The effect of a diet based on Iranian traditional (Persian) medicine versus a diet based on modern medicine on the birth weight of neonates with the history of asymmetric intrauterine growth restriction: a randomized clinical trial

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Abstract

Introduction: Due to the complications and high incidence rate of Low Birth Weight in Iran, it is one of the most important challenges of obstetrics. In the absence of effective therapeutic approaches, attention to the potential of Iranian medicine along with modern medicine can be helpful.

Methods: A randomized, clinical trial was performed on 64 pregnant women with unexplained asymmetric Fetal Growth Restriction. Patients were randomly divided into two intervention groups: traditional diet and modern diet . During the 30 days intervention, every 10 days, food consumption was checked with food recall questionnaire. Finally, birth weight was recorded. Analysis of covariance was used to assess the effect of intervention on birth weight. In all analysis 0.05 was considered as statistical significance level.

Results: Although there was no significant difference between energy, macro and micronutrient intakes (after controlling magnesium intake) there was a significant statistical difference between the two groups in birth weight. The weight gain in the traditional diet group was better ($F = 38.61$; $df = 1$; $p \leq 0.001$) Similarly, the incidence of LBW in this group was significantly less, statistically ($P \leq 0.001$).

Conclusion: The potential of dietary treatment through Iranian traditional (Persian) medicine should be given more attention in helping to solve the challenges of modern medicine as a low-risk and low-cost method.

Key words: traditional persian medicine, birth weight neonates, asymmetric intrauterine growth restriction

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Introduction

Low birth weight (LBW), which refers to weight of a baby under 2500 grams, is one of the most important factors in the mortality and morbidity of neonates [1]. The cause of LBW is either preterm labor, or fetal growth restriction (FGR) or both. It is estimated that the risk of death of a term newborn from 1500 to 1999 is eight times that of infants weight between 2000 and 2999 [2]. Neonates with LBW are more likely than neonates with normal birth weight to have growth disorders and deal with chronic conditions, such as type 2 diabetes, high blood pressure, and other cardiovascular diseases in adolescence [3-5]. According to statistics released by UNICEF in 2000, twenty million infants born weighing less than 2500, account for 15.5% of the total births of 2000 in the world [6]. Given the high incidence of LBW and its complications, this has become a major global health problem [7]. In addition, due to the fact that air pollutants play an important role in the development of LBW and since Tehran is among the most polluted cities in the world, this problem can become a major national challenge [8-10]. The determinant of embryo weighing is its genetic potential, which is affected by maternal, fetal, placental and environmental factors. In order to achieve the maximum growth potential of the fetus, it is important to provide a suitable uterine environment [11]. Prevention of Low birth weight (LBW) is possible by providing a good level of health for mothers before and during the pregnancy particularly adequate nutrition for mothers from pre-pregnancy and during pregnancy [12]. The question is, whether the fetuses with unexplained FGR to be prevented from getting low birth weight through taking pregnancy interventions. According to some meta-analyses, Fetal Growth Restriction (FGR) has occurred when there is low birth weight with unknown cause; there were no interventions such as administration of glucose or amino acids, increased plasma levels, administration of oxygen and low dose aspirin to improve FGR. Even abstaining from smoking and prescribing anti-malarial drugs did not have any effect on the improvement of the condition and normalization of fetal development after the diagnosis of FGR and these factors just a preventive role [13, 14]. Nutritional interventions in mothers without malnutrition also have no effect on FGR and consequently are not effective in preventing the occurrence of LBW in these patients [15-17]. In Iranian traditional (Persian) medicine resources, some foods have been introduced that, regardless of the amount of calories produced, can increase body sizes according to the laws of Iranian medicine [18-21]. In Iranian traditional (Persian) medical clinics these dietary recommendations are recommended to improve the weight gain of fetuses and their mothers [22, 23]. In this study, it was decided to determine the effectiveness of a balanced diet containing recommended foods in the literature of Iranian traditional (Persian) medicine on birth weight of embryos with unexplained asymmetric FGR.

Methods

1. Design

In order to evaluate the efficacy of Iranian (Persian) medicine, a clinical trial was designed with two intervention groups. One group received a diet based on Iranian traditional (Persian) medicine and the second group received a modern medicine regimen. The diet was evaluated on entering the trial and every 10 days by a dietary recall questionnaire, and every five days with telephone call. The birth weight was recorded from the birth information card at the time of delivery.

2. Sample

Singleton pregnant women were selected from a prenatal clinic where their embryos were diagnosed FGR with ultrasound during the third trimester of pregnancy, and if any cause was not diagnosed for the FGR; mothers who did not have chronic disease, such as diabetes or hypertension; and if the BMI of the mothers was 18 to 30 in the pre-pregnancy period; the age of mothers was over 18 years of age; and they had normal Doppler or just umbilical artery resistance and did not have significant oligo-hydramnios, after signing the written consent.

The sample size was calculated using G*power 3.1.9.2 software for analysis of ANCOVA. The errors of the first type (alpha) and the second type (beta) were considered 0.05 and 0.2, respectively. Partial Eta Squared was considered 0.41 as well. Given that in this study, two variables were controlled during the analysis, hence the required sample size was calculated at 32 individuals in each group taking into account 10% of the fall . During the study, 30 patients were in the traditional Iranian diet group and 34 in the classical diet group.

3. Instrument

For diagnosis of FGR, Biometric Ultrasound was used and the weight was estimated using Hadlock formula [24]. According to the Callen criteria, the estimated weight under the 10% growth curve was considered equivalent to FGR [25]. The confidence level for the Hadlock formula has been reported between 0.73 and 0.91 [26]. CRL Ultrasound in the first trimester was used to estimate the fetal age.

Recall questionnaire was used to assess calories, macronutrient and micronutrient intake during intervention. The confidence coefficient of the recall questionnaire is calculated to be 0.58 to 0.74, which is particularly true for women in the adult age range [27].

4. Procedure

The present study was conducted at Akbarabadi Hospital, Tehran, during 8 months from September 2016 until the end of June 2017. The trial plan was registered with IRCT2017011631984N1 (IRCT2017011631984N1) and received from the Afzalipour Ethics Committee (Kerman, Iran) the Code of Ethics. (IR.KMU.AH.REC.1395.60)

Two groups were designed to evaluate the effectiveness of the diet based on Iranian traditional (Persian) medicine.

Mothers were randomly divided into two groups with four blocks. In order to control the socio-economic factors and the effect of fetal sex, the variables of embryo gender and maternal education level were used to block them to ensure their distribution in two groups. One group received a diet based on Iranian traditional (Persian) medicine and another group based on classical nutrition science. They were required to observe the diet for four weeks. The amount and manner of observation was monitored every four to five days by telephone. Every 10 days a food recall was taken. The results of the three recalls were analyzed with Food Processor program and for comparison of amount of calorie, macronutrients and micronutrients; the mean of three recalls was used. Patients were excluded from the study for any bug in Biophysical Profile or NSD, reluctance to continue cooperation, termination of pregnancy during intervention, failure to comply with at least 80% of the diet or hospitalization for any reason.

5. Diet design

In this study, in order to design and modify the pregnant mother's diet, Harris Benedict's formula (proportional to pre-pregnancy weight, height, and age) was used to calculate the amount of energy required for the basal metabolism. The basal energy was multiplied by the activity factor, and the amount of energy needed for pregnant women in the third quarter (452 kcal) were added then the amount of daily needed energy was calculated [28], and finally the amount of energy was divided according to the exchange list among food groups [29].

Food formulations that are supposed to lead to the growth of the body according to the Iranian traditional (Persian) medicine from the five books: Exireazam (in Persian), Quanoon (in Arabic), Moalejateaghili (in Arabic), Sharholasbab (in Arabic) and Tebeakbari (in Persian), were prioritized and selected on the basis of availability, compliance with the current taste of the people, and the lack of risk in pregnancy. The amount of received calorie and macronutrients were the same between the two intervention groups and only the type of foods were different.

6. Statistical analysis

The statistical package for social sciences (SPSS) software version 22 was used for the statistical analysis. Variables were assessed for normality based on the Shapiro-Wilk test. Baseline characteristics of the intervention and control groups were compared using independent-test for continuous variables and chi-square test for categorical variables.

Analysis of covariance (ANCOVA) was used to evaluate whether the means of the birth weight were equal across the treatment groups, while statistically the effects of other continuous variables that are not of primary interest (i.e. gestational age and magnesium intake). 0.05 was considered as statistical significance level.

Result

In the classic diet group (CDG), 44% of the newborns were female and 56% were male. In the traditional diet group (TDG), the number of female and male newborns was equal and there was no statistical difference between two groups in fetal gender.(diagram1)

At the beginning of the study, difference of the mean age of mothers in the two groups was not statistically significant ($p = 0.2$). Also, there were no significant differences in the mean of other variables including maternal weight, pre-pregnancy BMI, gestational age and estimated embryo's weight, but the difference of delivery age was statistically significant between the two groups ($p = 0.014$) (Table 1).

The results of comparing the mean calories and macronutrient intakes and the effective micronutrients in embryo weighing in the two groups showed that there was no significant difference between the two groups during the intervention except in magnesium (Table 2).

Table 3 shows the average birth weight based on the covariance analysis (adjusted according to the gestational age and mean magnesium intake) by the TDG and CDG group. Analysis of covariance shows that the average weight in the TDG group is generally higher than the CDG group (254 g) and the difference of birth weight in the two groups is statistically significant.

Incidence in the TDG and CDG groups was 13.3 and 76.5%, respectively. Regarding the occurrence of LBW, there was a statistically significant difference between the two groups ($P \leq 0.001$).

Discussion

According to the findings of this study, a one-month diet containing foods resulting in growth in accordance with Iranian medical texts led to an increase in the birth weight of newborns with asymmetric FGR during the third trimester of pregnancy and a reduction in the incidence of LBW, which contradicts the findings of articles that resulted in nutritional interventions not reducing the incidence of LBW in mothers without malnutrition [17, 30]. There are, of course, limited articles that have influenced the type of food regardless of the amount of calories in improving the weight gain of the human embryo [31]. For example, in a study in Japan, the foetuses of mothers who had rice and fresh vegetables in their diet was more heavy in comparison with the foetuses of mothers who had breads mostly in their diet [32].

Based on the results of this study and similar studies on the independent effect of the type of food on the development of the fetus, it may be concluded that food in addition to providing calories and nutrients is also effective on the growth mechanism.

There is widespread evidence of placental abnormalities in FGR and today it is reported as a cause of the occurrence

Table 1: Comparison of baseline Mean (SD) of variables in CDG and TDG groups

Group	Gestational age	Delivery date	Maternal weight1	BMI	Age	Fetal weight1
CDG	228.12 ±11.8	264.21±6.13	71.58 ±6.1	23.08± 0.39	27.00 ±5.2	1410±266
TDG	231.57 ±13.1	269.30±9.84	72.28 ±8.6	23.25 ±0.46	28.57 ±4.4	1519± 340.5
P value	0.27	0.014	0.71	0.79	0.20	0.15

Note: CDG: classical diet group; TDG: traditional diet group; BMI: body mass index

Table 2: The Mean (SD) intake of energy, micro and macronutrients during intervention in the intervention groups

group	Carbohydrate	Iron	Magnesium	Protein	Energy	Fat	Folate	Cobalamin
CDG	248 ±30.9	11.5 ±2.8	225 ±31.4	58±10	1925 ±128	80 ±15.1	285 ±73.1	2.1± 0.65
TDG	252±30.7	12±3.2	243±36.2	60±8.5	1962±122	83±11.6	293±53.5	2.2±0.76
P value	0.57	0.36	0.033	0.39	0.25	0.48	0.69	0.44

Note: CDG: classical diet group; TDG: traditional diet group

Table 3: Comparison of Mean (SD) birth weight in the intervention groups after adjustment by the variables of delivery age and magnesium intake

group	Crude	Adjusted*	N
CDG	2383.24±217.65	2441.41±26.93	34
TDG	2761.00±303.64	2695.06±28.80	30

Note: F =38.61; df =1; p=<0.001
*Adjusted by the variables of gestational age and magnesium intake

of no reason asymmetric FGR [11]. The mechanism of the probability of the effect of air pollution on the growth of the embryos is also assumed to be the effect of some contaminants on the growth and blood supply of the placenta [33]. It is assumed that any treatment that can improve the weight of these fetuses will be affected by the improvement of the placental blood supply. The active metabolism of the placenta like hormone secretions, nutrient supply to the fetus and waste material disposal makes the proper function and the size of the placenta vital in the health and well-being of the fetus. And when in the presence of proper food and in the absence of secondary causes of FGR, the birth weight is inadequate, it can be concluded that the transfer of food to the fetus is disturbed through the placenta. Considering that according to the Iranian medicine texts, easy digesting nutritious foods with warm and humid quality (ba keyfiate garm va martoob in Persian) are easy to pass through narrow channels and rapidly absorbed [18, 20, 34]. It may be concluded that in the TDG group type of food and observance of the rules of nourishment in the Iranian (Persian) medicine have led to the improvement of blood supply in the placenta and thus the improvement of nutrient delivery from the mother.

The most important limitation of this study was the lack of access to Doppler ultrasounds, which could be helpful in evaluating the effect of diet on placental perfusion.

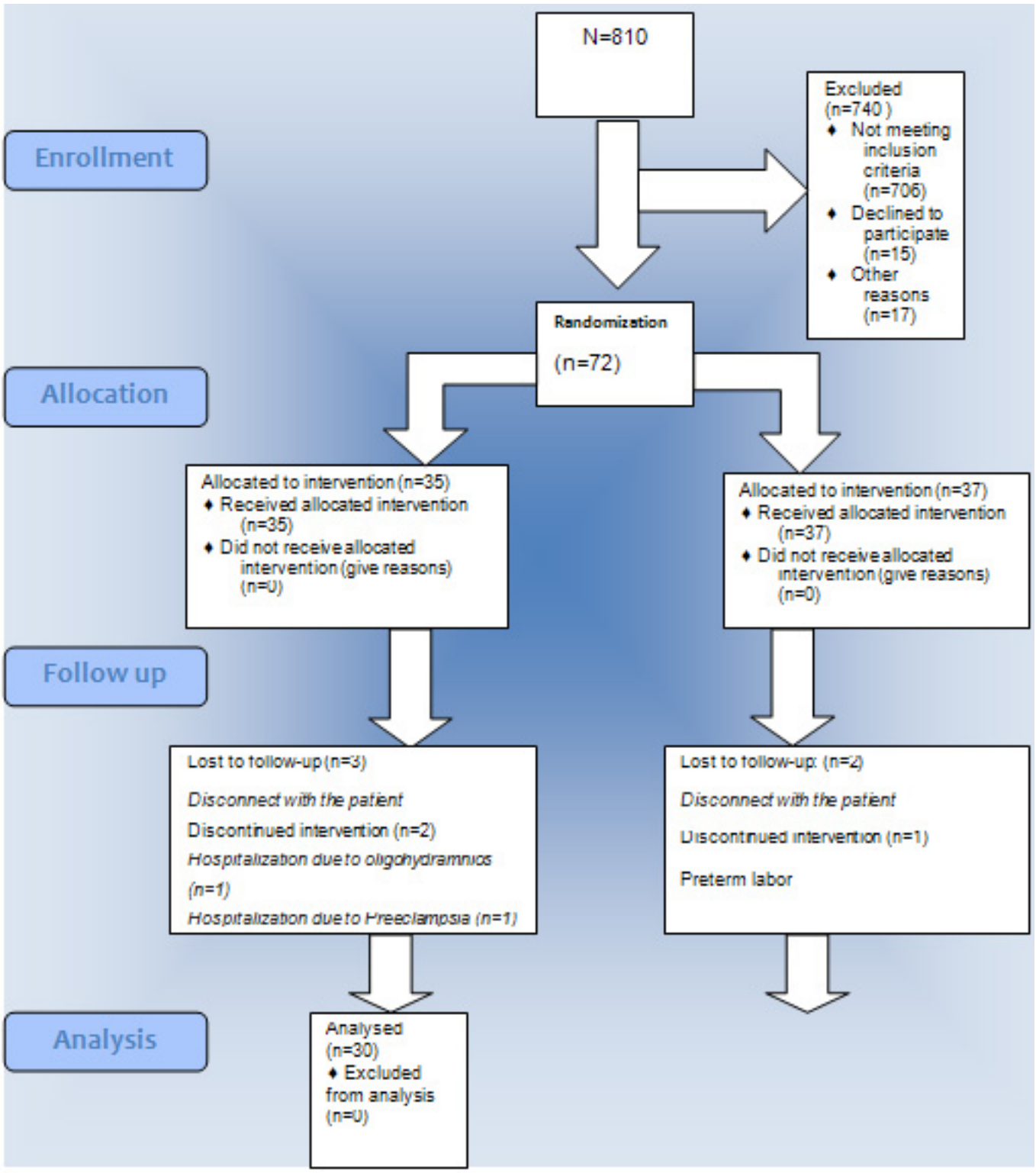
The strong point of this study is that it is the first study on evaluation of the effect of an Iranian (Persian) medicine-based diet on weight gain and birth weight of neonates with FGR.

Finally, reviewers recommend re-evaluation along with a Doppler ultrasound record in order to study the effect of a diet containing warm and humid quality (ba keyfiate garm va martoob in Persian) on embryonic growth.

Conclusion

Considering the importance of LBW in the health of the community and the growing uncontrollable air pollution in large cities as an accepted factor in the incidence of LBW and FGR, using safe and low-cost methods and the potential of complementary medicine along with modern medicine such as in this study can be helpful. The potential of food therapy through the teachings of Iranian (Persian)

Figure 1:


N=810
Excluded
(n=740)
Not meeting inclusion criteria (n=706)
Declined to participate (n=15)
Other reasons (n=17)
Enrollment
Randomization
(n=72)
Allocation
Allocated to intervention (n=35)
Received allocated intervention (n=35)
Did not receive allocated intervention (give reasons) (n=0)
Allocated to intervention (n=37)
Received allocated intervention (n=37)
Did not receive allocated intervention (give reasons) (n=0)
Follow up
Lost to follow-up (n=3)
Disconnect with the patient
Discontinued intervention (n=2)
Hospitalization due to oligohydramnios (n=1)
Hospitalization due to Preeclampsia (n=1)
Lost to follow-up: (n=2)
Disconnect with the patient
Discontinued intervention (n=1)
Preterm labor
Analysis
Analysed
(n=30)
Excluded from analysis (n=0)

medicine along with modern medicine should not be forgotten in helping to solve the challenges of modern medicine.

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Appendices

Figure 2: diet plan based on Persian (Iranian) medicine

Breakfast	*Harire badam**, bread & honey	Rice-milk, bread & honey	Eggs & bread	Butter & carrot/quince jam	*Halim**, sugar & cinnamon	Almonds, bread & honey	Milk-rice & honey
Snack I	Milk & dates	Apple juice	Apple juice	Milk and dates	Milk and dates	Milk and honey	Apple juice
Lunch	Mung, rice& lamb	Lamb Kebab& Bread & & basil	Rice , chicken kebab & olives	*Abgoosht**, bread & basil	Rice with quince & prunes stew	Rice , lamb kebab & basil	Abgoosht*, bread & basil
Snack II	Sweet Pomegranate	Dried Figs & almonds	Almond and raisins	Sweet Pomegranate	Almond	Apple	Sweet Pomegranate
Dinner	Chicken Kebab & bread	Bread & barley soup	Milk-rice & bread	lamb, carrot, green beans & bread	Bread & barley soup	Nargessi* & bread	Chicken kebab & bread
Before sleep	Milk & honey	Milk & honey	Milk & dried figs	Milk	Milk	Milk & dried figs	Milk & honey

Note:
*Harire Badam in Persian language which is a kind of Pudding containing almond and rice floor
*Halim in Persian language which is a kind of supp containing lamb and wheat and ate with sugar and cinnamon
*Abgoosht in Persian language which is a kind of broth containing lamb meat, chick pea, rice, potato spices like cinnamon, turmeric
*Nargessi in Persian language which is a kind of omelets containing cooked spinach with fried egg

Figure 3: diet plan based on classic medicine.

Breakfast	Walnut, bread, cheese, cucumber, tomato	Bred, egg, tomato, milk	Boiled lentils and bread	Bred, egg, tomato	Walnut, bread, cheese, cucumber, tomato	Walnut, bread, cheese, cucumber, tomato	Bread, butter, jam or honey
Snack I	Milk or yogurt	Milk or yogurt	Milk or yogurt	Milk or yogurt	Milk or yogurt	Milk or yogurt	Milk or yogurt
Lunch	Rice, Stew, Green vegetables	Kebab, Rice, Salad salad	*Tahchin**, salad	Rice, Stew, yogurt	Rice , Kebab, yogurt	*Tahchin*, yogurt	Rice, Stew, Salad salad
Snack II	fruit	fruit	fruit	fruit	fruit	fruit	fruit
Dinner	Soup, bread	Soup, bread	Meat cutlet, bread	Meat stew, bread,	Baked beans bread, salad	Bread & chicken	Olivier salad, Tomato, bread
Before sleep	Milk or yogurt	Milk or yogurt	Milk or yogurt	Milk or yogurt	Milk or yogurt	Milk or yogurt	Milk or yogurt

Note:
*Tahchin: Rice cooked with yogurt, egg, meat and saffron