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EXERCISE IN PREGNANCY: EFFECT ON OBESITY PARAMETERS IN INDIAN WOMEN – A RANDOMIZED CONTROLLED TRIAL

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Abstract

Background and aims: *The purpose of this study was to investigate the effect of physical activity and diet during prenatal period and its effect on gestational weight gain (GWG), BMI, waist circumference (WC), hip circumference (HC) and post-partum weight retention (PPWR).* ***Materials and Methods:*** *This was an experimental study (pre-post comparison) with 45 pregnant women having singleton pregnancy of >16 weeks of gestation, BMI>18.5 Kg/m^2 and having a mobile phone. They were randomly divided into 3 groups (n=12 each; compliance rate 80%) (i.e.) exercise (n=12), exercise with diet advise (n=12) and control (n=12) group. Exercise groups attended weekly antenatal exercise sessions at the hospital during pregnancy; diet group received regular diet counseling followed by mobile text-messages (reminder, motivational, guidelines and benefits) to maintain adequate diet. The data was analyzed using IBM-SPSS software.* ***Results:*** *Exercise groups gained less weight then control. Similarly, had mean GWG less as compared to control group though not statistically significant. The mean WC changes were significant amongst the groups with the exercise groups having least gain in WC ($p<0.05$).* ***Conclusion:*** *Adopting an active lifestyle along with proper diet care can prevent development of abdominal obesity and metabolic syndrome in Indian pregnant women which could prevent them from other associated lifestyle diseases in future.*

key words: *Abdominal Obesity, Waist Circumference, Pregnancy, Weight Gain, Obesity*

Background and aims

As per the new BMI classification for Asians (WHO), Indians are more obese at a lesser BMI as compared to their western counterparts [1]. Guidelines for obesity and overweight based on BMI indices for Asian Indians were revised based on consensus developed through discussions by a prevention and management of obesity and metabolic syndrome group [2]. It was reported that due to the specific Asian Indian phenotype of south Asians they come in one of the ethnic groups for which waist size may reflect more body fat at a given body mass index. Studies have found a higher percentage of body fat in Asians at lower BMI [3,4] as well as an increased prevalence of truncal fat, compared to Caucasians [5]. Women

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are reported to be more obese than men [6]. Prevalence of overweight and obesity in Indian women was reported to be increased in reproductive age [7,8].

Pregnancy is cited as one of the risk factors associated with rapid weight gain and retention hence triggering obesity in women of this age group. Of the various reasons reported for this, one of the major reasons is physical inactivity, which is more common in females than the male population [9]. In India, only 10% of women meet the physical activity recommendations given by American College of Obstetrics and Gynecology (ACOG) during pregnancy as opposed to 42% in USA [10]. Irrespective of whether the weight has been gained in teenage or during pregnancy, it is well known that obesity is associated with several non-communicable diseases causing greater burden to the entire nation [11]. Various observational studies have evaluated the effect of physical activity in controlling excessive gestational weight gain (GWG) and post-partum weight retention (PPWR) in pregnancy [12,13]. Based on this, western world has formulated exercise guidelines for pregnant women [14]. In fact, WHO has recently drawn antenatal guidelines for pregnant women [15] but no such exercise guidelines are available, specifically for Indian women. However, beliefs and practices faced by Indian pregnant women are entirely different from that of western population. Owing to this, there was an urgent need for developing specific physical activity (PA) intervention strategies involving pregnant women in India, which can prevent development of obesity during the child bearing years. Therefore, the current study was planned to assess the effect of a physical activity and dietary intervention along with physical activity during pregnancy on the weight and obesity parameters and in preventing obesity among pregnant Indian women. To the best of author's knowledge there are no such intervention studies reported earlier in India, which includes pregnant women.

Material and Methods

The current study is a part of an ongoing doctoral research registered with Clinical Trial Registry India vide no CTRI/2017/04/008322 and was undertaken at a maternity hospital on panel of Guru Jambheshwar University of Science & Technology in Hisar, Haryana, India from June 2016 to September 2017. Necessary ethical approval for the study was obtained from the Institutional Ethical Committee.

Expecting women ≥18 years age, with singleton live pregnancy confirmed by ultrasound scan of not < 16 weeks of gestation, having a BMI of ≥18.5 kg/m^2 and having access to mobile phone were included in the study. They were excluded if had any pregnancy complication at time of recruitment, with multiple gestations and if declared unfit by gynecologist for trial. They were screened for their similar physical activity levels and socioeconomic status by standardized questionnaires. The total study duration was of 12 months [16]. Eligible pregnant women were randomized into three groups (i) Supervised exercise group, which included weekly antenatal exercises at the study hospital along with regular walking throughout pregnancy, (ii) Supervised exercise and Diet group where along with the exercise sessions regular telephonic messages for dietary advice to be followed during pregnancy were given during pregnancy and (iii) control group. The baseline study reading was taken in pregnant women of >16weeks gestation, having a singleton pregnancy and declared fit by the study gynecologist as per inclusion criteria (reading 1), followed by second reading at full term or at the time of delivery (reading 2) and then finally at two months post-delivery (reading 3).

Participants

Pregnant women visiting to the study hospital were counseled about the importance of a healthy lifestyle during pregnancy with the help of educational brochures. They were also encouraged to join weekly antenatal exercise classes at the hospital. Posters were put up in the waiting area and pamphlets highlighting the benefits of being physically active during pregnancy in both local and English language were put up in the waiting area of the hospital and were also distributed in local newspapers (n= 6000) for increasing the awareness about the availability of such classes in Hisar city. The investigator personally contacted women coming for regular antenatal checkup in the hospital. Women who showed interest in exercise classes were screened for eligibility and their consent was obtained. They were further randomized into two exercise groups of with and without dietary advice. Women who did not give their consent for the supervised exercise classes formed the control group. This paper gives details about the first 36 subjects (12 in each group) who were found eligible for the trial as per the selection criteria and also gave their consent for measuring baseline readings and completed follow up data at 2 months post-delivery too. Some subjects were lost to follow up; they are not included in this paper.

Intervention

Supervised exercise group

Women in supervised exercise group attended weekly antenatal exercise sessions at the study hospital. A female physiotherapist, certified in providing prenatal and postnatal care led these sessions. The intervention consisted of supervised exercise training of 60-90 minutes duration, at moderate intensity (12–14 on Borg Scale of perceived exertion), consistent with exercise guidelines of the ACOG. The complete details about the exercise protocol are published elsewhere in detail [16] briefly, the session started with meditation followed with light warm up exercises, breathing exercises, stretching exercises for all muscle groups, pelvic floor and Kegal's exercises in sitting and standing, abdominal and back care exercises and also endurance & strengthening exercises with resistance tubes were included. Exercises with Swiss ball were done for relaxation and developing balance towards the end of pregnancy. Each session was concluded with a 5-10 minute meditation session for relaxation. These sessions were held twice weekly in the hospital. Both morning and evening sessions were planned for having a good compliance and providing convenient time options for participants. Women were asked to do the same exercises at home for at least 3 day/week apart from the supervised session. The intensity of exercise sessions was moderate and kept patient specific. To prevent over exertion women were instructed to use the Borg scale of Perceived exertion (RPE) while doing any physical activity. There is evidence for the efficacy of this approach as when exercise is self-paced, most pregnant women voluntarily reduce their exercise intensity as pregnancy progresses [14].

Women were also encouraged to walk daily for a minimum duration of 30 minutes and to do so at least 4 days/week throughout pregnancy. Walking component was emphasized the most, they were explained about its appropriate intensity, and proper precautions to be taken that included how to slowly and gradually progress without being fatigued or exhausted. Borg's scale of perceived exertion and 'talk test' were used to monitor the exercise intensity as they are found to be more effective during pregnancy than the heart rate parameters. Women were advised to exercise cautiously and stop immediately if any warning signs (which were

explained to them) were seen during the exercises.

Supervised exercise and diet group

In addition to attending supervised exercise classes, women in this group also received timely telephonic messages emphasizing the need for adequate and healthy food choices to be followed during pregnancy. These messages encouraged women to include foods such as more fruits and vegetables, dry fruits, to give preference to seasonal foods and to avoid unhealthy foods such as junk, oily, greasy and processed snacks from the market. Importance of home cooked food was explained. These messages were formulated with the help of the study gynecologist and trained dietician. All subjects were counseled to follow the dietary advice.

Control group

Women in control group received standard regular antenatal consultations with the gynecologist. They were advised once at recruitment for following a proper diet care and explained about the importance of being physically active during pregnancy. Some women wanted to learn exercises during pregnancy after they were allocated to control group. Such subjects were taught exercises for home, as not doing so would have been ethically wrong but they were excluded from the study in final analysis to prevent contamination.

Outcome measures

The primary outcome variables are weight, waist circumference, hip circumference, waist to hip ratio, Body Mass Index (BMI), Gestational Weight Gain (GWG) and Post Partum Weight Retention (PPWR). These are measured as per the standard procedures and the details for measuring the above are published elsewhere [17]. All the participants were prescreened for similar physical activity and socio-economic status using standard questionnaires.

Statistical analysis

Statistical analyses were performed using SPSS, version 21 with significance set at $\alpha = 0.05$. Normality tests were conducted to determine the distribution of data. In addition to descriptive statistics, data were analyzed using paired t test for within group differences and One-way ANOVA was used to determine between group differences. Intention to treat analysis was not conducted, as this paper represents a sub sample from an ongoing study with small numbers in each group.

Table 1. Baseline demographics and birth data of the RCT participants.

Participants Characteristics	Control Group (12)	Ex +Diet Group (12)	Exercise Group (12)	p-values	All (36)
Age	26.75±2.73	26.83±3.83	26.0±3.04	0.788	26.52±3.2
Height (m)	1.59±0.05	1.61±0.05	1.59±0.04	0.491	1.59±0.04
Pre Wt. (kg)	61.66±7.11	57.75±10.75	56.08±8.89	0.313	58.49±6.44
WC (cm)	80.91±7.39	76.75±5.98	76.83±5.96	0.214	78.16±6.44
HC (cm)	96.20±8.07	91.12±2.98	89.20±4.47	0.013	92.17±5.17
BMI (kg/m^2)	24.29±3.40	22.06±3.30	21.88±3.27	0.157	22.74±3.32
Multiparous, N (%)	4/12 (33)	3/12 (25)	2/12(16)	-	9/36 (25)
Infant Gender M/F N (%)	5/6 (45/54)	7/5 (58/42)	5/7(42/58)	-	17/19 (47/53)
Birth Weight (kg)	3.06	3.0	2.80	0.001	2.95

Mean ±SD for the study participants

Results

The baseline characteristics and birth data for all participants are summarized in Table 1. The mean age of the study population was 26.52±3.2 years and 75% of participants were having their first birth. Just over half the babies were female (53%) and the mean birth weight was 2.95 kg. All participants had completed minimum 12 years of basic education level and had similar socioeconomic status.

Table 2 summarizes the weight and obesity markers during pre-pregnancy, delivery and postpartum of the trial participants. Self-reported pre-pregnancy mean weight was 58.49±6.44 kg and the mean BMI was 22.74±3.32 kg/m^2. The average GWG was 12.88±4.29 kg while retention was 6.36±4.07 kg.

Table 2. Weight and Obesity markers of RCT participants.

Time	Variable	Control Group	Exercise+ Diet Group	Exercise Group	All
Pre-Pregnancy	Weight (kg)	61.66±7.11	57.75±10.75	56.08±8.89	58.49±6.44
	WC (cm)	80.91±7.39	76.75±5.98	76.83±5.96	78.16±6.44
	HC (cm)	96.20±8.07	91.12±2.98	89.20±4.47	92.17±5.17
	W/H	0. 84±5.51	0.84±4.77	0.86±6.04	0.84±5.44
	BMI (kg/m^2)	24.29±3.00	22.06±3.30	21.88±3.27	22.74±3.19
Pregnancy	GWG (kg)	13.33±5.33	12.91±3.65	12.41±3.91	12.88±4.29
Post-Partum (2 month)	Weight (kg)	69.25±8.32	63.58±10.60	61.83± 9.26	64.88±9.39
	WC (cm)	89.16±7.33	80.83±6.51	81.45±6.61	83.81±6.81
	HC (cm)	101.66±9.37	95±5.93	94.16±6.67	96.94±7.32
	W/H	0.87±4.96	0.85±3.53	0.86± 4.53	0.86±4.34
	BMI (kg/m^2)	27.12±2.82	24.40±3.03	24.24±3.62	25.25±3.15
	PPWR (kg)	7.58± 4.29	5.75±3.59	5.75±4.35	6.36±4.07

Mean ± SD for weight throughout pregnancy and up to 2 months post-partum. There were no significant differences found between study groups. GWG = weight measured at time of delivery – self-reported pre-pregnancy weight. PPWR = weight at 2 months post-partum– self-reported pre-pregnancy weight.

Table 3. Comparison of changes in mean values of variables, pre-pregnancy and post-partum (2 months) between three groups using one way ANOVA.

Variable	Control Group	Exercise + Diet Group	Exercise Group	F value	Sig.
Mean Weight Gain	7.58±4.29	5.83±3.68	5.75±4.35	0.75	0.477
Mean BMI Gain	2.83±1.75	2.34±1.24	2.36±1.75	0.362	0.690
Mean WC Gain	8.25± 3.80	4.08±3.57	4.62±4.53	3.85	0.031
Mean HC Gain	5.45±4.12	3.87±3.51	4.95±4.89	0.443	0.646
Mean W/H	3.68± 3.25	0.89±5.03	0.36±3.77	2.26	0.119
Mean GWG	13.33±5.33	12.91±3.65	12.41±3.91	0.133	0.876
Mean PPWR	7.58±4.29	5.83±3.68	5.75±4.35	0.802	0.477

Table 3 shows comparison of 3 groups for pre & post pregnancy mean values of weight, HC, W/H ratio and BMI, shows statistically non-significant differences but results were statistically significant for WC ($p<0.05$; $p=0.031$).

Table 4 shows the comparison for all parameters between pre and post pregnancy variables in all the groups.

Discussion

This is the first study from India to compare the effectiveness of providing an exercise and dietary intervention during pregnancy, with an aim to reduce development of obesity in expecting women. This study reported the average GWG of12.88±4.29 kg which is consistent with the WHO guidelines for optimal weight gain in pregnancy.

Table 4. Comparison of Pre Pregnancy and Post-Partum Weight (Wt), BMI, WC, HC, W/H& GWG using related t-test for different groups.

Groups	N	Variables	Pre-Pregnancy	Post-Partum (2 months)	t	p (2 tailed)
Control	12	Wt (kg)	61.66±7.11	69.25±8.32	-6.11	0.000
		BMI (kg/m^2)	24.29± 3.00	27.12± 2.82	-5.60	0.000
		WC (cm)	80.91±7.39	89.16± 7.33	-7.51	0.000
		HC (cm)	96.20± 8.07	101.66± 9.37	-4.58	0.001
		WC/HC	84.19±5.51	87.87±4.96	-3.91	0.002
		GWG(kg)	61.66±7.11	75.08± 7.21	8.65	0.000
Diet + Exercise	12	Wt (kg)	57.75±10.75	63. 58±10.60	-5.47	0.000
		BMI (kg/m^2)	22.06±3.30	24.40±3.03	-6.50	0.000
		WC (cm)	76.75±5.98	80.83± 6.51	-3.95	0.002
		HC (cm)	91.12±2.98	95±5.93	-3.82	0.003
		WC/HC	84.15±4.77	85.05±3.53	-6.17	0.550
		GWG(kg)	57.75±10.75	70.66±12.30	12.24	0.000
Exercise	12	Wt (kg)	56.08±8.89	61.83±9.26	-4.57	0.001
		BMI (kg/m^2)	21.88±3.27	24.24±3.62	-4.67	0.001
		WC (cm)	76.83±5.96	81.45±6.61	-3.53	0.005
		HC (cm)	89.20±4.47	94.16± 6.67	-3.51	0.005
		WC/HC	86.19±6.04	86.56± 4.53	-0.33	0.740
		GWG(kg)	56.08±8.89	68.50± 9.08	10.97	0.000

The Indian Council of Medical Research (ICMR) too recommends, the overall weight gain of 10-12 kilograms during pregnancy is optimal, however gain of up to 16 kg is considered alright. The intervention showed its effectiveness in controlling the weight within the recommended weight gain guidelines and most importantly in preventing the development of abdominal obesity in women post pregnancy ($p<0.05$). Indian women (80.6%) have a high prevalence of abdominal obesity than men (56.7%) [17]. Incidence of isolated abdominal obesity is also more common in Indian women [18]. This type of obesity is associated with development of various lifestyle diseases and eventually development of metabolic syndrome [19]. The effect of differences in waist circumference for a given BMI, have reported that individuals with similar BMI values but with different waistlines had different metabolic risk profiles and showed differences in their risk of developing diabetes and CVD [20]. Pregnancy could add to this increasing girth size and eventually increases the associated risk of developing lifestyle diseases in future. A recent study showed WC and W/H are the most useful indices for identifying South Asian adults with prevalent diabetes and hypertension more so in women than the men [21]. Therefore, interventions targeted at preventing development of excess abdominal obesity could be of a great help in the containment of the ever-rising epidemic of lifestyle diseases in young Indian women. Our results did not show statistically significant results for mean weight gain and BMI change among the groups with reported mean weight change of 7.58±4.29 kg, 5.83±3.68 kg and 5.75±4.35 kg and mean BMI change of 2.83±1.75 kg/m^2, 2.34±1.24 kg/m^2 and 2.36±1.75 kg/m^2 in the control, exercise with diet and exercise group respectively. It could be explained due to the effect of physical activity in the two exercise groups, there could be development of mean muscle mass and hence weight too leading to no changes in the final weight and hence the BMI values. Earlier studies have reported such findings where there was no change in the weight parameters but had reduced

WC measures pointing at improved metabolic profile due to substantial loss of visceral fat [22].

Pregnant women and their families often take the common belief of eating for two during pregnancy too seriously. The diet during pregnancy should be having adequate nutrition value and not allowing for excess weight gain. This could be done by improving the quality of daily food habits and preferences than just adding more calorie rich foods. Inappropriate eating habits could lead to excess weight gain and then it becomes difficult to get back in shape post-delivery. The exercise with diet group received regular informative diet messages emphasizing the importance of healthy alternative food choices and how to eat adequately without adding the extra calories, throughout pregnancy. However, both the exercise groups showed similar improvement in terms of all the parameters as compared to control but did not showed any differences between exercise groups. It could be possibly due to the small sample for comparison or reluctance in change pertaining to diet advice, especially during pregnancy amongst Indian women. No attempt was made to access the calorie intake in diet group.

Recruiting women for supervised exercise sessions was a challenge in itself. Direct involvement of the healthcare providers in the recruitment process, providing constant motivation and connecting to the expecting women via social media (telephonic messages, informative messages, pamphlets, providing written informative materials, and brochure) helped in the recruitment and retention rates in such a challenging set of population. Such strategies have been found to effective in earlier studies too [23,24]. The small sample was a limitation for the study, as it reduces the statistical power of the study. The power of a study is its ability to detect an effect when there is one to be detected. This depends on the size of the effect because large effects are easier to notice and increase the power of the study. The power of the study is also a gauge of its ability to avoid Type II errors. The sample size is inversely proportional to the margin of error. Consequently, reducing the sample size increases the margin of a Type II error skewing the results, which decreases the power of the study and can render the study meaningless. Also, small sample size reduces the confidence level of the study. The main problem with small sample studies is interpretation of results, in particular confidence intervals and p-values. Study with Small sample size have large standard error, wide 95% Confidence Interval (CI) and imprecise estimate of the effect and hence no firm conclusions. Another major limitation of small studies is that they can produce false-positive results, or they over-estimate the magnitude of an association. Also recruiting women for such a trial was a challenge with many dropouts and loss to follow up. However, such cases are not included in the final data, eliminating the need for intention to treat analysis. The results could have been different had all the enrolled subjects been included in final analysis even after loss to follow up. Since this study represents a part of the entire data planned from an ongoing trial the final results could be more enlightening in this area.

Conclusion

Encouraging expecting women for adopting a physically active lifestyle and explaining the importance of the same could result in decreasing the chances of developing abdominal obesity in Indian women. Since the concept of exercise during pregnancy is new and has less acceptability, constant motivation and involving the healthcare providers in encouraging women for exercises could be more effective in

recruiting expecting women for such supervised exercise sessions. WC has a direct relation with associated lifestyle diseases in Indians hence the results from the study could be a positive step towards curbing this rising trend of abdominal obesity right at the time of conception leading towards a better future health of the nation.

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