



# Pregnant women, weight gain and Auriculotherapy: a protocol for a randomized controlled trial

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## Abstract

**Introduction:** The demographic characteristics of women who become pregnant have changed dramatically over the past decade. Most women are overweight or obese during pregnancy, so the growing global trend of being overweight during pregnancy has been accompanied by a concomitant increase in pregnancy complications. This study will evaluate the effect of ear acupressure (auriculotherapy) on the weighting pattern of overweight women during pregnancy.

**Methods:** This study will be a single-blind randomized clinical trial with two intervention and control groups. A total of 130 eligible pregnant women will be selected by a purposeful sampling method and then divided into two groups of intervention and control by a random blocking method with quadruple blocks. In the intervention group, two seeds were placed in the left ear on the metabolism and stomach points, while two seeds were placed in the right ear on the mouth and appetite points. Participants in the intervention group must press the seeds 6 times a day, preferably 20 minutes before a meal. The seeds will be changed twice a week (once every three days) by the researcher. The total duration of the study will last for 5 weeks. For the control group, instead of the real seed, the Vaccaria seedless label (waterproof cloth adhesive) will be placed by the researcher at the same points as the intervention group.

**Results:** Primary results include weight gain during 5 weeks of intervention compared to baseline weight. Secondary results include weight gain at the end of the intervention, then 2 and 4 weeks after the intervention compared to baseline weight. Adverse events during treatment and follow-up periods, regardless of the relationship with the interventions, are documented, reported to the ethics committee, and treated with appropriate treatment.

**Conclusion:** This study is expected to support the effect of ear acupressure on the weight gain status of overweight women during pregnancy.

**Keywords:** Ear Acupressure, Auriculotherapy, Weight Gain, Overweight, Pregnancy.

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## Background

Obesity and being overweight are common metabolic disorders that have an impact on both the physical and mental health of individuals<sup>1</sup>. Adult overweight and obesity are defined by WHO as follows: Obesity is defined as having a BMI greater than or equal to 30 kg/m<sup>2</sup> and BMI greater than or equal to 25 kg/m<sup>2</sup> indicates overweight. The worldwide prevalence of obesity nearly tripled between 1975 and 2016<sup>2</sup>. The latest

WHO estimates show that at least one in three adults in the world is overweight and approximately one in 10 people are obese<sup>3</sup>. Developing countries like Iran are also affected by this epidemic, so 34% of Iranian women are overweight. Cardiovascular diseases are the most important cause of death in women, and Iranian women are 3\_4 times more exposed to cardiovascular diseases than women in other parts. Being overweight or obese are major risk factors for a number of chronic diseases,

including cardiovascular disease and stroke, which are the leading causes of death worldwide<sup>2</sup>.

Obesity is the most common healthcare problem in women of childbearing age, which has made it the most common medical complication in pregnancy<sup>4</sup>. It may be associated with a variety of pregnancy complications, which are also the most common complications during pregnancy and affect approximately 50% of women in low-income countries<sup>5</sup>.

Over the past few decades, the growing global trend of being overweight during pregnancy has been accompanied by a simultaneous increase in pregnancy complications<sup>6</sup>. Maternal complications include gestational diabetes, gestational hypertension, preeclampsia and eclampsia, cesarean delivery, sleep apnea, and stroke. Maternal obesity is a global public health concern that affects all aspects of pregnancy care, including the short-term and long-term health of the mother and her children. Obese pregnant mothers are at increased risk for complications during the prenatal, postpartum, and postpartum periods<sup>7-9</sup>.

Proper pregnancy weight gain may be important for pregnant women to achieve safe outcomes of pregnancy, childbirth, and birth, as well as long-term health. Therefore, in 2009, the Institute of Medicine (IOM) published revised guidelines for pregnancy weight gain based on the pre-pregnancy body mass index (BMI) recommended by the World Health Organization for underweight normal weight, overweight, and obese women regardless of age, race, and ethnicity. The instructions of the Institute of Medicine recommend general weight gain for overweight pregnant women in the range of 6.8-11.3 kg. The purpose of weight gain recommendations during pregnancy is to optimize the outcomes for the mother and baby. Despite regular and planned care of pregnant women in Iran, only half of them achieve the recommended weight during pregnancy<sup>10-13</sup>.

Auriculotherapy (treatment through the ear) is a type of acupuncture that has become a separate and unique alternative treatment method in the last 60 years. This method was first proposed in 1957 by Dr. Paul Nogier and officially recognized by the World Health Organization in 1990,<sup>14</sup> the organization stated that auriculotherapy is probably the most advanced, accurate, scientific, and practical type of Acupuncture microsystem. Ear acupuncture can reduce the pleasure of eating and the feeling of hunger and increase the feeling of satiety. It is also more effective in weight loss than body acupuncture. Therefore, it can be a useful and safe non-drug treatment. On the other hand, the prenatal period is considered an ideal time for intervention due to the provision of a

suitable opportunity for regular contact with health professionals. Because mothers are motivated to make changes that can improve the health of themselves and their children<sup>15</sup>.

In a study conducted by Bradford, acupuncture was performed unilaterally on 5 points (hypothalamus, hunger, stomach, zero point, and Shenman). The results showed that within 30 minutes after treatment in the intervention group compared to the control group, appetite decreased. As a result, acupuncture can reduce the feeling of hunger and increase satiety, although the difference was not statistically significant. In the Ching Hsiu Hsieh study, the ear points used to treat weight loss were the Shenman points, mouth, stomach, small intestine, and endocrine glands. The group treated with Vaccaria seed showed rapid weight loss in the short term and it was found that acupressure can be a good option in the treatment of overweight and obesity in young adults<sup>16</sup>.

In a study by Hosseini, a press needle was placed on the tragus point and the results showed that acupuncture performed on a specific point of the ear (tragus) after one day (24 hours) can lead to a significant reduction in the pleasure of eating and the feeling of hunger<sup>12</sup>.

In the systematic review and meta-analysis performed by Mendonca, the most common sites of stimulation were shenmen; stomach, endocrine, hunger, mouth, small intestine, anti-aggression, spleen, San Jiao, large intestine and, the center of the ear points were also used. It was found that auriculotherapy may be effective in reducing weight and/or BMI in overweight or obese individuals. This study will investigate the effect of ear acupressure (auriculotherapy) on the weight gain status of overweight women during pregnancy.

## Methods

This study is a single-blind randomized clinical trial with two intervention and control groups. This study is designed according to CONSORT standards.

## CONSORT 2010 Flow Diagram

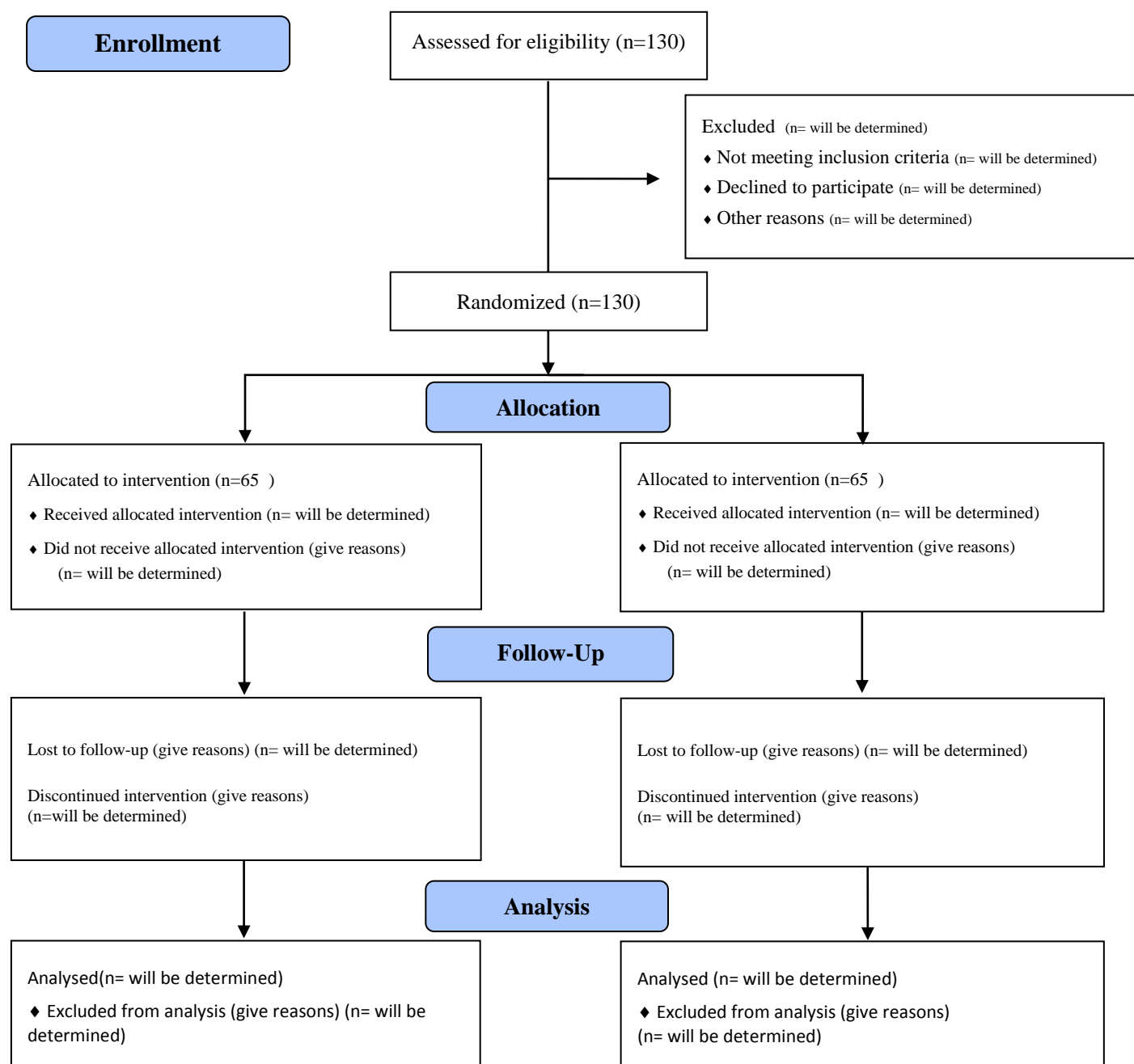


Diagram 1. proposed consort diagram

In this study, 130 pregnant women referring to selected health centers in Qom (Iran) that are overweight and are between 20 to 24 weeks of pregnancy and have inclusion criteria are invited to participate. BMI 25 to 29.9 kg / m<sup>2</sup> before pregnancy or during the first trimester of pregnancy who have an abnormal pattern of weight gain according to the order. ( Excess weight gain for the specific gestational age, which will be (more than 300 g per week in second half of pregnancy) - Age 18 to 40 years - Singleton pregnancy – Gestational age at least 20 full weeks (due to reduced nausea and increased maternal

appetite after the end of the first trimester of pregnancy and excessive need to help for these group of women) and at most 24 full weeks (for meeting the complete duration of 5 weeks for each women in study groups)- No history of miscarriage, stillbirth and infertility - No medical problems affecting body weight (untreated thyroid disease) - No history of diabetes mellitus 1 or 2 and overt diabetes, drug-dependent hypertension, addiction, nutritional problems, chronic disease, kidney disease, anemia - no medication - no psychiatric illness and history of eating disorders - no

pregnancy complications In the mother (bleeding, placenta previa, Placental abruption, preterm labor, etc.) - no abnormalities or ear infections - no use of other therapies to control weight - literacy. Reluctance to continue participating in the study for any reason - Failure to complete the intervention period due to preterm labor or the other causes - Occurrence of any side effects following the intervention - Creating new medical conditions during the study period (complications of pregnancy such as gestational diabetes mellitus, Hypothyroidism, bleeding, hypertension, preterm labor, rupture or leakage Water bag and etc.) - Using any other weight control method (under the diet of a nutritionist, etc.) and terminating the pregnancy for any reason. In the first meeting, after explaining the objectives of the research and the method of intervention and answering the questions of the samples, the first author provides the informed consent form and the samples sign the text of the informed consent after reading it. This study is based on a randomized design with two groups of intervention and control with a random blocking method with 4 blocks because this method minimizes sampling error and strengthens the power of statistical tests.

### Sample size calculation

The sample size is calculated to compare weight gain changes in the ear acupressure group and the control group. If we want the average weight of the intervention group to be 1.06 kg less than the control group to be considered statistically significant considering the 95% confidence level and 80% test power and using the formula below the sample size for each group is 59 The person is calculated, taking into account 10% of the sample loss in each group, 65 people will be considered.<sup>17</sup>

### Sample size calculation formula:

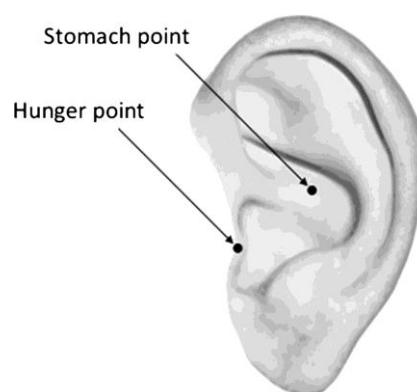
$$n = \frac{(z_{1-\frac{\alpha}{2}} + z_{1-\beta})^2 \times (\sigma_1^2 + \sigma_2^2)}{(\mu_1 - \mu_2)^2}$$

$$n = \frac{(1/96 + 0/84)^2 \times (2/06^2 + 2^2)}{(1/02 - 2/08)^2} \approx 59$$

This study will be a single-blind randomized clinical trial with two intervention and control groups, in which the effect of ear acupressure (auriculotherapy) on the weight gain status of overweight women during pregnancy will be investigated. The research environment includes selected health centers of Qom University of Medical Sciences in Qom city. Sampling will be done first by

available method and then by random blocking method with quadruple blocks and, women referring to selected centers that meet the inclusion criteria are selected and after obtaining informed written consent from them, they enter the study.

After providing explanations to familiarize the samples with the working method and answer their questions, the samples are requested to be in a comfortable position. The intervention begins by disinfecting both ears with a 70% alcohol solution. After determining the location of metabolism and stomach points in the left ear and mouth and appetite points in the right ear (Figure 1) that are related to weight and appetite control, the researcher will place the seeds on the desired points.



**Figure 1.** Metabolism (hunger point) and stomach point in Auriculotherapy

The intervention will last for a total of 5 weeks. The seeds will be changed twice a week (once every three days) by the researcher. The samples in the intervention group are taught to press the seeds 6 times a day for one minute. The pressure method will be to use moderate stimulation with continuous pressure. Samples are recommended to preferably do these 20 minutes before eating. The researcher will remind the participants in the intervention group of their daily interventions by phone or text message. Each night they are asked to check if they follow the instructions and if they complete the daily registration checklist. In each seed replacement session, which will be done every three days, the checklist of the previous session is viewed and checked, and a checklist is received every week at the same time as the samples are weighed. Samples are also emphasized in case of any symptoms of allergies or infections and pain as soon as possible through the contact number provided to them to discuss the issue with the researcher to remove the seeds. In the control group, instead of real seeds, a label without Vaccaria seed (waterproof fabric adhesive) is placed the researcher at the desired points in both ears, and the

samples will not receive training to compress the points. They also do not receive the list of daily pressing points. All follow-ups and replacement of labels will be done in the same way as the intervention group in the control group. Finally, all samples are requested to notify the researcher if any seeds or labels are removed for any reason. It should be noted that pregnant mothers will be unaware of the nature of the group to which they belong. When mothers visit, women in each center will be weighed using a digital scale. This digital scale has a minimum capacity of 0 kg and a maximum of 150 kg and an accuracy of 0.1 kg. Height will be measured with a Portable stadiometer with a maximum permissible error of 0.5 cm between two measurements. All anthropometric measurements are performed by the researcher and are standardized according to the recommended instructions. Participants in the intervention group will receive active intervention for 5 weeks, which is achieved by attaching Vaccaria seed by the researcher in 4 ear points and pressing the seeds 6 times a day, preferably 20 minutes before eating and for one minute performed by samples in the left ear points the stomach and metabolism in the right ear are points of the mouth and appetite. The reasons for selecting these points were summarized based on the traditional Chinese medicine meridian theory (TCM), the results of literature review, and clinical work experience.

### Results:

Primary results include weight gain during 5 weeks of intervention that compare to the weight of women before the intervention. Secondary results include weight gain at the end of the intervention, then 2 and 4 weeks after the intervention compared to baseline weight. Adverse events during treatment and follow-up periods, regardless of the relationship with the interventions, are documented, reported to the ethics committee, and treated with appropriate treatment.

#### Research Highlights

##### What we know:

In a study conducted by Bradford, acupuncture was performed unilaterally on 5 points (hypothalamus, hunger, stomach, zero point, and Shenman). The results showed that within 30 minutes after treatment in the intervention group compared to the control group, appetite decreased

##### What does the research add?

This study is expected to support the effect of ear acupressure on the weight gain status of overweight women during pregnancy.

### Conflict of interest

We didn't have any conflicting interests.

### Ethics approval

IR.TUMS.FNM.REC.1400.117

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