Exercise intervention in Pregnancy: A feasibility study in Thailand

ABSTRACT

Background: Exercise during pregnancy can increase physical fitness, decrease risk of noncommunicable diseases (NCDs) and control gestational weight gain (GWG) including association to enhance psychological well-being. Pregnant women generally have lower exercise behaviour than in the pre-pregnancy period.

Objectives: The objectives were to determine the acceptability of a programme based on Thai Government guidance for exercise in pregnancy, and assess preliminary effects of the exercise programme.

Methods: A total of 61 women between 12-16 weeks gestation were randomly allocated to the 10 week exercise intervention (n = 31) or control group (n = 30). Baseline measures were collected before intervention and preliminary effects data after completion of intervention and two weeks after expected date of delivery (EDD).

Results: Analysis of Covariance (ANCOVA) showed the exercise group had lower gestational weight gain than control group after controlling for maternal age, pre-pregnancy body mass index (BMI), gestational age, and baby birth weight (p < .001). The study indicated significant increases over time in physical activity after controlling for maternal age, and pre-pregnancy BMI (p < .001).

Conclusion: The study demonstrated feasibility of conducting a larger RCT with an intervention to improve exercise behaviour in pregnant women.

Keywords: Exercise, pregnant women, exercise programme, antenatal, obesity

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Introduction

The prevalence of global Obesity and overweight is increasing (World Health Organization (WHO), 2015) including in Thailand (Aekplakorn & Mo-Suwan, 2009, Ministry of Public Health (MoPH), Thailand, 2010; Teerawattananon, & Luz, 2017). Obesity has direct and indirect impacts on physical and mental health (Davies et al, 2010; Mahmood & Arulkumaran, 2013; Özdemir, 2015). In pregnant women, obesity and overweight may impact on maternal health and baby outcomes, including both medical and obstetric complications. Moreover, being obese is associated with next generation obesity (Poobalan et al, 2009; Keeley, Gunning & Denison, 2011; Centers for Disease Control and Prevention (CDC), 2012; Marchi et al, 2015), thereby compounding this public health issue for future generations.

Evidence strongly supports the benefits of regular exercise during pregnancy, which increases physical fitness. Several studies show that exercise is associated with a decrease in the risk of Non Communicable Diseases such as coronary heart disease, hypertension etc. and obstetric complications, control of gestational weight gain, reduction in antenatal depression symptoms, reduced rates of macrosomia (a birth weight more than 4,000 grams) and reduced risk of the overweight baby (Prather, Spitznagle & Hunt, 2012; Siebel, Carey & Kingwell, 2012; Millard et al, 2013; Makinde, Adeyemo & Ogundele, 2014; Seneviratne et al, 2014). Generally, guidelines recommend that low risk pregnant women without any contraindications should conduct moderate exercise of at least 30 minutes of accumulated exercise a day for at least 3 days a week (Royal College of Obstetricians and Gynaecologists (ACOG), 2015). In Thailand, the policy promotes exercise during pregnancy for all antenatal care units (Department of Health, Thailand, 2014).

Antenatal clinics (ANC) in Thailand do not have routine exercise programmes for pregnant women (Ministry of Public Health (MoPH), Thailand, 2012). Generally, prenatal education classes are led by one nurse who teaches a range of subjects during pregnancy and provides exercise advice (3rd Regional Health Centre, Thailand, 2011; Parnkasem, 2013). Research studies indicate that pregnant women may receive insufficient information and that current practice may be ineffective for motivating them to exercise during pregnancy (Bauer,

Broman & Pivarnik, 2010; Jones, Housman & McAleese, 2010; Krans & Chang, 2012; Melton et al, 2013). The objective of this study was to determine the preliminary effects and acceptability of an exercise programme based on Thai Government guidance for exercise in pregnancy in a feasibility randomised controllled trial (RCT).

Methods

Study design and participants

The study was a two-armed feasibility randomised controlled trial (RCT) designed to test three aspects of the intervention: acceptability, feasibility, and preliminary effects. The primary outcome was the gestational weight gain. The secondary outcomes were the effects on mother and baby as follows: 1) mother in terms of physical activity including frequency and duration of exercise behaviour, blood pressure, stress score, and adverse events; and 2) baby in terms of baby birth weight. Ethical approval for the study was obtained from the Faculty of Medicine and Health Sciences Research Ethics Committee, University of East Anglia (UEA), Norwich, United Kingdom (UK) and the Health Promoting Hospital, 3rd Regional Health Centre, Nakhon Sawan, Thailand, where the study was conducted from December 2016 to September 2017.

Participants

Target sample size for the feasibility RCT was 66 pregnant women (33 for the control group and 33 for the intervention group), allowing for a 10% dropout rate in each arm (Hertzog, 2008). This calculation was not based on a formal sample size calculation as this was a feasibility study. Sample size was calculated according to the number of attendees at the antenatal care clinic where recruitment took place. The consideration was given to how many women could feasibily be accommodated within an exercise programme to arrive at a pragmatic decision on recruitment. The sample size justification for a feasibility study varies widely depending on the research objective, question, population and context (Arain et al, 2010; Billingham, Whitehead, & Julious, 2013). The United Kingdom Clinical Research Network (UKCRN) reported the median sample sizes per arm of feasibility trials were 36, in a range of 10 to 300 participants and pilot trials were 30, in a range of 8 to 114 participants (Billingham, Whitehead, & Julious, 2013).

Participants were pregnant women aged 20 years or more who exercised less than 30 minutes a day and/or three days a week. Those with any contraindications to exercise during pregnancy, as verified by the Physical Activity Readiness Medical Examination for Pregnancy

3

Thai version (PARmed-X) (Davies, Wolfe, Mottola & MacKinnon, 2003; Suputtitada, 2005) and with extremely high stress scores (score \geq 30 points) were excluded from the study. After completion of the baseline measures, participants were randomised to either control or intervention group at GA 16-18 weeks by groups of four and six blocked randomisation.

Exercise intervention

The exercise intervention was co-designed with women and Health Care professionals including physiotherapists based on Thai Government guidelines for exercise in pregnancy. Intervention group participants were offered 10 prescribed hospital-based group exercise sessions, once a week, between 18-20 weeks gestation (GA) and 28-30 weeks. All exercise classes were instructed by SK in consultation with a physiotherapist who attended the first, fifth, and tenth weeks. Each exercise training session included dynamic exercises: five-minute warm up of muscle stretching, 10-15 minutes muscular workout, 10-15 minutes cardiovascular exercise and five-minute cool down of muscular progressive relaxation. The exercise training session increased progressively from 20 minutes during the first week to 40 minutes at the fifth week. The control group continued with usual care comprising exercise information and nurse demonstrated workouts during a 30 minute general prenatal education class at 16-28 weeks of gestational age.

Data collection

Data were collected through questionnaires at baseline (GA 16-18 weeks) and after intervention (GA 30-32 weeks) and by telephone at two weeks after EDD. Global Physical Activity Questionnaire (GPAQ) Thai version was used to assess the exercise behaviour of women (Division of Physical Activity & Health, Thailand, 2009). Evidence based safety information was provided (ACOG, 2002, 2015; ACSM, 2014, Suputtitada, 2005). Stress score was routinely collected at GA 16-20 and 28-32 weeks in antenatal clinic with stress selfassessment tool (MoPH, Thailand, 2012). Acceptability of the exercise programme questionnaire, developed by the researcher, comprised acceptability, satisfaction, reason for adherence or discontinued participation and suggestions for any changes to the exercise programme. These data were collected from pregnant women who participated in the exercise intervention group only. Exercise checklist was used to record the participants' attendance and adherence to the intervention, after each exercise class by the researcher.

Statistical analysis

Data were analysed using SPSS for Windows version 24.0 (IBM Corp, 2016). Analysis of covariance (ANCOVA) was conducted to compare the difference of exercise intervention and control group on gestational weight gain, baby birth weight. Baseline values: maternal age,

pre-pregnancy BMI, and gestational age were included as covariates in the model due to the interaction among gestational weight gain, baby birth weight, stress score, blood pressure, and physical activity (Nascimento, Surita & Cecatti, 2012; Bazyar et al, 2015; Zanardo et al, 2016; Yang et al, 2017). Repeated measures ANCOVA was used to test group effects between intervention and control groups on total physical activity, blood pressure, and stress score over time at baseline (16-18 weeks of gestation) and 30-32 weeks of gestation (Vickers & Altman, 2001; Field, 2015). These tests were carried out to enable future design of a trial.

A two-tailed statistical evaluation of the study was performed with an alpha of 0.05 as the cut-off for significance, although the feasibility study was not powered to measure the effectiveness of the exercise intervention (Eldridge, et al, 2016). Descriptive data were presented as means and standard deviations, and numbers and percentages for continuous and categorical variables respectively (Field, 2015). Pre-pregnancy BMI values were square roottransformed because of moderate right skewness. Square root-transformed pre-pregnancy BMI was entered as a covariate in ANCOVA and repeated measures ANCOVA model. Diastolic blood pressure at 30-32 weeks of gestation, stress score at baseline and 30-32 weeks of gestation values were log-transformed due to right skewness (Field, 2015).

Results

Recruitment

The feasibility study is summarised in Figure 1 (CONSORT, 2010). One hundred and four women were assessed for eligibility to participate in the exercise intervention (88.89%). Initially 66 women who met the inclusion criteria were enrolled (63.46%). They completed a baseline questionnaire and were randomised to either the intervention (n = 33) or the control group (n = 33). Five women were excluded from the study. The dropout rate was 7.58%. During the exercise intervention, three women were excluded from the control group. Two women were excluded from the exercise intervention. The total sample for analysis was 61 pregnant women: the intervention group (n = 31) and the control group (n = 30).

Around one fifth (20 of 104 women) were excluded as verified by the Physical Activity Readiness Medical Examination for Pregnancy Thai version (PARmed-X) (Davies, Wolfe, Mottola & MacKinnon, 2003; Suputtitada, 2005). Four women already regularly exercised at least 30 minutes a day for 3 days a week. Four were aged under 20 years. Further, four had history of vaginal bleeding. Three women had a severe anaemia (haemoglobin < 10 mg%) due to thalassaemia. Another three had a previous premature labour. Two women had a history of mental health problems and stress score > 30 points, and eight women had high risk of medical conditions: hypertension and diabetes. Nearly one tenth (10 of 104 women) declined to participate in the study for personal reasons and planned to move back to their hometowns. Five of these 66 (7.58%) were excluded during the period of the exercise intervention due to health problems. The dropout rate was under 10% in each arm (control and intervention groups).

Demographic characteristics of the sample

In keeping with CONSORT guidelines, the tests of significance were not carried out on baseline characteristics (Eldridge, et al, 2016) (Table 1). The sample was aged between 20 and 40 years. The mean maternal age was 28.23 years with standard deviation (SD) of 5.67 years. The sample had pregnancy number between 1 and 4. Most were multigravida (n=40, 65.57%). The sample had pre-pregnancy body mass index (BMI) between 17.07 and 31.22 kg/m². Nearly half of them had a healthy pre-pregnancy BMI between 18.5 and 22.9 kg/m² (n=29, 47.54%).

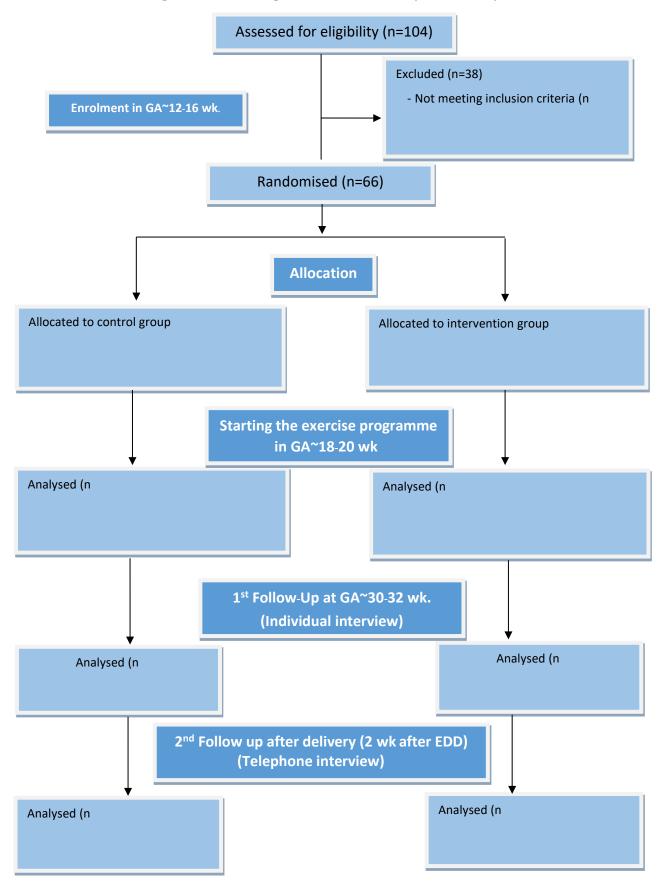


Figure 1: Flow diagram of the feasibility RCT study

Preliminary effects of the exercise intervention

Analysis of Covariance (ANCOVA) was used to analyse the difference between intervention and control groups (Vickers & Altman, 2001) for total gestational weight gain (TGWG), and baby birth weight. The normality assumption was tested using Kolmogorov-Smirnov and Shapiro-Wilk tests. The assumption of homogeneity of variance for ANCOVA was tested using Levene's test. The assumption of sphericity for repeated measures ANCOVA was tested using Mauchly's test (Field, 2015). Pre-pregnancy BMI values were square root-transformed because of moderate right skewness. Square root-transformed pre-pregnancy BMI was entered as a covariate in ANCOVA and repeated measures ANCOVA model. Diastolic blood pressure at 30-32 weeks of gestation, stress score at baseline and 30-32 weeks of gestation values were log-transformed due to right skewness.

TGWG was calculated as weight at delivery minus pre-pregnancy weight. TGWG was the dependent variable in the ANCOVA model. Groups of study (intervention and control groups) were used as a fixed factor while maternal age, pre-pregnancy BMI, gestational age at delivery, and baby birth weight were entered as covariates (Table 2). TGWG differed significantly between the intervention and control groups after adjusting for maternal age, pre-BMI, gestational baby birth pregnancy age at delivery, and weight, F (1, 55) = 58.934, p < 001., partial $\eta^2 = .517$. More women in the intervention group had appropriate TGWG, according to the recommendation made by the Institute of Medicine (IOM, 2009), than the control group with an average weight gain of $12.64 (\pm 2.51)$ kilograms (kg.) for the intervention group and 17.73 (+ 4.61) kg. for the control group (ACOG, 2013).

Baby birth weight (BBW) was the dependent variable in an ANCOVA model with maternal age, pre-pregnancy BMI, gestational age at delivery, and TGWG as covariates (Table 3). There was no significant effect of the exercise intervention on baby birth weight with an average birth weight of 3,084.84 (\pm 307.63) grams for the intervention group and 3,176 (\pm 485.09) gramsfor the control group, after controlling for maternal age, pre-pregnancy BMI, gestational age at delivery, and TGWG, F (1, 55) = 3.891, *p* = .054, partial η^2 = .066. Most of the babies in the intervention and control groups had appropriate birth weight (BBW 2,500-3,499 grams) between 90.32% and 60% respectively.

Baseline characteristics	Intervention group	Control group (n = 30)		
mean (<u>+</u> SD) or n (%)	(n = 31)			
Maternal age ^a	29.10 <u>+</u> 6.28	27.33 <u>+</u> 4.90		
Family income ^c	30,258.06 <u>+</u> 9,332.13	23,933.33 <u>+</u> 9,303.07		
Pre-pregnancy weight ^a	55.48 <u>+</u> 8.15	59.67 <u>+</u> 11.72		
Pre-pregnancy BMI ^a	21.95 <u>+</u> 3.11	23.22 <u>+</u> 4.55		
-Underweight (BMI < 18.5 kg/m ²)	6 (19.35%)	2 (6.66%)		
-Healthy (BMI 18.5-22.9 kg/m ²)	15 (48.39%)	14 (46.67%)		
-Overweight (BMI 23-29.9 kg/m ²)	10 (32.26%)	9 (30%)		
-Obesity (BMI \ge 30 kg/m ²)	0	5 (16.67%)		
Educational level ^b				
-Primary school	1 (3.23%)	0		
-Secondary school	5 (16.12%)	7 (23.33%)		
-High school	11 (35.48%)	10 (33.34%)		
-College degree	2 (6.46%)	1 (3.33%)		
-Bachelor degree	12 (38.71%)	11 (36.67%)		
- \geq Master degree	0	1 (3.33%)		
Gravida ^b				
-Primigravida	11 (35.48%)	10 (33.33%)		
-Multigravida	20 (64.52%)	20 (66.67%)		
Occupation ^b				
-Government /employee	10 (32.25%)	12 (40%)		
-Self-employed	6 (19.35%)	4 (13.33%)		
-Agriculture	4 (12.90%)	3 (10%)		
-Housewife	11 (35.50%)	11 (36.67%)		

Table 1: Demographic characteristics at 16-18 weeks of gestation

^a t-test for continuous variables
^b x² test for categorical variables
^c Non-parametric test :Mann-Whitney U test

Baseline characteristics	Intervention group	Control group
mean (<u>+</u> SD) or n (%)	(n = 31)	(n = 30)
Location of work ^b		
-Inside home	7 (22.58%)	5 (16.67%)
-Outside home	13 (41.94%)	14 (46.66%)
-None	11 (35.48%)	11 (36.67%)
Area of living ^b		
-Urban area	15 (48.39%)	15 (50%)
-Rural area	16 (51.61%)	15 (50%)

 Table 1: Demographic characteristics at 16-18 weeks of gestation (continued)

^a t-test for continuous variables

 ${}^{b}x^{2}$ test for categorical variables

^c Non-parametric test :Mann-Whitney U test

The total PA was calculated from different behavioural domains: work, transport, and recreation. The Metabolic Equivalent of Task (MET) is commonly used to express the intensity of physical activities, and also to analyse physical activity data in minutes per week (WHO, 2004; Singh & Purohit, 2011). A repeated measures ANCOVA was conducted to compare PA in the intervention and control groups over time at baseline (16-18 weeks of gestation and 30-32 weeks of gestation). Maternal age and pre-pregnancy BMI were entered as covariates in the model (see Table 4). There was a significant effect of the exercise intervention on the total PA after controlling for maternal age, and pre-pregnancy BMI, F (1, 57) = 21.283, *p* <.001, partial $\eta^2 = .272$. Pregnant women in the intervention group increased their total PA from the average of 1,601.94 (±530.97) MET-minutes/week at baseline (16-18 weeks of gestation to 2,385.16 (±516.63) MET-minutes/week at the end of the exercise intervention (30-32 weeks of gestation), while women in the control group decreased their total PA from the average of 1,546 (±633.47) MET-minutes/week at baseline to 1,340 (±314.87) MET-minutes/week at the end of the intervention.

The exercise diary was used to assess adherence to the intervention to be completed from the beginning of the intervention (at GA~18-20 weeks) until delivery by the participants. The exercise diary consisted of the type and duration of exercise in a day, including the assessment of exercise intensity by pulse rate and talk test. The participants were phoned by the researcher to ask about exercise behaviour from exercise diary at two weeks after the expected date of delivery (EDD). Data (n = 31) were analyse as a descriptive statistic. Most

women who participated in the exercise intervention at 30-32 weeks of gestation did exercise during pregnancy, following ACOG's recommendation (ACOG, 2002, 2015; ACSM, 2014; Suputtitada, 2005), at least 30 minutes a day, 3 times a week (24, 77.42%). On the other hand, most women in the control group indicated they did not perform exercise at 30-32 weeks of gestation 22 (73.34%). Five women stopped recording their exercise behaviour after the end of the exercise intervention (16.13%) due to their duties, tiredness from work, and a lack of motivation. They thought it was a waste of time to keep the exercise record every day. Most of the women who continued exercise after the end of the exercise intervention until delivery (26, 83.87%) exercised at least three days a week for at least 30 minutes a day (19, 73.08%). Seven women continued exercise less than three days a week for at least 30 minutes a day (7, 26.92%). Most of them gave as their reasons for continuing exercise until delivery that they wanted to reduce discomfort during pregnancy, especially low back pain, leg cramp, muscle strain and insomnia.

Systolic and diastolic blood pressure were taken as the dependent variable in the repeated measurement ANCOVA model over time at baseline and 30-32 weeks of gestation. Groups of study (intervention and control groups) were entered as a fixed factor while maternal age and pre-pregnancy BMI were entered as covariates. After controlling for maternal age and pre-pregnancy BMI, systolic blood pressures differed significantly between the intervention and control groups over time at baseline and 30-32 weeks of gestation, F (1, 57) = 11.126, p = .002, partial $\eta^2 = .163$. However, diastolic blood pressure did not differ significantly after controlling for maternal age and pre-pregnancy BMI, F (1, 57) = 1.418, p = .239, partial $\eta^2 = .024$.

Stress score was taken as the dependent variable in the repeated measurement ANCOVA model over time at baseline (16-18 weeks of gestation) and 30-32 weeks of gestation. Groups of study were entered as a fixed factor while maternal age and pre-pregnancy BMI were entered as covariates. Stress scores differed significantly between the intervention and control groups over time at baseline and 30-32 weeks of gestation after controlling for maternal age and pre-pregnancy BMI, F (1, 57) = 14.079, *p* <.001, partial η^2 = .198. Pregnancy outcomes: blood pressure and stress score are summarised in Table 5. In this study, there was no report on any adverse events or low birth weight related to pregnant women who participated in the exercise programme.

Variable	Intervention	Control	Absolute effect size	<i>p</i> -value ^a	Adjusted effect size	Adjusted
mean (<u>+</u> SD)	(n = 31)	(n = 30)	(95%CI)		(95%CI)	<i>p</i> -value ^b
Total weight gain (kilograms)	12.64 <u>+</u> 2.51	17.73 <u>+</u> 4.61	-5.09 (-6.98 to -3.2)	<001.	-5.73 (-7.22 to -4.23)	<001.
-Appropriate GWG	26 (83.87%)	6 (20%)				
-Excessive GWG (>IOM)	3 (9.67%)	24 (80%)				
-Inadequate GWG (<iom)< th=""><td>2 (6.46%)</td><td>0</td><td></td><td></td><td></td><td></td></iom)<>	2 (6.46%)	0				

Table 2: Total gestational weight gain in the control and intervention groups

^a Unadjusted analysis

^bLinear or generalised linear mixed model for covariate factor, maternal age, pre-pregnancy BMI, gestational age at delivery, and baby birth weight

Variable mean (<u>+</u> SD)	Intervention $(n = 31)$	Control (n = 30)	Absolute effect size (95%CI)	<i>p</i> -value ^a	Adjusted effect size (95%CI)	Adjusted <i>p</i> -value ^b	
Baby birth weight (grams)	3,084.84 <u>+</u> 307.63	3,176 <u>+</u> 485.09	-91.16 (-298.6 to 116.2)	.383	257.69 (-4.12 to 519.5)	.054	
-Low birth weight (BBW < 2,500 grams)	0	3 (10%)					
-Appropriate birth weight	28 (90.32%)	18 (60%)					
(BBW 2,500-3,499 grams)							
-Large birth weight (BBW \geq 3,500 grams)	3 (9.68%)	9 (30%)					

Table 3: Baby birth weight in the control and intervention groups

^a Unadjusted analysis

^bLinear or generalised linear mixed model for covariate factor, maternal age, pre-pregnancy BMI, gestational age at delivery, and total gestational weight gain (TGWG)

Interver	ntion	Control (n = 30)		F	<i>p</i> -value ^a	Adjusted effect size (95%CI)	Adjusted
(n = 3)	51)						<i>p</i> -value ^b
				21.283	<.001		
1,889.4 <u>+</u>	493.2	1,852 <u>+</u> 587.1				31.94 (-256.9 to 320.8)	.826
2,643.6 <u>+</u>	493.2	1,635.5 <u>+</u> 288.2				1,010.4 (793.6 to 1,227.2)	<001.
Baseline (GA	16-18 wk.)	Follow-up (GA 30-32 wk.)					
Intervention	Control	Intervention	Control				
(n = 31)	(n = 30)	(n = 31)	(n = 30)				
24 (77.42%)	24 (80%)	0	22 (73.34%)				
7 (22.58%)	6 (20%)	7 (22.58%)	4 (13.33%)				
0	0	24 (77.42%)	4 (13.33%)				
	(n = 3) $1,889.4 \pm$ $2,643.6 \pm$ Baseline (GA Intervention (n = 31) 24 (77.42%) 7 (22.58%)	(n = 31) (n = 30) $24 (77.42%) 24 (80%)$ $7 (22.58%) 6 (20%)$	(n = 31) $(n = 31)$ $(n = 31)$ $(n = 31)$ $(n = 31)$ $(n = 30)$	$(n = 31)$ $(n = 30)$ $1,889.4\pm493.2$ $1,852\pm587.1$ $2,643.6\pm493.2$ $1,635.5\pm288.2$ Baseline (GA 16-18 wk.)Follow-up (GA 30-32 wk.)InterventionControl $(n = 31)$ $(n = 30)$ $(n = 31)$ $(n = 30)$ $24 (77.42\%)$ $24 (80\%)$ $7 (22.58\%)$ $6 (20\%)$ $7 (22.58\%)$ $6 (20\%)$	$(n = 31) \qquad (n = 30)$ 21.283 1,889.4±493.2 1,852±587.1 2,643.6±493.2 1,635.5±288.2 Baseline (GA 16-18 wk.) Follow-up (GA 30-32 wk.) $\overline{\text{Intervention Control Intervention Control}} (n = 31) (n = 30) (n = 31) (n = 30)$ 24 (77.42%) 24 (80%) 0 22 (73.34%) 7 (22.58%) 6 (20%) 7 (22.58%) 4 (13.33%)	$(n = 31) \qquad (n = 30)$ $21.283 < .001$ $1,889.4 \pm 493.2 \qquad 1,852 \pm 587.1$ $2,643.6 \pm 493.2 \qquad 1,635.5 \pm 288.2$ Baseline (GA 16-18 wk.) Follow-up (GA 30-32 wk.) $\overline{\text{Intervention}} \overline{\text{Control}} \overline{\text{Intervention}} \overline{\text{Control}}$ $(n = 31) \qquad (n = 30) \qquad (n = 31) \qquad (n = 30)$ $24 (77.42\%) \qquad 24 (80\%) \qquad 0 \qquad 22 (73.34\%)$ $7 (22.58\%) \qquad 6 (20\%) \qquad 7 (22.58\%) \qquad 4 (13.33\%)$	$(n = 31) \qquad (n = 30)$ $21.283 <.001$ $21.283 <.001$ $1,889.4\pm493.2 \qquad 1.852\pm587.1 \qquad 31.94 (-256.9 \text{ to } 320.8) \\ 2,643.6\pm493.2 \qquad 1,635.5\pm288.2 \qquad 1,010.4 (793.6 \text{ to } 1,227.2)$ $Baseline (GA 16-18 \text{ wk.}) Follow-up (GA 30-32 \text{ wk.}) \\ \hline Intervention Control Intervention Control \\ (n = 31) \qquad (n = 30) \qquad (n = 31) \qquad (n = 30) \\ \hline 24 (77.42\%) 24 (80\%) \qquad 0 \qquad 22 (73.34\%)$ $7 (22.58\%) 6 (20\%) 7 (22.58\%) 4 (13.33\%)$

 Table 4: Total physical activity in the control and intervention groups

^a *P* value differences within groups ^b *P* value for effect of intervention between groups (Repeated-measurements ANCOVA for covariate factors: maternal age and pre-pregnancy BMI)

Variable	Intervention	Control	F	<i>p</i> -value ^a	Adjusted effect size (95%CI)	Adjusted
mean (<u>+</u> SD)	(n = 31)	(n = 30)				<i>p</i> -value ^b
Systolic blood pressure (mmHg.)			11.126	002.		
-Baseline (GA 16-18 wk.)	109.03 <u>+</u> 12.7	112.67 <u>+</u> 10.52			-3.346 (-9.42 to 2.73)	.274
-Follow-up (GA 30-32 wk.)	108.35 <u>+</u> 6.48	121.2 <u>+</u> 11.38			-12.187 (-16.90 to -7.48)	<.001
Diastolic blood pressure (mmHg.)			1.418	.239		
-Baseline (GA 16-18 wk.)	61.48 <u>+</u> 9.79	59.8 <u>+</u> 7.64			2.465 (-1.65 to 6.582)	.235
-Follow-up (GA 30-32 wk.)	60.13 <u>+</u> 7.14	63.1 <u>+</u> 7.29			017 (041 to .008)	.174
Stress score (point)		_	14.079	<.001		
-Baseline (GA 16-18 wk.)	11.94 <u>+</u> 2.63	11.73 <u>+</u> 2.73			.017 (036 to .069)	.523
-Follow-up (GA 30-32 wk.)	8.77 <u>+</u> 1.87	13.23 <u>+</u> 2.27			178 (224 to131)	<.001
	<u></u> 1107	10.20 12.21				

Table 5: Pregnancy outcomes: blood pressure and stress score

^a *P* value differences within groups ^b *P* value for effect of intervention between groups (Repeated-measurements ANCOVA for covariate factors: maternal age and pre-pregnancy BMI)

Adherence to the exercise intervention

Adherence rate was calculated from the number of times each woman attended over the course of the exercise intervention (n = 31). Around half of the women who participated in the exercise programme adhered for 80% of the exercise programme, which mean that they attended at least 8 weeks (17, 54.84%). Nearly one-third of women adhered to the exercise programme between 60-79% (9, 29.03%). Five women participated less than 60% (16.13%). The total number of their absence was 86 times. Reasons for their absence included: being busy with work and duties (43, 50%), transportation (no car) (8, 9.30%), poor weather (6, 6.98%), making merits on Buddhist days (5, 5.81%), and visiting family in another town (4, 4.65%) respectively.

Acceptability of the exercise intervention

All women who participated in the exercise intervention (n = 31) agreed that the exercise programme should be part of care at antenatal clinic. Most were satisfied with the overall exercise programme (30, 96.77%). Women were highly satisfied with the duration of each class, saying that it provided sufficient demonstrating and training time (28, 90.32%).

The programme encouraged women to gain a better understanding of exercise, changing their attitudes to exercise, and increasing the frequency and duration of their exercise behaviour. Women indicated that the exercise programme was helpful in maintaining their fitness level (13, 41.94%) and reducing discomfort during pregnancy (20, 64.52%) such as leg cramp, backache, insomnia, and muscle strain, including stress and anxiety while increasing relaxation. Women also enjoyed the exercise programme partly because there was an exercise group network for sharing their experiences (24, 77.42%) and motivating them to continue exercise (during pregnancy and after delivery).

Most of the women suggested that an exercise appointment should be made on the same day of their visit at ANC clinic (18, 58.06%). Women felt it was a waste of time and money when they travelled to hospital for the exercise only over 10 weeks. In their opinion, it would be better to conduct such a class every three or four weeks. It is unnecessary to arrange a weekly class as they have many other duties to fulfil (20, 64.52%). They added that exercise programme should be reduced from a weekly basis to at least once a month during the second and third trimesters or around four or five weeks (22, 70.97%) over 10-12 times during the second trimester. Women also said that HCPs should regularly update their exercise knowledge so that they will be able to deliver such knowledge to pregnant women in a proper and effective way (19, 61.29%).

Discussion

The study demonstrated that the significant parameters and process feasibility to conduct a larger RCT with an exercise programme to improve exercise behaviour in pregnant women. Verbal invitation and direct distribution of the leaflets by the reception nurse were added into the recruitment process after the first week which resulted in a recruitment rate which was three times higher compared to the first week of the recruitment process. This finding indicated that face-to-face recruitment by healthcare providers is more efficient for attracting pregnant women to participate in the study (Kim & Lennon, 2008). This is an important element to build into future trial recruitment.

The screening question for recruiting pregnant women for the exercise intervention was useful for screening as well as randomisation. In this study, nearly one third of women (19 of 61 women) were overweight and only five women were obese. However, in a larger trial, it will be better to categorise pregnant women into three groups: healthy (BMI 18.5-22.9 kg/m²), overweight (BMI 23-29.9 kg/m²), and obese (BMI \geq 30 kg/m²) by adding this criterion in to the screening questions. In this way, it will be possible to compare each group's results for the exercise intervention.

Adherence rates to the exercise intervention group was greater in the first five weeks of the exercise programme. Around half of the pregnant women (less than 60%) who participated in the exercise programme cited work and duties as reasons for their absences. Even so, the study data from exercise diaries indicated that pregnant women in the exercise group increased their total physical activity (PA) while women in the control group decreased their total PA at the end of the intervention. This warrants consideration in designing a trial. The implication for women financially of having to attend separate appointments for exercise and for antenatal care may have impacted on their adherence to attending exercise classes. Considering lessons learned during the current public health crisis when exercise classes on line soared in popularity this should be considered as a potential solution to attendance.

The data collection process revealed that the questionnaire and telephone interviews were successful in collecting the data at baseline as well as at the end of the exercise programme. The interview data not reported here gave insight into the views of women and the other lements of lifestyle that can be taken into account in designing a trial. The exercise programme supported Thai pregnant women to explore the value of exercise in pregnancy as a result of Westernisation. The influence of celebrity and social media in highlighting the benefits of exercise in pregnancy is a new movement in Thailand that is influencing modern motherhood attitudes.

This exercise programme was drawn from the Thai Government guidance for exercise in pregnancy. It was successful in encouraging pregnant women to increase physical activity and exercise behaviour. The findings also revealed that pregnant women also intended to engage the exercise programme and to continue exercise because they received guidance from the programme. They also perceived that exercise during pregnancy assisted them in achieving such benefits as increasing physical fitness, reducing discomfort during pregnancy, feeling fresh and relaxed, being able to sleep well, especially getting a better body shape and beauty during pregnancy and after childbirth.

Physical activity of pregnant women who participated in the exercise programme was significantly higher at the end of the exercise intervention, compared to that of the control group as well as the baseline. The exercise intervention group possessed significantly lower systolic blood pressure than the control group. The mechanism of regular exercise during pregnancy decreases arterial stiffness and increases blood circulation (Kawabata et al, 2012). It also enhances vagal activity that reduces cortisol and substance P, as well as increases serotonin. This could reduce blood pressure and heart rate in low risk pregnant women (Horak & Osmam, 2012). Blood pressure during pregnancy can also be reduced by exercise (Field, 2011; Horak & Osmam, 2012). Hence, exercise during pregnancy reduces systolic blood pressure that is an influential factor reducing the risk of gestational hypertensive disorders (Soresen et al, 2003; Scholten et al, 2014).

The intervention group had significantly lower stress scores than the control group. Pregnant women felt more relaxed when engaging in the exercise programme. The exercise programme helped pregnant women who participated in the exercise programme with reducing discomfort during pregnancy such as low back pain and fatigue. These findings are in line with other studies that found benefits of exercise during pregnancy include a decrease in stress, anxiety, and insomnia symptoms of women (Prather, Spitznagle & Hunt, 2012; Guszkowska et al, 2013; Fieril et al, 2014).

The present feasibility study illustrated several factors that need to be considered before conducting a larger scale of RCT with an exercise programme to improve exercise behaviour in pregnant women. The important parameters gained from this present study can be used to calculate an appropriate the sample size and prepare processes in designing a full-scale of study in terms of recruitment, exercise intervention, data collection, and outcome measures. Total gestational weight gain and baby birth weight including total physical activity and maternal outcomes on blood pressure and stress score would be important outcome measures of the effects of the exercise intervention during pregnancy in a larger trial.

In Thailand, the current Thai national policy has not made clear how to promote exercise behaviour in Thai pregnant women. A larger scal study is required to inform clinical practice.

Strengths and limitations of the study

The randomisation blocking in groups of four and six were employed with women to either the control or the intervention group for reducing any selection bias and securing an equal sample size (Altman & Bland, 1999; Efird, 2011).

The study was designed to improve exercise behaviour in Thai pregnant women. The co-design element of the study provided a programme that considered the needs of women's lives. A physiotherapist was a consultant in designing the exercise programme and the exercise intervention to ensure the safety of the exercise programme for pregnant women.

Most of the participants represented a medium to high level in education and family income. Consideration would need to be given to recruiting a wider more representative sample in a full-scale trial

Conclusion

This study demonstrated feasibility to conduct a larger scale trial with an exercise programme for pregnant women. Recruitment and retention rates demonstrated a good likelihood of implementing such a programme in a larger trial. However consideration needs to be given to the number of classes and how they can be grouped to reduce number of visits to antenatal clinic. Preliminary effects of the exercise intervention were noted for a future trial that can be used to calculate an appropriate sample size and prepare processes such as collecting and analysing the data. The exercise programme was helpful to improve exercise behaviour and health outcomes. Finally, the study suggests that pregnant women showed high fidelity in the intervention.

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