Author's response to reviews

Title: Effect of physical activity intervention based on a pedometer on physical activity level and anthropometric measures after childbirth: a randomized controlled trial

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Response to the Editor

Dear Editor

Many thanks as you checked my article carefully. I did my best to provide appropriate explanations for your questions. I hope you will be satisfied with answers.

1- Sample size calculation carried out using a formula recommended by previous studies: 
\[ d = \frac{\Delta}{SD}, \] where “d” is standardized difference, \(\Delta\) is the smallest clinically significant difference and \(SD\) is standard deviation of the test group. Power was set at 0.8; Alpha level was set at 0.05 and confidence interval set at 95%. According to the Harris et al’s study [4], and changes in the BMI after physical activity, considering \(SD=0.93\), \(\Delta=0.82\), that for more confidence we consider \(\Delta=0.5\) and calculated “d” was 0.53, the sample size calculated 28 for each group with adding 30% attrition size it changed to 35 women in each group (page 6).

1- Some detail of educational program was added to the material and methods (page 7-8). Participants received a reminder about physical activity by cell phone text message once weekly, a phone call once every 2 weeks, and a pamphlet by the name of “losing weight is so easy” by the 8th week. The telephone counseling was designed to provide regular, credible, individualized counseling. During the first few minutes of each telephone counseling call, the researcher asked a woman how many steps she had accumulated each day over the previous week, then provided her with supportive feedback regarding attainment of her physical activity.
2- Actually we applied for trial registration few months prior to the end of the study; however in Iran it takes few months to register the trial.

3- Some explanation about blinding was missing from the article that I provided it. Health clinics have chosen by stratified method and group allocation was achieved through computer generated randomized sequencing. Researchers were blinded to group allocation and it was done with the party who was not aware of this study. One of the researchers (MM) was responsible to train and follow-up participants after recruitment.

4- Table 1 is consisting of some sociodemographic characteristics of participants.

5- An average of the first three days of normal ambulation served as an individual baseline. The pedometer was reset to zero at the beginning of each day by participants.

Participants recorded the pedometer readings (steps/day) on a calendar provided by the researcher. At the baseline visit, participants had an individualized counseling session with one of the researchers (MM). During this session women in the intervention group discussed the benefits of physical activity and also benefits of using pedometer.
6- We checked the food frequency of participants pre and post intervention, to control the
effect of food intake as a confounding variable and to be sure there were not on a diet
during our study. I expand an explanation a little bit. The food frequency questionnaire
including 11 food groups and totally 46 items according to the Iranian food composition
table was used for assessing food intake of participants pre and post intervention. If you
recommend we can omit it or add two tables that contain information about food intake
of participants.

7- More detail of IPAQ provided in page 8. An International Physical Activity
Questionnaire (IPAQ), short version was used to gather data. *International Physical
Activity Questionnaire (IPAQ)* short version (7 questions) was used to assess physical
activity across a variety of different domains including leisure-time, domestic, work and
transport related physical activity over seven days [20]. Each domain assesses walking,
moderate and vigorous physical activity performed for at least 10 consecutive minutes
each day, over seven days. An average metabolic equivalent (MET) score was calculated
for total physical activity performed per week as a continuous variable whereby total
physical activity in MET-minutes/week = sum of total [Walking + Moderate + Vigorous] MET minutes/week scores. Individual MET scores for walking, moderate and vigorous
activity were calculated within each domain and combined to provide a total score using
the following equations: total MET-minutes/week = Met-level × minutes per day × days
per week, where 1 MET is equivalent to resting energy expenditure[23].

8- The mistake in figure 1 has corrected.
9- SD was added to the figure 2.

10- All continues data were checked about normality with the Kolmogorov- Smirnov test. The results revealed that physical activity was not normally distributed, therefore we used non-parametric tests to analyze them (page 9-10).

11- We tested the correlation between changes in anthropometric measures and steps/day and found; there were significant inverse associations between the number of steps per day and weight ($r = -0.6, p < 0.001$), waist circumference ($r = -0.57, p = 0.001$). There was no association between the number of steps per day and changes in hip circumference ($r = -0.04, p = 0.82$), WHR ($r = -0.26, p = 0.14$) and BMI ($r = -0.21, p = 0.22$).

12- It seems that the amount that participants are able to increase their steps per day is not related to their baseline BMI and physical activity based on pedometer can improve anthropometric measures even in overweight and non obese women (31).
Response to the reviewer 2

Dear Dr Graham Baker

Many thanks as you reviewed our article very carefully. I think it took many times from you. Following you can see the answers; I did my best for preparing proper answers. I hope you will be satisfied with them.

1-The results of two systematic reviews were provided in an introduction (page 5).

2- Actually we did not use any behavioral change techniques (for instance theory of Reasoned Action or Health Belief Model). As we mentioned in the method, our educational program was including: a phone call every Friday, a pamphlet with an educational CD under the name of “losing weight is so easy”. According to your comment I think it would be better we change the title and omit the word of educations program. The suggested title is “Effect of physical activity
intervention based on a pedometer on physical activity level and anthropometric measure after childbirth: a randomized controlled trial”

3- According to the (Tudor-Lock et al, 2011) Normative data indicate that healthy adults typically take between 4,000 and 18,000 steps/day, and that 10,000 steps/day is reasonable for this population, although there are notable "low active populations." Interventions demonstrate incremental increases on the order of 2,000-2,500 steps/day. Because the first three days evaluation of pedometer showed that mean steps of participants was 3249, and they were low active population, we recommended them to increase their steps to minimum 5000 and then continue to increase until to catch the 10,000 steps/day. According to the 2008 physical activity guidelines for Americans, healthy women should get at least 150 minutes (2 hours and 30 minutes) per week of moderate-intensity aerobic activity, such as brisk walking, during and after their pregnancy.

Because the average step/day in three days was 3249 and according to the pedometer instruction 20% is a reasonable increase in number of steps, it was roughly 70 per day, means every woman should increase her steps 70 per day (How to increase your pedometer steps. Available at: fitness for weightloss.com). We recommended women to increase their steps around 10,000 per day and it is equivalent of almost one hour walking per day that is in turn more than the recommendation.

4-The details of recruitment and randomization were provided in the Methods and Materials (Page 6). We have chosen 7 health clinics amongst 23 centers in Abadan with stratified method. Then 70 women randomly recruited from these centers. Because most of the women in Iran undergo cesarean section especially those who have their first pregnancy. Women, who give
birth with cesarean section, usually start their physical activity around twelve weeks after section. On the other hand, women who give birth vaginally usually start their activities before 12 weeks. Because of this, we have chosen 6 weeks to 6 months for better coverage of cesarean and normal vaginal delivery. Our results showed that; the mean of weeks after birth was 12.84 and 12.73 in the intervention and control groups respectively.

5- The article changed according to the CONSORT guidelines 2010.

6- The information’s about IPAQ were provided in Material and Method (page 7). *International Physical Activity Questionnaire (IPAQ)* short version (7 questions) was used to assess physical activity across a variety of different domains including leisure-time, domestic, work and transport related physical activity over seven days [18]. Each domain assesses walking, moderate and vigorous physical activity performed for at least 10 consecutive minutes each day, over seven days. An average metabolic equivalent (MET) score was calculated for total physical activity performed per week as a continuous variable whereby total physical activity in MET-minutes/week = sum of total [Walking + Moderate + Vigorous] MET minutes/week scores. Individual MET scores for walking, moderate and vigorous activity were calculated within each domain and combined to provide a total score using the following equations: total MET-minutes/week = Met-level × minutes per day × days per week, where 1 MET is equivalent to resting energy expenditure[18].

7- We used T-test when we wanted to compare two groups before or after intervention in isolation. When we wanted to compare after intervention changes in the BMI, waist circumference, we were not able to see the before after intervention changes in each group and using ANCOVA we were able to do that. Exploratory analysis (Kolmogorov- Smirnov test) revealed that baseline data of physical activity were not normally distributed. Non parametric
tests were therefore used to analyze these data. Mann-Whitney U test was used for between

group differences and Wilcoxon’s signed–rank test was used to assess within-group changes

over the time.

**Minor essential revisions**

1- SD provided for figure 2.

2- The reasons for drop-out during the screening stage provided in figure 1.