BMJ Open

KEPT-app trial: a pragmatic, single-blind, parallel, cluster-randomised effectiveness study of pelvic floor muscle training among incontinent pregnant women: study protocol

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To cite: Sidik SM, Jaffar A, Foo CN, *et al*. KEPT-app trial: a pragmatic, single-blind, parallel, cluster-randomised effectiveness study of pelvic floor muscle training among incontinent pregnant women: study protocol. *BMJ Open* 2021;**11**:e039076. doi:10.1136/bmjopen-2020-039076

► Prepublication history and additional material for this paper is available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2020-039076).

Received 06 April 2020
Revised 17 November 2020
Accepted 13 December 2020

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ABSTRACT

Introduction Pelvic floor muscle training (PFMT) strongly recommended to incontinent pregnant women. The Kegel Exercise Pregnancy Training-app trial is a multicentre cluster-randomised study aims to assess the effectiveness and its cost-effectiveness of the mobile app guidance in PFMT among incontinent pregnant women.

Methods and analysis 370 pregnant women (aged 18 years old and above) will be recruited with International Consultation on Incontinence Questionnaire-Urinary Incontinence-Short Form. Ten clusters (primary care clinics) will be randomly assigned to either PFMT or usual care in a 1:1 ratio by an independent researcher (sealed envelope). The primary outcome will be urinary incontinence, and the secondary outcomes (quality of life; PFMT adherence, psychological status and mobile apps' usability) will be assessed at four measurement time points (t0: baseline) and postintervention (t1: 4 weeks, t2: 8 weeks and t3: 8 weeks postnatal). T-test analysis will determine any significant differences at the baseline between the control and intervention groups. The mixed-model analysis will determine the effectiveness of the intervention at the population-average level for both the primary and secondary outcomes. For the cost-effectiveness analysis, expenditures during the study and 6 months after the intervention will be compared between the groups using the multiway sensitivity analysis. The recruitment planned will be in December 2020, and the planned end of the study will be in August 2021.

Ethics and dissemination This study protocol was approved by the Ethics Committee for Research Involving Human Subjects, Universiti Putra Malaysia (JKEUPM-2019–368) and Medical Research and Ethics Committee (MREC), Ministry of Health Malaysia, NMRR-19-412-47116 (IIR) with the ANZCTR registration. This study will obtain informed written consent from all the study participants. The results which conform with the Consolidated Standards of Reporting Trials and the Recommendations for Interventional Trials will be published for dissemination in peer-reviewed journals and conference proceedings.

Strengths and limitations of this study

- To our knowledge, this study is the first pragmatic study at the primary care level to examine the effectiveness of pelvic floor muscle training (PFMT) delivered via a mHealth app among incontinent pregnant women (primigravida and multigravida).
- The mHealth app was designed based on the Cognitive, Opportunity, Motivation-Behaviour embedded in Behavioural Change Wheel using the Intervention Mapping framework.
- The study will include only 10 clusters in which all will be in one district in the state of Selangor, Malaysia. Therefore, the decision of whether the findings can be generalised to another district remains to be further studied.
- The PFMT adherence among pregnant women as a secondary outcome will only be measured until 8 weeks postnatal.
- The self-efficacy assessment will be done via a validated questionnaire without any objective assessment, which may not provide accurate results.

Trial registration number ACTRN12619000379112.

INTRODUCTION

Urinary incontinence (UI) occurs when a person is unable to control urine, leading to its involuntary leakage.[1] It is stated as one of the greatest burdens in 2018 by affecting about 423 million globally.[2]

Pregnancy consists of three trimesters: first (early until week 12 of pregnancy); second (week 13 to week 27 of pregnancy) and third trimester (28 weeks onwards).[3] UI significantly increases in the second and then the third trimesters, as well with an increased number of pregnancies.[4] A study in Norway

composed of 43 279 pregnant women reported that parity was a strong risk factor for UI with the (OR: 2.1, 95% CI 2.0 to 2.2) with the increased prevalence of UI from 35% before pregnancy to 67% during week 30.[5] Similarly, one primary care clinic reported prevalence of UI was 40.1% (N=440) with double the risk of UI among multigravida (OR 2.01, 95% CI 1.24 to 3.26).[6]

There are three types of UI: stress UI (SUI) with increased abdominal pressure leading to extra stress on the bladder; urge UI (UUI) with an unstable or overactive bladder and mixed UI (MUI) (a combination of stress and urge).[7 8] SUI is the most common during the pregnancy due to excessive stress on the bladder from the uterus enlargement, with 17%–54% of the female population experiencing their first UI during pregnancy.[9 10] A study among primigravida reported that SUI in the third trimester was the most prevalent (64.8%), followed by MUI (24.8%) and UUI (6.7%).[11] A similar finding reported among mixed parity at a primary care clinic with a majority of them having SUI (75.6%, n=136).[6]

Studies have shown that pelvic floor muscle training (PFMT) or Kegel exercise is most effective in treating SUI and MUI, by strengthening the pelvic floor muscles.[8 12–15] PFMT has been recommended as the first-line treatment in UI.[8] There were a few barriers for pregnant women to do PFMT, for example; poor knowledge, attitude and practice towards PFMT[6 16] and to remember the daily PFMT.[17] mHealth app has shown its importance (Level of evidence II) as it enables reminders and improvement to the accessibilities of PFMT for the patients.[18]

Several studies reported promising results using mHealth apps in managing UI.[19] Similarly, a recent randomised controlled trial (RCT) on the effectiveness of a mHealth app-based audio guidance home training PFMT among primipara (after receiving personal PFMT by a physiotherapist) showed a positive outcome. The study reported with significant improvement in SUI, especially after 3-month training with β=−5.520 (p<0.001) from 54 primiparas.[20]

In conclusion, PFMT via mHealth app shows improvement in UI due to PFMT adherence. The essence in managing UI is to be able to adhere to the correct PFMT.[21] Furthermore, mHealth app improves the accessibility of PFMT to pregnant women as supervised PFMT is time-consuming and involves healthcare workers which may lead to less cost-effectiveness and poor adherence to training.

Despite the positive outcomes of PFMT as the treatment for incontinent pregnant women, a recent Cochrane review reported an uncertain outcome effect.[22] The risk of bias and low-quality evidence skewed the pooled results into the uncertain effect.[22] This review may steer physicians, stakeholders and policy-makers away from promoting PFMT as the treatment for UI among pregnant women.

Therefore, it is vital to conduct a good quality pragmatic, single-blind cluster RCT (CRCT) to determine the effectiveness of PFMT in primary care (usual care) settings. The findings from this study bridge the implementation gaps as it balances between internal validity and generalisability.[23] Hence, it enables us to provide essential evidence about PFMT's effectiveness as the treatment of choice for pregnant women with UI in the healthcare system.

Pragmatic effectiveness trial of PFMT as a treatment for pregnant women: the Kegel Exercise Pregnancy Training mHealth-app trial

The Kegel Exercise Pregnancy Training mHealth app trials (KEPT-app) study is a multicentre cluster-randomised trial. The aim is to assess the PFMT delivered via the mHealth app as a treatment approach among pregnant women in community-based healthcare in comparison to standard-care (usual care) antenatal clinic follow-up. We examine the following hypotheses: at 1-month (early third trimester), 2-month (late third trimester) and 8 weeks postnatal (early postnatal) follow-up, the intervention groups (IGs) show significant improvement in their UI symptoms, quality of life (QoL), knowledge, attitude and practices of PFMT, adherence to PFMT and self-efficacy in PFMT compared with the control groups (CGs) which receive the usual care (waitlist groups).

Aim

This study aims to determine the effectiveness of mHealth app guidance PFMT on the treatment of UI in pregnant women. The app is named as the KEPT-App. The primary objective is to determine whether KEPT-app results in improving UI in pregnant women. The secondary outcomes are QoL, knowledge, attitude and practices of PFMT, PFMT adherence, self-efficacy towards PFMT, psychological status and usability of the KEPT-app.

METHODS AND ANALYSIS

Study design

This study is a pragmatic, single-blind, cluster CRCT involving 10 primary care clinics in Hulu Langat district, which is one of the nine districts in the state of Selangor, Malaysia. The district chosen for this study has the largest number of clinics with the second-highest number of deliveries in Selangor. Selangor had the highest number of antenatal cases in 2017 with more than 1 million pregnant women attendees.[24]

This cluster trial is based on the administrative unit (Hulu Langat District Health Office) which enables to clearly map the boundaries between the neighbouring district, decrease concerns over contamination and reduction between-cluster variability.[25]

Each primary care clinic will be randomised to either the intervention or CG for at least 16 weeks as the intervention starts at 28 weeks until delivery at 36 weeks and PFMT continues up to 8 weeks postnatal) as illustrated in figure 1.

This study will use cluster randomisation with allocation concealment in order to reduce selection bias.[26] The

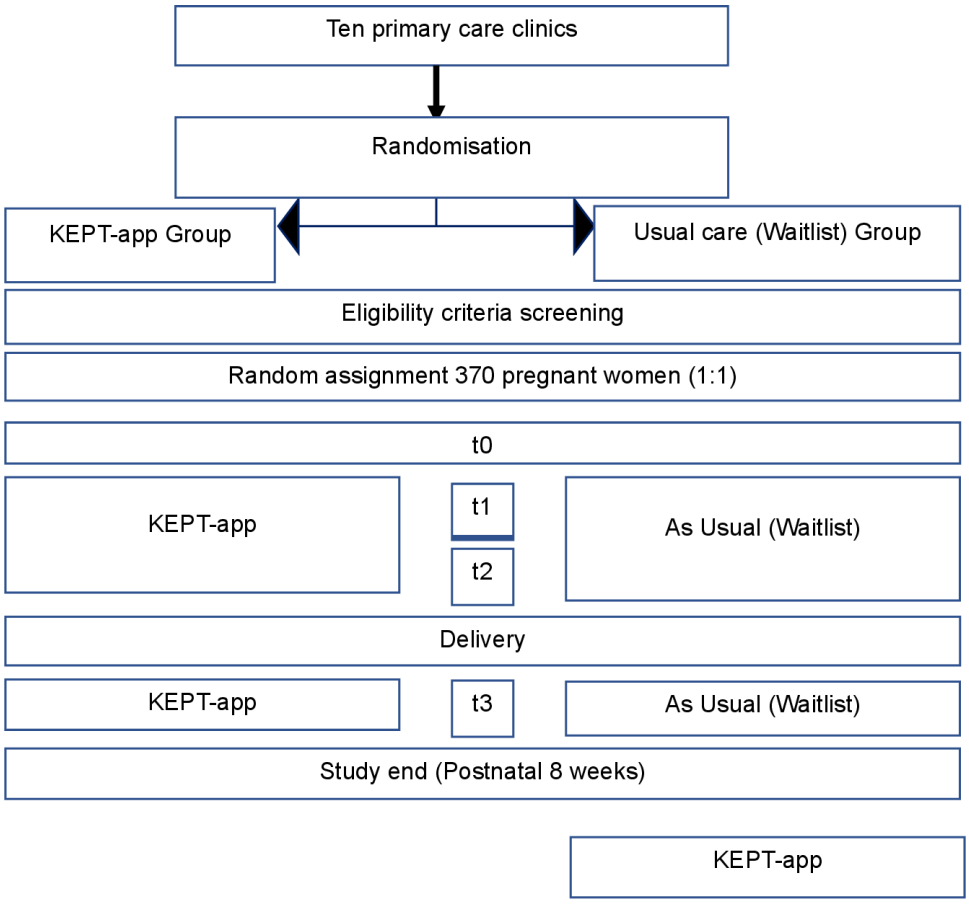

Figure 1 Study design. KEPT-aPP, Kegel Exercise Pregnancy Training mHealth app.

name of 10 clinics in Hulu Langat will be written in separate envelopes and concealed from the researchers. A blinded independent researcher will randomly assign ten clusters (primary care clinics) to one of two groups: IGs which receives KEPT-app and CGs which receive the treatment as usual (waitlist group). He/she will pick one by one, envelopes with the five clinics name tagged as either IGs or CGs each in alternate sequence. Therefore, there will be five clinics in each group which as per recommendation to have at least four clusters per arm.[25 27]

The total participants of 370 will be randomly allocated in a 1:1 ratio to either the IGs or the CGs according to their usual antenatal care clinic follow-up. The number of women recruited from respective clinics will depend on the total number of antenatal patients in each clinic: a higher proportion of participants will be recruited from clinics with a larger number of antenatal patients and vice versa.

The interventions will start immediately after the baseline data (t0: baseline) has been collected. The participants will download the KEPT-app instruction for a short introduction briefing and are encouraged to contact the research assistants (RAs) for further clarification if needed. The PFMT video and the training will start on the same day the KEPT-app is downloaded, and the diary with the reminder will start the next day.

After 4 weeks, both groups will receive follow-up assessments as t1. Two more follow-up assessments will be delivered at t2: 8 weeks (after treatment initiation) and t3: 8 weeks postnatal. Two weeks before the date of the assessment, a booster (cue to watch the video) will be delivered to the IGs. All participants in both groups will receive three follow-up assessments (t1: 4 weeks after treatment initiation/enrolled into the CGs, t2: 8 weeks after treatment initiation/enrolled into the CGs, t3:8 weeks postnatal, respectively), primary and secondary outcome measures will be assessed via online assessment as in table 1 and figure 2.

KEPT-app trial will be a single-blind study whereby the researcher and assessor will be blinded to the group affiliation. The participants will not be blinded as they are aware of which groups they belong to.

This study protocol is designed and reported according to the recommendations in the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT)[28] and Consolidated Standards of Reporting Trials (CONSORT) statements extensions for pragmatic trials,[29] CONSORT CRCTs[27] (see online supplemental file 1), and checklist from the Pragmatic-Explanatory Continuum Indicator Summary-2.[30]

This pragmatic design will give a real-world view and provide information on the internal validity of the

Table 1 Overview outcome measures

	Enrolment	Baseline	Postallocation					
Time point**	0	t0	B	t1	B	t2	B	t3
Enrolment:	26–27 weeks	28 weeks		32 weeks		36 weeks		8 weeks postnatal
Eligibility screen	√							
Informed consent	√							
Allocation		√						
Intervention:		→						
KEPT app		√		√		√		√
Usual care (Waitlist)		√		√		√		√
Booster*				√		√		√
Assessments:								
Urinary incontinence	√							
Primary outcome		√		√		√		√
Secondary outcomes		√		√		√		√

B: Booster (Cue to revisit the video)

KEPT, Kegel Exercise Pregnancy Training mHealth.

intervention in improving the intended problem.[31] In this context, the effectiveness of the KEPT-app in improving the UI symptoms experience of pregnant women. There are four steps to ensure the pragmatism of a study with nine domain indicators.[30] This present study scores 4.6, which is high pragmatic (see online supplemental file 2). The journal abstract for this study is according to the recommendation from the CONSORT extension for journal abstracts[32] (see online supplemental file 3).

Participants eligibility

We will recruit a total of 370 pregnant women presenting to 10 primary care clinics in Hulu Langat district, Selangor state in Malaysia. Each clinic will be expected to recruit between 20 and 60 pregnant women, proportionate with their pregnant women attendances based on the sample size calculation.

Participants who are more than 18 years old, primipara and multiparas at 26–27 weeks' gestation with UI scores of 3–18 according to the International Consultation on Incontinence Questionnaire-UI-Short Form are eligible to participate in the study. They are Malaysian citizens who consist of Malay, Chinese, Indian and native ethnicities, and will be included in this study, as the main language used in this study will be Malay, which is the national language of Malaysia.

Pregnant women with a chronic medical problem(s) before pregnancy (diabetes, hypertension, HIV positive, a neurological condition affecting bladder control, stroke, pelvic organ prolapse) will be excluded as UI in this condition should not be treated by PFMT only. In addition to the exclusion list are complicated pregnancies or conditions which are not advisable to practise PFMT (such as pre-eclampsia, persistent bleeding, preterm, labour, incompetent cervix, acute febrile infection, fetal growth restriction or placenta previa and cephalopelvic disproportion).

The researchers will be blinded to the participants' responses and their group allocation. RAs will be responsible for the recruitment of the participants and assist them with the electronic informed consent and data collection. The RAs will have a short training on communication skills, the KEPT-App and short message system (SMS) link for questionnaires and will contact with the main researcher to discuss any issues during the recruitment or data collection.

The RAs will screen for participants at 26 weeks or 27 weeks of pregnancy based on the information written in their antenatal books. Those who fulfil the study criteria will be invited using consecutive sampling method by recruiting every patient who meets the selection criteria within the recruitment period of 3 months.[33] We acknowledge the commitment and the importance of participant retention and their adherence participating in our study. We will give the CG the KEPT-app once they complete the study after 8 weeks postnatal. The detail of the recruitment, as illustrated in figure 3.

The RAs will explain to the participants they can leave this study at any time when they demand to do so, without any consequences. If any pregnant women have any health issues during the research, they will be encouraged to seek help from their healthcare professionals during antenatal follow-up or at any primary care clinic to receive any treatment. Evidence has shown no harm to perform PFMT among pregnant women.[34]

Intervention

The KEPT-App will guide correct techniques of PFMT and encourage pregnant women to adhere to the PFMT. The intervention consists of a KEPT-app implementation

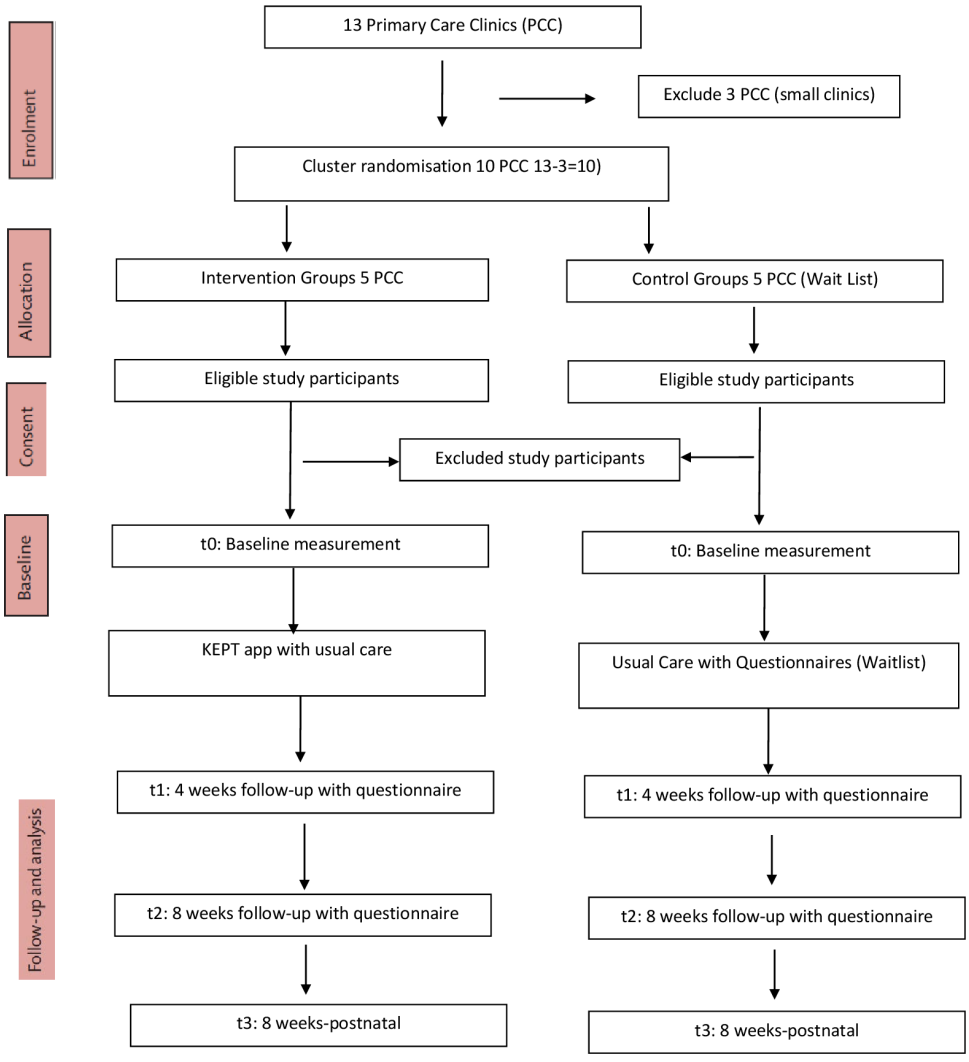

Figure 2 CONSORT 2010 flow diagram. CONSORT, Consolidated Standards of Reporting Trials.

which will be started at 28 weeks of gestation, and its effectiveness will be evaluated at 8 weeks postnatal.

The IG will receive a KEPT-app additional to the usual care while the CG will receive usual antenatal care and SMS with the link to the questionnaires. During recruitment and before obtaining the consent, RAs will explain the aims, justification, and process of the intervention to the participants.

The KEPT-app will be developed according to an 'Intervention Mapping'. It is a guided and systematic approach protocol which incorporates the theory-based and evidence-based health promotion programmes in developing the health promotion intervention. Intervention Mapping has six steps which are[1] the needs assessment (logic model),[2] the definition of the programme outcome and change,[3] the choice of the most appropriate theory-based intervention methods to design the programme,[4] the programme production,[5] implementation of the programme, and[6] evaluation of the programme.[35 36]

KEPT-app is a design from the Cognitive, Opportunity, Motivation-Behaviour (COM-B) theory embedded in the Behaviour Change Wheel (BCW) Framework to adopt PFMT as the new habit. The BCW Framework are recent developments that provide a systematic and theoretical basis for understanding and changing behaviour.[37] It has eight steps to bring theory-based tool together into a coherent intervention design: define the problem in behavioural terms, select the target behaviour, specify the target behaviour, identify what needs to change, identify the intervention functions, identify the policy categories, identify the behaviour change techniques and identify the mode of delivery.[37 38]

In the (COM-B) theory, KEPT-app will use the social cognitive theory as one of its behavioural change theory, which states that behavioural change is dependent on a person's autonomy and self-efficacy is essential for PFMT adherence.[39] A pregnant woman is more likely to adhere with PFMT if she has good self-efficacy about the exercise. PFMT techniques will be delivered using an instructional video which demonstrates different positions, guides the users on the correct method, and explains the common mistakes and myths of PFMT. A certified, experienced physiotherapist conducts the demonstration in line with the recommendation guidelines.[21 40] The KEPT-app

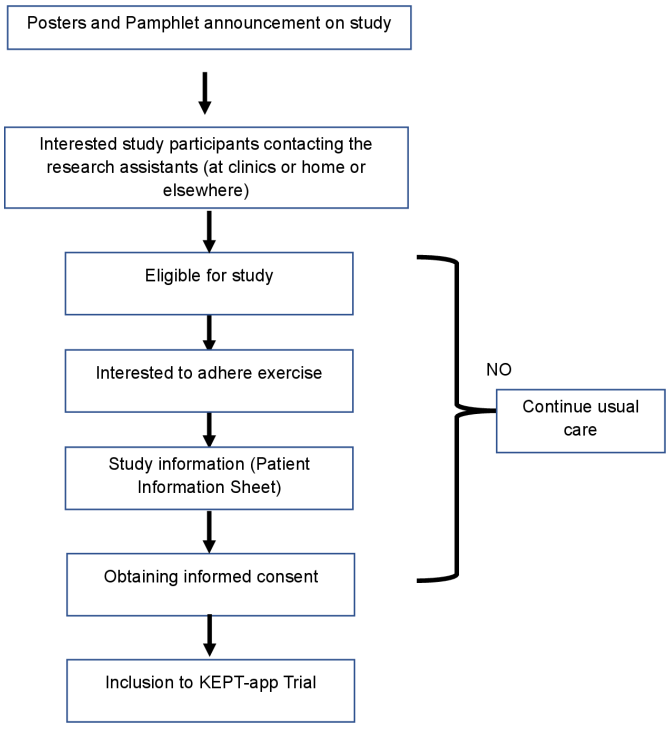

Figure 3 Recruitment flow chart.

development in the process of manuscript writing to publish in the peer-reviewed journal, as recommended in the Good Practice Guideline Health Apps and Smart Devices (Mobile Health or mHealth).[41]

After participants have understood the video, they will enter the training mode of the KEPT-app. This training mode will guide them step by step with the instructor's voice to be ready at the position, take a deep breath and contract for a few seconds (to get the feel of the contraction). After they have understood the correct feeling of their muscles contracting, they will move to the next level, which is the training mode of 10 s. The aim is to be able to do PFMT for 10 s each time (a few seconds resting) for ten times per cycle with a total of three cycles per day.

The study participants will move out of the training mode, once they can perform the PFMT confidently. They proceed to the adherence phase, where the aim is to perform ten cycles three times a day. KEPT-app will record the exercise activities during the study period to capture the actual adherence rate with a reminder occurring on the screen if no activities are recorded.

Participants will be able to track their improvement in the UI symptoms and PFMT adherence. KEPT-app will undergo its validity and usability testing before its implementation in this study according to the recommendation by the CONSORT extension PRO.[42]

Sample size calculation

The sample size for this interventional phase is using the individually randomised trial formula of continuous outcome $N=2(Z_{\alpha/2}+Z_{\beta})^2(\sigma^2)/(\mu_1-\mu_2)^2$.[43]

The details of the formula whereby $Z_{\alpha/2}$ and Z_{β} are the standard normal values corresponding to the upper tail probabilities of $\alpha/2$ and β respectively. The α is the two-sided significance level and $1-\beta$ is the power, $\mu 1$ and $\mu 2$ are the means in the two arms, and σ is the SD of the outcome.

Clustering method involves multiplying of the sample size that requires to be as equally as an individually randomised trial, multiplying with the design effect or formerly known as variance inflation factor.[44 45] The formula for the design effect is: $Deff=1+\rho(m-1)$, where ρ is the intercorrelation coefficient (ICC), and m is the cluster size.[45]

The ICC is a between—cluster variation measurement or the homogeneity of individual measures within a cluster. The ICC's level is according to the setting and type of outcome.[46] For process variables, the ICCs are higher than those for patient outcomes, and similarly, the ICCs of the secondary care are higher than those from primary care. ICCs for process variables in primary care are of the order of 0.05–0.15 with the ICCs for patient outcomes in primary care are generally lower than 0.05.[46]

However,if the actual cluster sizes are unknownn, the design effect needs to be readjusted according to the coefficient of variation of the cluster sizes, CV_c, the formula: $cv_c=s_c/\dot{m}$ where s_c is the SD of cluster sizes and $\dot{m}$ is the average cluster size.

The cv_c is unknown; hence we can estimate using the likely minimum and maximum cluster size.[45] The s_c is estimated by SD=*CSrange*/4. The SD in this study is 40/4=5 (CS range of 40 is the estimated difference between the cluster size according to the previous attendees to the clinics in Hulu Langat). The formula to get the is cv_c=SD/$\dot{m}$[47] where the mean cluster size from previous CRCT at our primary care clinics was 63.[48] Following this, the design effect was then calculated by the formula $Deff=1+[(cv_c^2+1)\dot{m}-1]\rho$.[47 49] Therefore, the design effect (Deff) in this study is 1+[(1.03)63–1]=4.2.

In summary, referring to table 2, the sample size for this study is 368 and after round-up is 370 pregnant women.

Measures

This summary of the primary and secondary outcome assessment is given in table 3. Participants will be given the online assessments at four measurement time points (t0–t3) either via KEPT-app (IGs) or google-form link via SMS (CGs). At t3, there will be an additional assessment on the usability of the KEPT-app only for the IGs participants.

Cost efficiency

The expenditures to purchase incontinence aids will be collected to assess the cost of the UI in both groups during the study. As this will be from the participants' perspective, an estimate of the cost for their time will be included. Therefore, the participants will check back their PFMT record on time spent during the study. As for the usual care group, the assumption will be that the time spent remains constant during the study. This study will use its gross hourly wages to estimate the time cost. This study

Table 2 Sample size calculations from various variables

No	Variables	σ	ρ	μ1–μ2	Deff	Non-respondent (30%)	Attrition rate (20%)
1	UI Severity ICIQ-UI SF[64]	2.56	0.05	2.52	4.2	88	212
2	Quality of Life ICIQLuts Qol[64]	4.95	0.05	3.71	4.2	153	368
3	Knowledge PFMT[65]	3.4*	0.05	4.67	4.2	45	108
4	Attitude PFMT[65]	3.7*	0.05	3.77	4.2	82	198
5	Practices PFMT[65]	1.73*	0.05	3.45	4.2	22	52

*SD using Lemeshow *et al*[66] calculation.
ICIQ-UI SF, International Consultation on Incontinence Questionnaire-Urinary Incontinence-Short Form; PFMT, pelvic floor muscle training; QoL, quality of life.

will use the mixed-model analysis to compare treatment effects between groups using the available data on the UI and QoL. Sensitivity analysis will be performed according to the data available.

Data collection

Quantitative data

This study adheres with the Consolidated Standards of Reporting Trials flow chart to recruit the participants, assess them and report findings.

Data for primary and secondary outcomes

All data will be collected digitally via mobile apps and google documents (with a reminder a week before the data collection's date) and will be kept in data storage. Once the participants register into the system, they will be assigned a unique identification number.

Validation

The questionnaires used in this study have been translated and validated locally. The KEPT-app will be validated in its usability aspect among forty pregnant women who are not involved in the intervention study. The educational video will be validated using Patient Education Materials Assessment Tool audiovisual tool. The results of this validation study will be published either in conference proceedings or in a peer-reviewed manuscript.

Planned statistical analyses

This study will report the data at baseline (t0), post-1 month (t1), post-2 months (t2) and 8 weeks postnatal (t3) after the intervention. The data will be compared at the baseline to determine any significant differences between the control and IGs using the t-test. This study will apply the

Table 3 Study outcomes KEPT-app trial

	Primary outcome	Information
1.	International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF[67])	To measure the reduction in urinary incontinence score at 1 month, 2 months and postnatal in intervention and control groups. Therapy success is defined as absence of UI or change from baseline of at least three points on the ICIQ-UI-SF at 8 weeks postnatal.
	Secondary outcomes	**Information**
1	Knowledge, Attitude and Practice towards PFMT[16]	Improving the scores of knowledge, attitude, and practices towards PFMT in each category:
2.	Exercise Adherence Rating Scale (EARS).[68]	Increasing PFMT adherence from lowest score (0) to maximum score[24] of EARS.
3.	Self-Efficacy Scale For Practicing Pelvic Floor Exercise Questionnaire (SESPPFE)	Improving Self-efficacy by scores of higher than 70% of the SESPPFE.
4.	ICIQ Urinary Incontinence-Lower Urinary Tract Symptom quality of life (ICIQ-LUTSqol)[67]	Improving quality of life according to ICIQLUTSqol score of 3.7 minimum differences.
5	The Patient Health Questionnaire-9 (PHQ-9) consists of nine self-reported questionnaires, based on DSM-IV criteria for major depression.[69–71]	The improvement of PHQ-9 scores.
6	The Generalised Anxiety Disorder scale (GAD-7) has been developed to be used in primary care to diagnose the GAD, panic disorder, social anxiety disorder and post-traumatic stress disorder[72–75]	The improvement of GAD-7 scores.

KEPT app, Kegel Exercise Pregnancy Training mHealth app; PFMT, pelvic floor muscle training.

intention-to-treat principle appropriately for primary and secondary outcomes.

The statistical analyses will be as recommended by SPIRIT 2013, which is the intention-to-treat basis.[50] The participants who have completed the baseline (t0) will be included in the analyses, and their final observations will be carried forward. For example, if the pregnant woman at Clinic A call and request for drop out, the researchers will ask for her main symptoms and outcomes at that time. This study is a single-blind study whereby the researchers and assessor (who performs the statistical analysis) are blinded. Therefore, the IGs and CGs will only be revealed after the analysis of the primary outcome has completed.

Since this study uses multi-centres (primary care clinics), the random effect may exist. Therefore, generalised estimating equation (GEE) analysis will determine the effectiveness of this intervention programme at the population average as proposed by SPIRIT 2013 guideline.[28] GEE will be able to handle missing data with multiple imputations.[51] The IBM SPSS Statistics for Windows, V.25 software is used for all statistical analyses. All statistical tests are two sided with $p<0.05$ considered as statistically significant.

Methodological issues

Cluster RCT

The KEPT-app trial will recruit patients at the population level with intervention delivered individually; hence it is a combination of the population and individual intervention. The cluster size for each arm is five clusters and has achieved its minimum recommended by CONSORT 2010 statement.[27] Unfortunately, this study has two arms with a total of 10 clusters, and this could be at risk of type I error.[52] Therefore, the authors suggest using GEE with a small-sample correction to accommodate this error.[53 54]

This study aims to improve the antenatal care system at primary care level, and cluster-randomised trial approach is preferred despite the KEPT-app being delivered individually. By evidence of treatment success among non-pregnant women with UI using a mobile app (Tät), there is an advantage to deliver this intervention at the population level.[55]

Pragmatic approach

Pragmatic RCT approach is to ensure the effectiveness study on KEPT-app as closely as possible to the real antenatal clinic in primary care practices. Unfortunately, this study only includes one district which consists of ten primary care clinics which put the external validity at risk. The small number of clusters which is due to limited resources will affect the internal validity of this study. However, it is essential to find a balance between internal and external validity in a pragmatic study while strictly adhere to its methodological requirements and recommendations.[28 56–58]

Patient and public involvement

Participants and members of the public will be involved in the study design and the conduct of the trial. The feedback and expectations from the participants of the KEPT-app in terms of designs and content will be analysed. The researchers will conduct pilot testing to improve its version before trial implementation to enhance its cost-effectiveness.

Data management and clinical trial unit support

The data will be collected via the KEPT-app link and SMS-link and entered directly into the trial database. Data gathered from the KEPT-app enables the participants to access their data, monitor their UI symptoms and act as PFMT motivation. The data will be stored in the cloud-based Azure storage.

The research progress will be shared to the Universiti Putra Malaysia and ethical committee 6 monthly. However, the researcher will keep the research notes for 5 years following the publication of the study's results to provide background information for future mHealth applications. Technical appendix, statistical code, and dataset will be available from the Dryad repository, DOI 10.13140/RG.2.2.34968.34568.

Data privacy, protection, security and access

A unique study identification data (ID) code will be used to ensure anonymity and confidentiality. This unique ID will be used to identify participants and the group they belong to. The participants' usernames, patient's registration number and other personal information, will never be linked to their responses nor personal data. The researcher is responsible for ensuring data safety. The participants will have access to the results of their assessments. They will be able to monitor their UI progression via their apps.

To protect the confidentiality, researcher assistants (RA) will discuss confidentiality issues with all participants. In addition to this, all codes, notes, or files, will be encrypted or encoded and stored in only one computer. The RA will ensure that all research files, notes and codes are password-protected, and these files and passwords will be only accessible to one designated RA. The researcher will ensure the maintenance of confidentiality during the study with the compliance by the Data Privacy Act to be highlighted to all study participants.[59]

Mobile apps data protection and security

The data exchange between client and server will be encrypted using the Rivest-Shamir-Adleman algorithm.[60] In addition to encrypting the data transmitted between client and server, Hypertext Transfer Protocol Secure is enabled and powered by Transport Layer Security that helps authenticates the server and protects the transmitted data from tampering.[61]

Data governance

Data governance: To be able to reach effective data governance, this study will apply a Malaysia Data Protection Act

2010 as its formal guidelines. This study will have a specific independent researcher in charge of data handling and managing. The independent researcher will be briefed on the policy guidelines to avoid any mishandling or mismanagement of the data.

Maintenance of anonymity: There will be an identifying number on KEPT-app downloaded during recruitment and follow-up from each participant to maintain anonymity in this research.

Data control: Using the Malaysian Data Protection Act 2010, only the researchers able to access the data, to ensure the data security, confidentiality and management strategy.

Data monitoring: The data will be given to the Universiti Putra Malaysia and ethical committee 6 monthly to update the research progress. All hard copies, for example, the consent forms with the digital recordings will be demolished and destroyed on the publication of this study' results (see online supplemental file 4). However, the researcher will keep only the research notes for 5 years following the publication of the study' results as this study' data will provide some background information for the future mHealth apps development.

Dissemination

The study protocol, instrument validation and KEPT-app results will be disseminated and published through conference presentations and peer-reviewed manuscripts. There is a potential interest to distribute the crucial findings via our university's website to introduce the importance of the KEPT-app.

Publication policy

Trial result: Each manuscript or abstract, must be submitted to all co-investigators for review of its appropriateness and scientific quality before submission. The manuscript must get permission from the Ministry of Health before publication.

Dissemination policy: authorship

The Primary Investigator will disseminate the suggested topics for presentation or publication to the coinvestigators. The writing committee will be formed to ensure that the writing process is systematic and discusses the results comprehensively. The coinvestigators will settle any disagreements regarding authorship after consultation with the primary investigator.

Ethical issues and consideration(s)

This study will be conducted in compliance with ethical principles outlined in the Declaration of Helsinki[62] and Malaysian Good Clinical Practice Guideline.[63] This research has its own Universal Trial Number by WHO: U1111-1228-5103. The study methods are conformed with the SPIRIT guidelines for reporting randomised trials.[28 50]

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Acknowledgements The researchers appreciate and acknowledge National Medical Research Registration committee for their management support.

Contributors SMS, AJ, CNF, SIFI, PA developed the original protocol. Later, FG-S, NAM, RAM, AFAF, ZS contributed to improving the study design. AJ wrote the protocol with considerable input from all authors at all stages. The contribution from all authors has been recorded and approved before the final manuscript.

Funding Universiti Putra Malaysia supported this work, 43400 UPM Serdang, Selangor, Malaysia grant number UPM/800-3/3/1/GPB/2018/9668500.

Disclaimer The opinions expressed are from the author(s) and not necessarily those of the Public Health Department or Ministry of Health. This funding source had no role in the design of this study and will not have any role during its execution, analyses, interpretation of the data, or decision to submit results.

Competing interests None declared.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

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Supplementary Table 1 CONSORT checklist and its extensions for pragmatic and cluster-randomized trial

Section	Standard CONSORT description	Extension for pragmatic trials	Extension for cluster designs
Title and abstract	How participants were allocated to interventions (eg, “random allocation,” “randomised,” or “randomly assigned”) (Page 1) Structured abstract (Page 3-4).	Stated in the Title as in Page 1 Structured abstract (Page 3-4)	Identification as a cluster randomised trial in the title (Page 1) Structured abstract (Page 3-4)
Introduction			
Background	Scientific background and explanation of rationale (Page 3-4).	Describe the health or health service problem that the intervention is intended to address and other interventions that may commonly be aimed at this problem (Page 23).	Rationale for using a cluster design (Page 22).
Objectives	Specific objectives and hypotheses (Page 8)		Whether objectives pertain to the cluster level, the individual participant level or both (Page 22).
Methods			
Trial designs	Description of trial design (such as parallel, factorial)	Not applicable	Definition of cluster and description of how the design

Section	Standard CONSORT description	Extension for pragmatic trials	Extension for cluster designs
	including allocation ratio Important changes to methods after trial commencement (such as eligibility criteria), with reasons (Page 9).		features apply to the clusters (Page 22).
Participants	Eligibility criteria for participants; settings and locations where the data were collected (Page 12).	Eligibility criteria should be explicitly framed to show the degree to which they include typical participants and/or, where applicable - settings of care (Page 23)	Eligibility criteria for clusters (Page 22).
Interventions	Precise details of the interventions intended for each group and how and when they were actually administered (Page 14)	Describe extra resources added to (or resources removed from) usual settings in order to implement intervention. Indicate if efforts were made to standardise the intervention or if the intervention and its delivery were allowed to vary between participants, practitioners, or study sites (Page 14).	Whether interventions pertain to the cluster level, the individual participant level or both (Page 14)
		Describe the comparator in similar detail to the intervention (Page 14).	

Section	Standard CONSORT description	Extension for pragmatic trials	Extension for cluster designs
Outcomes	Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (eg, multiple observations, training of assessors) (Page 11, Table 1)	Explain why the chosen outcomes and, when relevant, the length of follow-up are considered important to those who will use the results of the trial (Page 11, Table 1).	Whether outcome measures pertain to the cluster level, the individual participant level or both (Page 11, Table 1).
Sample size	How sample size was determined; explanation of any interim analyses and stopping rules when applicable (Page 16)	If calculated using the smallest difference considered important by the target decision maker audience (the minimally important difference) then report where this difference was obtained (Page 16).	Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intracluster correlation (ICC or *k*), and an indication of its uncertainty (Page 16).
Randomisation—sequence generation	Method used to generate the random allocation sequence, including details of any restriction (eg, blocking, stratification) (Page 13).	Not applicable	Details of stratification or matching if used (Page 13).
Randomisation—allocation	Method used to implement the random allocation	Not applicable	Specification that allocation was based on clusters rather

Section	Standard CONSORT description	Extension for pragmatic trials	Extension for cluster designs
concealment	sequence (eg, numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned (Page 13).		than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level or both (Page 13).
Randomisation—implementation	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups		Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions (Page 13).
Blinding (masking)	Whether participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment (Page 9).	If blinding was not done, or was not possible, explain why	
Statistical methods	Statistical methods used to compare groups for primary outcomes; methods for additional analyses, such as subgroup analyses and adjusted analyses (Page 21).		How clustering was taken into account (Page 22).
Results			
Participant flow	Flow of participants through	The number of participants or	For each group, the numbers of

Section	Standard CONSORT description	Extension for pragmatic trials	Extension for cluster designs
	each stage (a diagram is strongly recommended)—specifically, for each group, report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analysed for the primary outcome; describe deviations from planned study protocol, together with reasons (Not available).	units approached to take part in the trial, the number which were eligible, and reasons for non-participation should be reported (Not available).	clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome (Not available).
Recruitment	Dates defining the periods of recruitment and follow-up (Not available).	Not available	Not available
Baseline data	Baseline demographic and clinical characteristics of each group (Not available).	Not available	Baseline characteristics for the individual and cluster levels as applicable for each group
Numbers analysed	Number of participants (denominator) in each group included in each analysis and whether analysis was by “intention-to-treat”; state the results in absolute numbers when feasible (eg, 10/20, not 50%) (Not available).	Not available	For each group, number of clusters included in each analysis (Not available).

Section	Standard CONSORT description	Extension for pragmatic trials	Extension for cluster designs
Outcomes and estimation	For each primary and secondary outcome, a summary of results for each group and the estimated effect size and its precision (eg, 95% CI) (Not available).		Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or k) for each primary outcome (Not available).
Ancillary analyses	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating which are prespecified and which are exploratory (Not available).		
Adverse events	All important adverse events or side effects in each intervention group (Not available).		
Discussion			
Interpretation	Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision, and the dangers associated with multiplicity of analyses and outcomes (Not		

Section	Standard CONSORT description	Extension for pragmatic trials	Extension for cluster designs
	available).		
Generalisability	Generalisability (external validity) of the trial findings (Page 23)	Describe key aspects of the setting which determined the trial results. Discuss possible differences in other settings where clinical traditions, health service organisation, staffing, or resources may vary from those of the trial (Not available).	Generalisability to clusters and/or individual participants (as relevant) (Not available).
Overall evidence	General interpretation of the results in the context of current evidence (Not available).		

CONSORT: Consolidated Standards of Reporting Trials

Supplementary 2

Table 2: Nine domains of PRECIS-2 tool

	Domain	**Explanation**
1.	Eligibility criteria	Pregnant women with UI who fulfil inclusion and exclusion criteria will be recruited. (4)
2.	Recruitment	The RA will recruit the study participants from ten clinics during the participants' usual antenatal appointment. (4)
3.	Setting	The usual primary care setting. (5)
4.	Organisation	There is no difference in provider expertise in the intervention group (mHealth app). (5)
5.	Flexibility (delivery)	The KEPT-app is delivered and it is flexible according to the participants' time. (5)
6.	Flexibility (adherence)	This is an individual-based intervention and range of exercises are recorded despite a reminder system. (3)
7.	Follow-up	The follow-up is as usual care for the antenatal check-up. (5)
8.	Primary outcome	Change in UI is the main outcome. (5)
9.	Primary analysis	This study will apply the intention-to-treat principle analysis. (5)

Extension of CONSORT for abstracts to reports of cluster randomised trials

Item	Extension for cluster trials	Reported on line number
Title	Identification of study as cluster randomised	2-3
Trial design	Title	2-4
Methods		
Participants	Eligibility criteria for clusters	6
Interventions		
Objective	Whether objective or hypothesis pertains to the cluster level, the individual participant level or both	3-4
Outcome	Whether the primary outcome pertains to the cluster level, the individual participant level or both	9-11
Randomization	How clusters were allocated to interventions	8-9
Blinding (masking)		Not available
Results		
Numbers randomized	Number of clusters randomized to each group	Not available
Recruitment		
Numbers analysed	Number of clusters analysed in each group (Not available).	9
Outcome	Results at the cluster or individual participant level as applicable for each primary outcome	Not available
Harms		Not available
Conclusions		Not available
Trial registration		27
Funding		Not available

Supplementary 4
PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT FORM

1. **Title of study:** ***KEPT-app trial- a pragmatic, single-blind, parallel, cluster-randomised effectiveness study of pelvic floor muscle training among incontinent pregnant women: study protocol***
2. **Name of investigator and institution:** Dr Aida Jaffar

3. **Name of sponsor**: Universiti Putra Malaysia

4. Introduction:

Urinary incontinence (UI) means loss of bladder control, affecting about 423 million or 21.6% women globally, especially among Asian women. Urinary incontinence is common during pregnancy, and pelvic floor muscle exercise or Kegel's exercise has been shown to be helpful in the management of this condition.

KEPT-App is a newly developed mobile application that aims to assist pregnant women with their urinary incontinence. This app will assist the user in assessing the presence of urinary incontinence and guide on pelvic floor muscle exercise.

You are invited to join this research as you are pregnant with urinary incontinence. This is a research looking at the effectiveness of the mobile application in detecting and managing urinary incontinence. This is a randomised control study in which all participants will be randomised systematically into intervention or wait-list control group. Both groups will have similar treatment but at different time. The intervention group will receive treatment during the antenatal period while the wait-list control group will have usual care. Subsequently, the wait-list control group will receive similar treatment during post-partum period.

This study has been approved by the Medical Research and Ethics Committee, Ministry of Health Malaysia.

5. What is the purpose of the study?

The purpose of this study is to assess the effectiveness of pelvic floor muscle exercise via mobile apps for the treatment of urinary incontinence. This research is necessary because urinary incontinence is very common during pregnancy and it can be prevented by doing the correct exercise
A total of 340 pregnant women will be recruited in Hulu Langat, Selangor. The whole study will last about 20 weeks from 28 weeks pregnancy till 8 weeks post-partum.

6. What kind of study products will I receive?

This study will only involve mobile application and all the assessments of your UI and pelvic floor muscle exercise will be done using the KEPT-App. You will not have any extra clinic appointment, invasive procedure like blood taking or imaging procedure like ultrasound or

urinary test to confirm your urinary incontinence. Please do not hesitate to contact person shall you have any inquiries or worries. Your involvement in this study is voluntary, you can withdraw from this study at any time with or without reason and this shall not affect your usual antenatal care.

This KEPT-app study needs you to answer sets of questionnaires, follow simple instruction to assess UI and pelvic floor muscle exercise using the KEPT-app. The exercise used is proven safe, has no known major risks or complications and there is no other alternative procedure. There is no time limit for KEPT-App, it is there for you to use even after completing this study.

Apart from using the KEPT-app, all participants of this study will have their usual antenatal care and follow-up at the health clinics. They can always seek their medical doctor for any medical or obstetric issues. As stated above, there is very minimal risk from the investigational product (KEPT-App) and this study procedure. On the other hand, the findings of this study will be potentially useful for health professionals to improve the overall management of UI among pregnant women.

By agreeing to participate in this study, you allow the main researcher to get access to your medical record. The researcher has the right to withdraw any participants from the study shall there be any urgent medical or obstetric issues/reasons that occur during the study period. Examples of obstetric emergencies are premature labour, severe high blood pressure, pre-eclampsia or bleeding due to abruptio placenta while medical emergencies include sepsis, heart attack, epilepsy and stroke. In assuring your confidentiality, no other researchers can access your medical records.

The data of this study will be analysed in aggregate. The findings of this study will be discussed and published as per report to the funding body, ethics committee(s), articles in peer-reviewed journals, presentation at conferences or other professional forums. In any report, publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your express permission. You will be informed if any new information relevant to consent becomes available via the apps. You will be informed automatically the study findings as it will in the “monitoring the progress”

7. What will happen if I decide to take part?

Thank you for agreeing to join this study. We would like to emphasize that this study will only involve mobile application and all the assessments of your UI and pelvic floor muscle exercise will be done using the KEPT-App.

This short note will explain how this KEPT-App and your responsibilities upon participating this study.

1. You will receive an email / short message system (SMS) / Whats-App with a link to download this app after signing the consent.
2. Once you have downloaded this app, you will need to log in the app using your username and password.
3. There will be a step-by-step instruction after you logged in. Please follow the instruction given.
4. There will be questions on your experience with Urinary Incontinence and pelvic floor muscle exercise (PFME). Kindly read carefully, please do not rush and enjoy the app.
5. Please report to us if you experience any discomfort (either feeling stress, anxious or any reason) while using the KEPT-app. The pelvic floor muscle exercise that is included in the KEPT-app has been proven safe and is used in managing pregnant women with urinary incontinence
6. It is very important for you to give your truthful answer to the questions and faithfully practice the exercise prescribed. As the result of this study will be used to help other pregnant women with UI in the future.
7. If you face any difficulty, you can ask at the (Frequently Asked Questions) FAQ section or do not hesitate to call the contact person given.

8. When will I receive the trial product and how should it be kept?

This KEPT-app will be available for you after completion of the study. There will be no added treatment except for the usual antenatal care as usual along with the KEPT-app.

9. What are my responsibilities when taking part in this study?

Your responsibilities upon participating this study:
1. To download the KEPT-App via the link provided after signing the consent form.
2. To follow the instruction given via the apps.
3. To report if you experience any discomfort (either feeling stress, anxious or any reason) due to this KEPT-App. This app is about urinary incontinence and pelvic floor muscle exercise and has been recommended in the guideline for the management in pregnant women with urinary incontinence. You should not be worry as it has been proven its effectiveness locally and internationally.
4. To do the assessments with your truly response. This is very important to help other pregnant women in future KEPT-App development.
5. Do not hesitate if you feel you would like to withdraw from this study as your involvement in this study is voluntarily and will not affect your future healthcare appointment or follow-up.

10. What kind of treatment will I receive after my participation in the trial?

No study product will be given to you at the end of your participation in the study. Whether you complete the study or withdraw early, your doctor will discuss the best alternatives for your future treatment with you.

11. What are the potential risks and side effects of being in this study?

There is also a risk that participants may feel pressured to provide information they believe is desirable by the data collector during the study phase. To ensure that participants answer honestly, the research assistant will explain and ensure them that their answers will be kept completely confidential, with no identifying information will ever be attached to the information given. There will be no other alternative procedures in this study.

12. What are the benefits of being in this study?

The benefit for this study, will be as the results will be used to develop new recommendations on ways to improve the antenatal care by our Ministry of Health under Maternal Child Health programme. The outcome of this study with the use of mHealth technology will be precious to the policy makers and local stakeholders. If this KEPT-App is shown to be effective, the efforts to share this intervention will benefit not just pregnant women but also elderly populations or anyone who has urinary incontinence. By downloading this KEPT-app, it will educate and improve the people awareness towards UI and PFME. Eventually, results of this study may contribute the quality improvement of our antenatal care and care of the elderly population.

13. What if I am injured during this study?

This study carries little risk to the participants as you may feel anxious answering the questions, or using the app. However, the KEPT-App will be designed in such a way that it will be user friendly and stress-free. There will be a trained research assistant to assist you during the recruitment, obtaining consent and downloading the mobile app. As participant, you can answer or use the app at your own time and convenience, thus we expect the psychological distress or anxiety that you may have is very minimal. This study is non-invasive, does not involve any biological product or blood, hence no added physical or biological risks to the participants. If any injuries do occur as a direct result of participating in the study, you need to visit your antenatal doctor or any doctor in primary care clinic immediately.

14. What are my alternatives if I do not participate in this study?

You do not have to participate in this study to get treatment for your disease or condition.

15. Who is funding the research?

This study is fully sponsored by Universiti Putra Malaysia which will pay for all research related products.

16. Can the research or my participation be terminated early?

Research doctors or sponsors may terminate this research or terminate your participation in this research at any time, if necessary.

17. Will my medical information be kept private?

Yes. The research assistant is a trained professional and we will ensure participants' (your) information are kept confidential and protected all the time. Your information will be then de-identified by the research assistant by removing all your personal identified information and replace with unique code prior to entry into the study database. This is very important as an essential step to create and preserve anonymity of the participants.

If you give us your permission by signing the consent document, we plan to discuss/publish the results in a variety of forums, including: reports to the funding body for monitoring purposes; annual reports to ethics committee(s) for monitoring purposes; peer-reviewed journals; presentation at conferences or other professional forums. In any report, publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your express permission. Any publications resulting from this study will not identify your place of work.

18. Who should I call if I have questions?

If you have any questions about the study or if you think you have a study related injury and you want information about treatment, please contact the study doctor, Dr Aida Jaffar at telephone number 0176776768.

If you have any questions about your rights as a participant in this study, please contact:
JAWATANKUASA ETIKA & PENYELIDIKAN PERUBATAN
MEDICAL RESEARCH & ETHICS COMMITTEE)
KEMENTERIAN KESIHATAN MALAYSIA
Kompleks Institut Kesihatan Negara (NIH),
No.1, Jalan Setia Murni U13/52,
Seksyen U13 Bandar Setia Alam,
40170 Shah Alam, Selangor.
No.Tel: 03-33628407/ 33628205/ 33628888

INFORMED CONSENT FORM

Title of Study: ***KEPT-app trial- a pragmatic, single-blind, parallel, cluster-randomised effectiveness study of pelvic floor muscle training among incontinent pregnant women: study protocol .***

By signing below I confirm the following:

- I have been given oral and written information for the above study and have read and understood the information given.
- I have had sufficient time to consider participation in the study and have had the opportunity to ask questions and all my questions have been answered satisfactorily.
- I understand that my participation is voluntary and I can at anytime free withdraw from the study without giving a reason and this will in no way affect my future treatment. I am not taking part in any other research study at this time. I understand the risks and benefits, and I freely give my informed consent to participate under the conditions stated. I understand that I must follow the researcher's assistant instructions related to my participation in the study.
- I understand that study staff, qualified monitors and auditors, the sponsor or its affiliates, and governmental or regulatory authorities, have direct access to my medical record in order to make sure that the study is conducted correctly and the data are recorded correctly. All personal details will be treated as STRICTLY CONFIDENTIAL
- I will receive a softcopy of this subject information/informed consent form signed and dated.

Subject:

Signature: I/C number:

Name: Date:

Investigator conducting informed consent:

Signature: I/C number:

Name: Date:

Impartial witness: *(Required if subject is illiterate and contents of participant information sheet is orally communicated to subject)*

Signature: I/C number:

Name: Date: