

# The design of maternal centered life-style modification program for weight gain management during pregnancy — a study protocol

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**Background:** Abnormal weight gain during pregnancy increases the adverse health outcomes during the pregnancy, delivery, and the postpartum period. Most of the pregnant women develop weight gain more than the recommended limits; therefore, interventions to manage such disproportionate weight gain are needed. In this paper, the design of the maternal centered life-style intervention study is described, which focuses on controlling weight gaining during pregnancy for all body mass index (BMI) groups. **Materials and Methods:** In our randomized field trial, 160 pregnant women with 6-10 weeks of gestational age who visit one of the participating Isfahan four urban public-health centers and 4 private obstetric offices are included. The maternal centered life-style intervention carried out by trained midwives is standardized in a protocol. All the participants are visited at 6-10, 11-15, 16-20, 21-25, 26-30, 31-34, 35-37, 38, 39, and 40 weeks of pregnancy. The women who are randomized in the intervention group receive maternal centered educational package of prenatal care for the pregnant woman and a log book in the first visit. Counselors accompany the pregnant women to maintain or develop a healthy life-style. Data collection will perform monthly measuring body weight, BMI. **Conclusion:** Because, we don't have structured protocol for weight management during pregnancy especially, in private sectors if the maternal centered life-style intervention proves to be effective, it will be suggested to merge this package to routine care. Therewith by empowering women to manage their weight the public-health burden can be reduced. Beside that private obstetricians also have structured protocol for their client management.

**Key words:** Empowerment, maternal centered life-style intervention, pregnancy, weight gain

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## INTRODUCTION

Abnormal weight gain during the pregnancy puts the mother into increased risk of serious health problems such as risk of cesarean delivery, delivery complications, preeclampsia, and postpartum weight retention and therefore, increasing the long-term risk of weight-associated diseases. Negative complications for infants include hypoglycemia, microsomal, prematurity, low neonatal birth weight, greater offspring adiposity, and adverse cardiovascular risk-factors and seizures.<sup>[1-9]</sup> In the United States, Approximately 40% of normal-weight and 60% of overweight women gained excessive weight, during pregnancy.<sup>[10]</sup> In Australia, an estimated 34% of the Australian obstetric populations have a body mass index (BMI) greater than 25 kg/m<sup>2</sup>.<sup>[11]</sup> Similar rates are seen in the United Kingdom with 25% of women overweight and over 15% obese during the first trimester of their pregnancy. Beside that recently mean gestational weight gain (GWG) has increased in developed countries.<sup>[12]</sup> A cross-sectional study in Iran, Rasht city, on Iranian women attending public-health

centers showed that weight gaining below the lower cut-off recommended by the Institute of Medicine (IOM) were 64% and 67% in underweight and normal weight women.<sup>[13]</sup> In another study in Tehran 37% of participants had weight gain below the standard level, and 35% above the standard level.<sup>[14]</sup> Excessive pregnancy weight gain associated with impaired life-style patterns before, during, and after pregnancy.<sup>[15]</sup> Therefore, pregnant women usually are more likely to be motivated to make life-style change<sup>[16]</sup> and hence interventions to promote healthy life-style during pregnancy may reduce excessive weight gain and could also be beneficial for long-term.

There is insufficient evidence to inform the design of an effective and appropriate intervention for pregnant women, besides that there are few reports of successful community-wide weight gain prevention interventions, and reports on interventions to prevent weight gain produced inconsistent results.<sup>[16-18]</sup> Local, community-based interventions have the possibility to support the life-style modifications.<sup>[8,9]</sup> Possible behavioral change

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success factors include goal setting, social support, self-efficacy, and self-monitoring.<sup>[19]</sup> Self-monitoring has not been broadly experienced for the prevention of weight gain; however, associated with better maintenance after weight loss in obese individuals. Self-efficacy is a potential predictor of weight loss and behavior change.<sup>[20]</sup> Therefore, interventions enhancing self-efficacy have the potential to develop better outcomes. Improved outcomes may achieve by more efficient delivery formats such as tailored and interactive programs with more concentration on diet and physical activity.<sup>[15,20,21]</sup> Hence, interventions that are low-cost deal with the participation barriers to achieve the sustainable behavior change and improve self-efficacy and self-monitoring are needed.

### Objective

In this article, we explain the design of a maternal centered life-style intervention during pregnancy, which may offer benefit to pregnant women with the different BMI by improving their own physical and psychological well-being. Our intervention will address weight measurement, diet and food-intake pattern, physical activity, and emotional well-being.

The objective of our study are (1) to measure the maternal mean weight gain during pregnancy after providing the necessary knowledge and skills for them in the intervention group (2) to measure the maternal mean weight gain during pregnancy in control groups and comparing it with the intervention group (3) to compare the trend of weight gaining in the intervention group and control groups (4) to compare the mean and trend of weight gain in each group based on their pre-pregnancy BMI with the recommendation of IOM.

## MATERIALS AND METHODS

### Study design

The study is a randomized controlled trial (field trial) to assess the effectiveness of a maternal centered life-style modification program focusing on maternal empowerment to manage their weight development, diet nutrition habits, physical activity, and stress during pregnancy. Pregnant women with 6-10 weeks of gestational age are randomly assigned to the intervention or to the control group. They are studied until their delivery. The Medical Ethics Committee of Isfahan University of Medical science has approved the study design, protocols, and informed consent process.

### Setting

This trial is carried out in Isfahan, the capital of Isfahan Province and Iran's third the largest city after Tehran and Mashhad, located about 340 km south of Tehran, with a population of 1,583,609 in the 2006 Census. Four urban public-health centers and 4 private obstetric offices are

selected randomly. Participation in the study is voluntary. Midwives working in these places explain the study for eligible women and ask them to participate in the study from October 2012 until the end of their pregnancy. By selecting practices in different urbanized locations, we aim to include a selection of midwives and the participants that is representative of these subgroups.

### Selection of midwifery practices

A list of all urban public-health centers and obstetric offices are extracted from Vice-Chancellery for health and Vice-Chancellery for treatment of Isfahan University of medical science.

Out of 60, 10 urban public-health centers were selected randomly. The selected practices received a brochure about the study and were called 1 week later by the research team, to ask for participation. 2 of the 10 practices were too busy to participate in a study, three practices had no spare room, and one did not have enough personnel to participate in the study. Ten obstetric offices were selected randomly, 2 of them weren't interested in the subject of study and 4 offices didn't have enough place and midwife, so 4 obstetric offices were ready to participate.

A total of 16 h workshops, held for participated midwives, consisted of counseling and health education Principles and the study protocols and content education. Hence no data exchange will occur between researchers and midwives during the study. Midwives will refer participants with questions about the study to the research team.

### Selection of participants

When a woman meets the inclusion criteria and wishes to join the study, she is included. Participating midwives recruit subjects and introduce the study to them, and after having received consent to do so, they complete a screening sheet contain the women name, address, telephone number, gestational age, body weight, height and last menstrual period. Subsequently, a research assistant calls participants and explains the aim and an implication of the study. An appointment is made for the first meeting at the midwifery practice individually. Informed consent forms will be obtained from each participant. Women are able to opt-out of study at any time they wish. If a woman doesn't meet inclusion criteria or does not want to take part in the study, she will be asked to complete a consent form to say that her demographic and the clinical data can be used. Characteristics of the non-participating group will be compared to the participants in the study.

Women who are included in the study will be divided based on their initial BMI in to three groups: BMI lower than 19/8 between 19/8 and 26 and more than 26. To select a random

sample, we will prepare a numbered population list for each BMI groups, using the table of random numbers, we will randomly assign mothers in to intervention or control group.

### Inclusion and exclusion criteria

The eligibility criteria for participation are being able to read, write and speak Persian; the gestational age of 6-10 weeks and having no disease or condition that require special medical care or drug consuming.

The exclusion criteria will be not interested to continue participation in the study, take weight control medication, any disease or condition required special medical care or hospitalization and multifetal pregnancies.

### Sample size

One hundred and sixty women with 6-10 weeks of gestational age will be included. Half of them will be selected from private obstetrical offices and others from the urban public-health centers. A power analysis has been based on the effects of the intervention program on BMI of participants in the intervention group. In order to be able to detect a clinically relevant difference in the BMI between the intervention and the control group ( $d = 0.9$ ), 160 participants are needed, 80 participants in each group. Participants will be divided based on their initial BMI. The power of study is (1-B) 0.80, and significance level 5% (two-sided) with a standard deviation of 2.0 kg/m<sup>2</sup>.

### Intervention program

During the maternal centered life-style modification program pregnant women in the intervention group themselves manage their weight during pregnancy by providing the maternal centered educational package of prenatal care for the pregnant woman (PCPW), prenatal care log book and ten counseling sessions. The personal counselor who is the participating midwife accompanies the subject and is also a supervisor and accompanist for the pregnant women. Women have appointments with their counselor at 6-10, 11-15, 16-20, 21-25, 26-30, 31-34, 35-37, 38, 39 and 40 weeks of pregnancy.

By using the PCPW package, pregnant women can gain a sense of control over their problems through increasing knowledge, enhancing competence to define the behaviors for change; learning to look for problem solutions, and setting goals to develop or maintain healthy behavior. PCPW package consists of 14 chapters, weight gaining during pregnancy, weight gain charting, principle of nutrition in pregnancy, nutritional guide for low and normal and high BMI, food calories, principle of personal hygiene, mental-health, stress management, suitable positions in pregnancy, stretching exercise, respiratory exercise,

relaxation, massage in pregnancy, and physical activity principle and guidelines. All the references are from the ministry of health and medical education of Iran and the different Vice-Chancellery for health publications. The log books contain 5 sections. First part includes calculating expected delivery date and determining time of referral for each counseling session. The second section related to weight gaining table and chart. Each subject should measure her weight weekly and complete the weight table and draw the curve. Part 3 pertain to diet and nutrition. The woman should write her food frequency consumption weekly, evaluate her status and set goals to enhance healthy diet. Section 4 and 5 are relevant to exercise-physical activity and the stress management technique and again the subject sets goal to improve her conditions.

Each counseling session takes 20 min; however, the first session takes about 30 min. In the first session, the midwife give details of the study and the intervention. The content of the package and log book, which the participants receive after the first counseling session of the intervention are discussed. After this, measuring weight and height and calculating BMI are educated to each subject and the participant assess their own BMI after the IOM guidelines introduction. The counselor explains how to chart the weight and plot the curve. At the end of the first session, the package and log book are delivered to the participant and the date of the next session is determined.

During each session, the subject interpret her weekly nutrition, exercise, stress status and weight gaining pattern, and sets the goal to improve her conditions. If weigh gaining trend is abnormal the counselor will evaluate the participant and help her to find a solution for her difficulties.

The control group also refers at 6-10, 11-15, 16-20, 21-25, 26-30, 31-34, 35-37, 38, 39, and 40 weeks of pregnancy. In each visit, the midwives measure their weight and plot the weight curve. They receive standard and regular prenatal care and write their weight weekly in weight table delivered them in the first visit.

### Study variables

We consider maternal weight gain as a dependent variable, maternal centered life style modification as an independent variable. Based on literature review, mother age, level of education, smoking, weight before pregnancy, and mother' job are confounders.

### Statistical analysis

We will use the Statistical Package for Social Scientists version 19 for data analysis and will analysis the data monthly. Findings will be displayed as frequencies, percentage, mean and standard deviation, using the tables

and plots. Chi-squared analysis used to explore associations in the data. We will use the logistic regression analysis for the dichotomous outcome, and linear regression analyses for all other outcome. Data will be examined using the Chi-squared and *t*-tests, ANCOVA, Repeated measures ANOVA analysis. Data will be analyzed based on intention-to-treat principle, and if the attrition rate find to be more than 20%, the drop out will be substitute.

## DISCUSSION

International institute of medicine (IOM), National Institute for Health and Care Excellence (NICE), and other organizations<sup>[22]</sup> have guidelines on weight gaining during and after pregnancy; however, it is not obvious how to implement these recommendations.<sup>[23]</sup> The published intervention trials results do not have sufficient quality for developing evidence-based recommendations for practice in midwifery care.<sup>[16,18]</sup> The aim of maternal centered life-style modification program is to help the pregnant women to have control over their life-style and manage their weight gaining by providing the necessary information and skills and therefore, improve self-efficacy. This program will provide guidance for pregnant women specially who don't receive standard care. Up to the present time, the weight management recommendations in pregnancy have mainly focused on obese and overweight women<sup>[24]</sup> and it is a distinguished aspect of this study to participate and have guidance for all BMI groups.

If the maternal centered life-style modification program proves to be effective, it can be merged to international guidelines of midwifery. Hence, that by empowering women to manage their weight, the public-health burden can be reduced. Beside that private obstetricians also have structured protocol for their client management.

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