutrition research.

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