

The Effect of Cognitive-Behavioural Counselling on Pregnant Women's Weight Gain during Pregnancy: A Randomised Controlled Clinical Trial

MAHNAZ FARHODIMOGHADAM¹, SOUSAN HEYDARPOUR², NADER SALARI³, NASRIN JABERGHADERI⁴

ABSTRACT

Introduction: Weight gain during pregnancy has a close relationship with fetomaternal health. An increase in BMI is associated with the risk of premature rupture of membrane, placental abruption and stillbirth. Insufficient weight gain during pregnancy is also associated with small for gestational age, low birth weight and infant mortality, preterm labour, and fetal neural defects.

Aim: To determine the effect of cognitive-behavioural counselling on weight gain in pregnant women.

Materials and Methods: This randomised controlled clinical trial was performed in health centres of Sanandaj, Iran. Sixty-six pregnant women with gestational age of 20-24 weeks were selected and randomly assigned to intervention (n=33)

and control (n=33) groups. The control group received routine care and the intervention group received 8-weekly sessions of 60 to 90 minutes counselling with a cognitive-behavioural approach in addition to routine pregnancy care. The weight of both groups was measured before, immediately and one month after the intervention using Seca Digital Scale. The collected data were analysed using repeated measures, Mann-Whitney U test and independent t-tests.

Results: There was no significant difference in mean weight of mothers between the intervention and control groups before the cognitive-behavioural intervention (p=0.824), immediately after (p=0.905) and one month after intervention (p=0.989).

Conclusion: Cognitive behavioural counselling did not affect the weight gain of mothers during pregnancy.

Keywords: Gestational age, Intervention, Mothers

INTRODUCTION

Obesity is a disease with high mortality and morbidity rates [1]. BMI higher than 25 kg/m² increases the Time to Pregnancy (TTP) [2]. Inappropriate weight before pregnancy leads to abnormal fetal growth, hard and risky labour in the mother [3]. Overweight and obese women are at increased risk of weight loss during pregnancy [4,5]. In 1990's, the American Institute of Medicine approved BMI and recommended specific guidelines for weight gain in healthy pregnancy. In 2009, the American Medical Institute revised the 1990's guidelines for weight gain during pregnancy according to the global epidemic of obesity and demand for a reduction in obesity [6], approved by American Congress of Obstetricians and Gynecologists (ACOG) [7]. Studies in recent years have shown that in general, 35-60% of women from different weight groups exceed the recommended range of weight gain [6]. The American Institute of Medicine has recommended weight gain for pregnant women based on BMI, with a weight gain of 13-18 kg, 11-16 kg, 7-11 kg, and 5-9 kg, respectively, for lean (BMI<18.5), normal (18.5≤BMI<24.9), overweight (25<BMI<29.9) and obese (BMI≥30) women. The maximum weight gain limit per week in the second and third trimesters is 0.5 kg/week for lean women, 0.45 kg/week for those with normal BMI, 0.3 kg/week for overweight women, and 0.2 kg/week for obese women [8].

Maternal weight gain during pregnancy affects prenatal outcomes [9]. Obesity and overweight during pregnancy is associated with maternal complications such as pre-eclampsia, gestational diabetes, cesarean section, instrumental labour, urinary tract infections [10], abnormal fetal presentation [11], uterine atony, placental-acreta, placenta retention [12] premature rupture of membrane, placental decollement, and stillbirth [13]. Also Excessive weight gain during pregnancy is associated with neonatal complications such as asphyxia, hypoglycaemia [14], stillbirth [15], neonatal death [16]

and low appgar score [12]. Insufficient weight gain during pregnancy is also associated with Small for Gestational Age (SGA), low birth weight and infant mortality, preterm labour [7] and fetal neural defects [17]. Research has determined that psychological interventions such as behavioural cognitive approach improve mental health and self-efficacy of overweight or obese women [18,19]. The actual mechanism of the effect of cognitive-behavioural counselling on lifestyle and weight gain of pregnant mothers is to help them identify intellectual errors, irrational and unreasonable beliefs, change the defined thoughts and ineffective behaviours, by organised discussions and behavioural assignments [20]. Asbee SM et al., stated that a dietary and lifestyle counselling did reduce excessive weight gain during Pregnancy [21]. Study of Hui AL et al., showed that "the lifestyle intervention program decreased gestational weight gain in pregnant women, with normal pre-pregnancy Body Mass Index" [22]. So the main study hypothesis was that 8 weekly sessions of 60 to 90 minutes counselling with a cognitive-behavioural approach would result to appropriate gestational weight gain.

MATERIALS AND METHODS

This randomised controlled clinical trial study was performed from February to June 2017, in health centres of Sanandaj, Iran. The sample size was chosen based on Hui AL et al., study [22] and based on the characteristic of gestational weight gain, therefore, using an 90% power and an alpha of 0.05. This required 33 participants in each group to achieve overall statistical significance. Sixty-six pregnant women who met the inclusion criteria were randomly assigned to intervention (n=33) and control (n=33) groups. In this study, simple randomization method was used for random allocation. The inclusion criteria for this study included age over 19, gestational age of 20-24 weeks, education level higher than primary school, wanted pregnancy, no disease or complications associated

with pregnancy (pre-eclampsia, gestational diabetes, history of a child born with IUGR, etc.), singleton pregnancy, no current mental illness, no known fetal disorder, no history of addiction, not using sedatives and not taking neurological drugs, having a BMI in the range of lean, normal, overweight and obese.

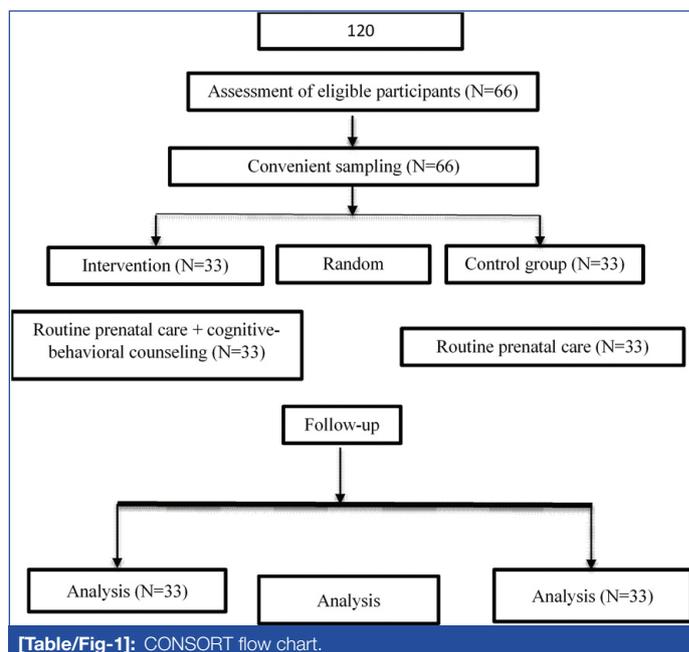
Exclusion criteria were abortion, labour or hospitalisation during the study period, and absence in ≥ 2 sessions. The research was done in the health centres in Sanandaj. Counselling sessions were held by the first author (student of Master's degree in midwifery counselling) and under the supervision of the third author in coordination with members of the intervention group in one of Sanandaj health centres not visited by members of the control group. The control group received routine pregnancy services and care. In addition to routine care, the intervention group received 8 group counselling sessions of 60 to 90 minutes in groups of 11-12 participants with cognitive behavioural approach through discussion, question and answer, free connotation and education every other week. During these meetings, the focus was on cognitive restructuring, transformation and correction of distorted thoughts, and teaching cognitive-behavioural exercises and techniques. After participants were randomly assigned to the groups, they completed demographic characteristics questionnaire.

In this study, maternal weight gain per week was calculated with her BMI, so before the intervention, the mother was weighed and her BMI was calculated. Mothers' weight was measured by the researcher using a calibrated Seca scale (made in Germany) and their height was measured by the height metre of the same scale without shoes. The measurements were performed twice, and then their mean was considered. Participants were weighed with light clothes and without shoes, and the weight in kilograms was divided by height in meters to determine their BMI. Women with $BMI < 18.5$ were considered lean, those with $18.5 \leq BMI < 24.9$ normal, those with $25 < BMI < 29.9$ overweight, and those with $BMI \geq 30$ were considered obese.

To determine the standard weight range for each BMI category, the maximum recommended weight gain per week (0.5 kg/week for the lean group, 0.4 kg/week for the normal weight group, 0.3 kg/week for overweight group, 0.2 kg/week for obese group) [8] was multiplied in the number of weeks of intervention (12 weeks including, 8 weeks intervention and 4 weeks follow-up) so that the standard weighing for each subgroup was obtained for each BMI subgroup (For example standard weighing for the lean group was calculated this way: $0.5 \times 12 = 6$ kg and values above this was considered as over standard weighing and values below this was considered as below standard) [23]. Immediately and one month after the intervention, weight of both groups were measured again.

The content and structure of the sessions were as follows: in the first session participants were introduced and the program was described for them (establishing a therapeutic relationship). In the second session, entitled "Stress Management" the irrational thoughts and beliefs about stressors were evaluated and challenged and stress management techniques were taught. In the third session, entitled "Sports", the irrational thoughts and beliefs about exercise during pregnancy were evaluated, challenged and discussed and suitable exercise for pregnancy was taught. In the fourth and fifth sessions, entitled "nutrition", the irrational thoughts and beliefs about nutrition were evaluated, challenged and correct nutrition during pregnancy was taught. In the sixth session, entitled "sleep and rest", their self-induced thoughts and cognitive disturbances (examining cognition deficits related to sleep and insomnia) were discussed. The seventh session, entitled "Gaining support and existence skills", the irrational thoughts and beliefs about support and existence skills were evaluated (Distinguishing expectations from tasks). In the eighth session a summing up and summary of the lessons learned were held.

Participants were informed of the study objectives and were assured that they could leave the study at any time. Informed consent forms were obtained from all participants and they were assured that their information would remain confidential. Also, the study was conducted by the code IR.KUMS.REC.1395.763, confirmed by the Ethics Committee of Kermanshah University of Medical Sciences, Kermanshah, Iran, and registered in IRCT by the code IRCT2017041014333N72. All the details of selecting, excluding and analysis are given in CONSORT flow chart [Table/Fig-1].



[Table/Fig-1]: CONSORT flow chart.

STATISTICAL ANALYSIS

Independent t-test was used to compare weight gain scores before the intervention between two groups. The repeated measures were used to compare weight gain scores before, immediately after and one month after the intervention, in the intervention and control groups.

Mann-Whitney test was applied to compare BMI before, immediately after and one month after the intervention between two groups.

RESULTS

The results of this study showed that before intervention, the groups were not significantly different in terms of educational level, place of residence, income level, number of pregnancies, mother's occupational status, and BMI [Table/Fig-2]. Results showed that the intervention and control groups had a similar BMI before the intervention and there was no significant difference between the two groups ($p=0.883$). Also, independent t-test results showed that: There was no significant difference in mean weight of mothers before, immediately and one month after the intervention, between two groups [Table/Fig-3]. To investigate BMI between intervention and control groups before intervention, chi-square test was used, the results of which showed that the intervention and the control groups had similar BMI before the intervention and there was no significant difference between the two groups ($p=0.883$) [Table/Fig-4].

The standard weighing scale based on BMI in the intervention and control groups immediately after the intervention is shown in [Table/Fig-5] and one month after the intervention is shown in [Table/Fig-6]. According to [Table/Fig-5], the chi-square test showed that immediately after the intervention, the intervention and control groups were identical in terms of weight range and there was no significant difference between the two groups ($p=0.278$). Also, the results of the chi-square test showed that within one month after the intervention, the intervention and control groups were similar in terms of weight gain and there was no significant difference between the two groups ($p=0.184$).

Variable		Intervention group N=33	Control group N=33	Test type
Mother's age		26.78±4.91	30.09±6.87	Independent t test, p=0.028
Gestational age		22.18±1.44	20.69±1.13	Mann Whitney, p=0.001
Body mass index		26.45±3.89	26.51±4.81	Independent t test, p=0.963
Mother's educational level	Diploma and Under Diploma	24 (72.7)	27 (81.8)	Yates correction, p=0.387
	University	9 (27.3)	6 (18.2)	
Mother's employment status	Housewife	30 (90.9)	28 (84.8)	Exact fisher, p=0.354
	Employed	3 (9.1)	5 (15.2)	
Income	Less than 10 million IRR	20 (60.6)	18 (54.5)	Yates correction, p=0.402
	More than 10 million IRR	13 (39.4)	15 (45.5)	
Gravida	1	23 (69.7)	21 (63.6)	Yates correction, p=0.397
	≥2	10 (30.3)	12 (36.4)	
Place of residence	Urban	28 (84.8)	26 (78.8)	Yates correction, p=0.375
	Rural	5 (15.2)	7 (21.2)	
Husband's education	Diploma and Under Diploma	14 (42.4)	19 (42.4)	Yates correction, p=0.162
	University	19 (57.6)	28 (84.8)	
Husband's job	Employed	27 (81.8)	28 (84.8)	Yates correction, p=0.162
	Others	6 (18.2)	5 (15.2)	

[Table/Fig-2]: Demographic characteristics of pregnant women.

Variable/Time		Before intervention	Immediately after intervention	One month after the intervention	Statistical index (p-value, Chi-square)
		X±SD (Mean rank)	X±SD (Mean rank)	X±SD (Mean rank)	
Weight	Intervention	69.3±9.8 (33.18)	74.2±9.47 (31.18)	75±9.53 (30.73)	p-value=0.001
	Control	68.7±11.58 (33.82)	73.05±11.51 (35.82)	75.03±11.35 (36.27)	
Statistical index		p-value=0.824	p-value=0.905	p-value=0.989	

[Table/Fig-3]: The pregnant women weight in the intervention and control groups before and after the intervention.

Group	Body mass index			p-value	Frequency		p-value	Percent		p-value
	Before intervention				Immediately after intervention			One month after the intervention		
		Frequency	Percent		Frequency	Percent		Frequency	Percent	
Control	Lean	1	3.1	0.946	0	0	0.464	0	0	0.948
	Obese	3	9.1		9	27.3		12	36.4	
	Overweight	14	42.4		14	42.5		13	39.4	
	Normal	15	45.5		10	30.4		8	24.3	
	Total	33	100		33	100		33	100	
Intervention	Lean	2	6.1	0.946	0	0	0.464	0	0	0.948
	Obese	3	9.1		7	3/21		13	39.4	
	Overweight	13	39.4		19	6/57		13	39.4	
	Normal	15	45.5		7	3/21		7	21.3	
	Total	33	100		33	100		33	100	

[Table/Fig-4]: The frequency of body mass index categories in pregnant women in the intervention and control groups before the intervention.

Group	Weight range	Frequency	Percent	Statistical index (z)	p-value
Control	Below standard	5	15.2		
	Standard	8	24.2		
	Higher than standard	20	60.6		
	Total	33	100		
Intervention	Below standard	6	18.2	-1.084	0.278
	Standard	12	36.4		
	Higher than standard	15	45.5		
	Total	33	100		

[Table/Fig-5]: Weight range based on body mass index in participants immediately after intervention.

Group	Weight range	Frequency	Percent	Statistical index (z)	p-value
Control	Below standard	5	15.2		
	Standard	8	24.2		
	Higher than standard	20	60.6		
	Total	33	100		
Intervention	Below standard	6	18.2	-1.084	0.278
	Standard	12	36.4		
	Higher than standard	15	45.5		
	Total	33	100		

[Table/Fig-6]: Weight range based on BMI in participants one month after intervention.

DISCUSSION

In this study, the effect of cognitive-behavioural counselling on weight gain of pregnant women was evaluated, and the results indicated no statistically significant difference between intervention

and control groups immediately after the intervention and one month after intervention. However, in the intervention group, a higher number of women had a standard weight range after intervention.

These results may be due to the small size of the studied population and limited sample size.

On the other hand, education of nutrition and physical activity, given to all pregnant mothers by health care providers and midwives of the health centres according to the Ministry of Health's guidelines, have led to increased awareness of all pregnant women in the control group and this issue may have reduced the impact on intervention.

In the intervention group, 42.4% of the subjects and in the control group 69.7% weighed above the standard range. In the study of Althuisen E et al., four face-to-face counselling intervention, did not affect excessive weight gain during pregnancy [23]. Guelinckx I et al., stated that lifestyle intervention based on a brochure or on active education did not affect gestational weight gain in obese pregnant women [24]. According to Ronnberg A et al., the low-cost intervention programme did not reduce the percentage of women gaining weight above the Institute of Medicine recommendations (IMO) on gestational weight gain [25].

Contrary to the present results, some studies have shown that counselling have positive effects on weight gain of pregnant women during pregnancy [22,26,27]. Asbee SM et al., stated that a dietary and lifestyle counselling did reduce excessive weight gain during Pregnancy [21]. According to Gesell SB, "a community-based cognitive-behavioural lifestyle intervention during pregnancy was feasible in a hard-to-reach, high-risk population of low-income Latina women, and showed efficacy in preventing excessive gestational weight gain" [28]. Study of Hui AL et al., showed that "the lifestyle intervention program decreased gestational weight gain in pregnant women, with normal pre-pregnancy BMI but not above normal" [22]. According to Peaceman AM et al., behavioural lifestyle interventions focusing primarily on diet and physical activity among women with overweight and obesity resulted in a significantly lower proportion of women with excess gestational weight gain [29]. Although the present study and other studies mentioned above have been designed to encourage pregnant women to have weight gain within the IMO but they got different results which are possibly related to the response of the pregnant women to counselling. Also, the methodology of study can affect the results. In the Hui AL et al., study [22], a food choice map software which has been proved to be a valid tool for assessing dietary intake was used [30] and participants received a logbook on their exercise activities as a motivator for exercise and participants who attended less than three times at the group exercise or did not complete the logbook were excluded. In this study exercise intervention was a combination of exercise at home and group exercise.

LIMITATION

The study was limited to short-term follow-up, using a self-report tool and sample size, which may influence the generalisation of the results.

CONCLUSION

The results of the study indicated no effect of cognitive-behavioural counselling on weight gain of pregnant women. Therefore, it is suggested that studies should be done for weight gain of pregnant women.

ACKNOWLEDGEMENTS

The present study is the result of a research project with the number 96077 at Kermanshah University of Medical Sciences and is the part of the master's degree dissertation in midwifery counselling. Researchers appreciate the deputy chairman of the Research Committee of Kermanshah University of Medical Sciences who sponsored this project. The colleagues working in the health care centres of Sanandaj and the pregnant mothers participating in this research are sincerely appreciated.

REFERENCES

- [1] World Health Organisation (WHO). Global Health Observatory (GHO) data. Obesity, situation and trends. 2009. [cited 2015 Accessed 28 Sep].
- [2] Heydarpour F, Mohammad K, Heydarpour S, Najafi F, Holakouie Naieni K. Factors affecting time to pregnancy, Kermanshah, Iran, 2011. *Journal of School of Public Health and Institute of Public Health Research*. 2013;10(3):77-90.(persian)
- [3] People Total fertility rate: Countries Compared [Internet]. 1381 [cited 2016 Sep 19].
- [4] Reynolds R, Osmond C, Phillips D, Godfrey K. Maternal BMI, parity, and pregnancy weight gain: influences on offspring adiposity in young adulthood. *The Journal of Clinical Endocrinology & Metabolism*. 2010;95(12):5365-69.
- [5] Crozier SR, Inskip HM, Godfrey KM, Cooper C, Harvey NC, Cole ZA, et al. Weight gain in pregnancy and childhood body composition: findings from the Southampton Women's Survey. *The American journal of clinical nutrition*. 2010;91(6):1745-51.
- [6] IOM (Institute of Medicine). *Io. Nutrition During Pregnancy. Part I, Weight Gain; Part II, Nutrient Supplements*. 1990. [Accessed 11 ebruary 2014].
- [7] National Research Council. *Weight gain during pregnancy: Reexamining the guidelines*. 2009. [www.nap.edu/catalog.php? record_id=12584]. Accessed 11 February 2014.
- [8] Bloom SL, Corton MM, Spong CY, Dashe JS, Leveno KJ. *Williams Obstetrics 24/E: McGraw-Hill Education*; 2014.
- [9] Arrish J, Yeatman H, Williamson M. Midwives and nutrition education during pregnancy: A literature review. *Women and Birth*. 2014;27(1):02-08.
- [10] Ebadi M, Rahmanian F. The Assessment of Relationship between Excessive Weight Gain and Urinary Tract Infection in Pregnant Women-Larestan-1387-88. *Journal of Microbial World*. 2009;2(3):177-82.
- [11] Persson M, Johansson S, Villamor E, Cnattingius S. Maternal overweight and obesity and risks of severe birth-asphyxia-related complications in term infants: a population-based cohort study in Sweden. *PLoS Medicine*. 2014;11(5):e1001648.
- [12] Nana P, Wandji J, Fomulu J, Mbu R, Tonye R, Ako S, et al. Materno-foetal outcome of labour in obese women in Yaounde, Cameroon. *Clinics in Mother and Child Health*. 2009;6(1).
- [13] Liu X, Du J, Wang G, Chen Z, Wang W, Xi Q. Effect of pre-pregnancy body mass index on adverse pregnancy outcome in north of China. *Archives of Gynecology and Obstetrics*. 2011;283(1):65-70.
- [14] Han Y, Ha E, Park H, Kim Y, Lee S. Relationships between pregnancy outcomes, biochemical markers and pre-pregnancy body mass index. *International Journal of Obesity*. 2011;35(4):570-77.
- [15] Chu S, Kim S, Schmid C, Dietz P, Callaghan W, Lau J, et al. Maternal obesity and risk of cesarean delivery: a meta-analysis. *Obesity Reviews*. 2007;8(5):385-94.
- [16] Kristensen J, Vestergaard M, Wisborg K, Kesmodel U, Secher NJ. Pre-pregnancy weight and the risk of stillbirth and neonatal death. *BJOG: An International Journal of Obstetrics & Gynaecology*. 2005;112(4):403-08.
- [17] Evenson KR, Bradley CB. Beliefs about exercise and physical activity among pregnant women. *Patient Education and Counselling*. 2010;79(1):124-29.
- [18] Estanely H, Beto J, Deyo R. Cognitive-behavioural therapy in self-efficacy and mental health on weighting of women's. *J Contemporary Res Business*. 2012;3:267-73.
- [19] Valutis S, Goreczny A, Wister J, Newton H, Popp S, Vavrek J. Relationships among coping, weight preoccupation, and body image in college undergraduates. *Journal of Psychiatry, Psychology and Mental Health*. 2008;8(01):01-11.
- [20] Howton K. *Cognitive Behaviour Therapy for Psychiatric Problems: A Practical Guide*. Oxford University Press, 1989.
- [21] Asbee SM, Jenkins TR, Butler JR, White J, Elliot M, Rutledge A. Preventing excessive weight gain during pregnancy through dietary and lifestyle counselling: a randomized controlled trial. *Obstet Gynecol*. 2009;113(2 Pt 1):305-12.
- [22] Hui AL, Jiang D, Sellers E, Shen GX, Sevenhuysen G, Dean HJ, et al. Effects of lifestyle intervention on dietary intake, physical activity level, and gestational weight gain in pregnant women with different pre-pregnancy body mass index in a randomized control trial. *BMC Pregnancy and Childbirth*. 2014;14(1):331.
- [23] Althuisen E, Van Der Wijden C, Van Mechelen W, Seidell J, Van Poppel M. The effect of a counselling intervention on weight changes during and after pregnancy: a randomised trial. *BJOG: An International Journal of Obstetrics & Gynaecology*. 2013;120(1):92-99.
- [24] Guelinckx I, Devlieger R, Mullie P, Vansant G. Effect of lifestyle intervention on dietary habits, physical activity, and gestational weight gain in obese pregnant women: a randomized controlled trial-. *The American journal of clinical nutrition*. 2009;91(2):373-80.
- [25] Ronnberg A, Ostlund I, Fadl H, Gottvall T, Nilsson K. Intervention during pregnancy to reduce excessive gestational weight gain-a randomised controlled trial. *BJOG: An International Journal of Obstetrics & Gynaecology*. 2015;122(4):537-44.
- [26] Herring SJ, Cruice JF, Bennett GG, Rose MZ, Davey A, Foster GD. Preventing excessive gestational weight gain among African American women: A randomized clinical trial. *Obesity*. 2016;24(1):30-36.
- [27] Aşçı Ö, Rathfisch G. Effect of lifestyle interventions of pregnant women on their dietary habits, lifestyle behaviours, and weight gain: a randomized controlled trial. *Journal of Health, Population and Nutrition*. 2016;35(1):7.
- [28] Gesell SB, Katula JA, Strickland C, Vitols MZ. Feasibility and Initial Efficacy Evaluation of a Community-Based Cognitive-Behavioural Lifestyle Intervention to Prevent Excessive Weight Gain During Pregnancy in Latina Women. *Matern Child Health J*. 2015;19(8):1842-52.

- [29] Peaceman AM, Rebecca G, Clifton RG, Phelan S, Gallagher D, Evans M. Lifestyle interventions limit gestational weight gain in women with overweight or obesity: LIFE-Moms Prospective Meta-Analysis. *Obesity*. 2018;26:1396-404.
- [30] Sevenhuysen GP, Gross U. Documenting the reasons people have for choosing their food. *Asia Pac J Clin Nutr*. 2003;12:30-37.

PARTICULARS OF CONTRIBUTORS:

1. Student, Student Research Committee, Kermanshah University of Medical Sciences, Kermanshah, Iran.
2. Department of Midwifery, Faculty of Nursing and Midwifery, Kermanshah University of Medical Sciences, Kermanshah, Iran.
3. Department of Biostatistics, Faculty of Public Health, Kermanshah University of Medical Sciences, Kermanshah, Iran.
4. Department of Psychiatry, Faculty of Medicine, Kermanshah University of Medical Sciences, Kermanshah, Iran.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:

Sousan Heydarpour,
Department of Midwifery, Faculty of Nursing and Midwifery, Kermanshah University of Medical Sciences, Kermanshah, Iran.
E-mail: s.heydarpour1394@yahoo.com

Date of Submission: **Aug 18, 2018**

Date of Peer Review: **Oct 03, 2018**

Date of Acceptance: **Jan 04, 2019**

Date of Publishing: **Aug 01, 2019**

FINANCIAL OR OTHER COMPETING INTERESTS: As declared above.