EFFECTS OF DIETARY COUNSELING ON GESTATIONAL WEIGHT GAIN AND PREGNANCY OUTCOMES IN OBESE PREGNANT WOMEN

PROSPECTIVE RANDOMISED CONTROLLED TRIAL

IN HOSPITAL SULTANAH BAHIYAH, ALOR SETAR, KEDAH

(DEC 2013 – DEC2014)

BY

DR SHARIFA AZLIN BINTI HAMID

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To all women who have problem with weight gain in pregnancy

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“In the name of Allah, The Most Gracious, The Most Merciful”

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LIST OF ABBREVIATIONS

BMI	Body Mass Index
kg	kilogram
m	meter
WHO	World Health Organization
IOM	Institute Of Medicine
NMRR	National Medical Research Register
LMP	Last Menstrual Period
GWG	Gestational Weight Gain
GDM	Gestational Diabetes Mellitus
PIH	Pregnancy Induced Hypertension
PE	Pre Eclampsia
LGA	Large for Gestational Age
PPH	Post Partum Haemorrhage
IOL	Induction Of Labour
A'S	Apgar Score
SVD	Spontaneous Vertex Delivery
LSCS	Lower Segment Caesarean Section
MOGTT	Modified Oral Glucose Tolerance Test
RCT	Randomized Controlled Trial
HSB	Hospital Sultanah Bahiyah
HUSM	Hospital Universiti Sains Malaysia
O&G	Obstetrics and Gynaecology
CMR	Close Monitoring Room
PAC	Patient Assessment Center
OT	Operation Theatre
EPAU	Early Pregnancy Assessment Unit

ANC	Antenatal Clinic
MFM	Maternal Fetal Medicine
ART	Assisted Reproductive Technology
OSCC	One Stop Crisis Center
IVF/ICSI	In Vitro Fertilization / Intra Cytoplasmic Semen Insemination
SPSS	Statistical Package for the Social Sciences
SD	Standard Deviation
OR	Odds Ratio
CI	Confidence Interval
n	number
df	degree of freedom
%	Percents
<	less than
>	more than

ABSTRACT (ENGLISH VERSION)

Objective

To evaluate the effects of dietary counseling in obese pregnant women on gestational weight gain and pregnancy outcomes

Methods

This was a prospective randomized controlled trial, commenced on the 1st December 2013 and ended on the 30th December 2014. It was carried out in Hospital Sultanah Bahiyah, Alor Setar, Kedah.There were 120 patients with obesity Class I,II and III recruited in this study, equally randomised into two groups; obese patients in intervention group with dietary counseling and control group with routine prenatal care group.The intervention group received dietary counseling from the only one dedicated nutritionist for at least once in each trimester of pregnancy. The main dietary counseling remains on diet and caloric restriction. The main outcome measured was the mean difference of gestational weight gain between two groups. Secondary outcomes included maternal outcome such as incidence of Gestational Diabetes Mellitus,Pregnancy Induced Hypertension,Pre Eclampsia, mode of delivery, Post Partum Haemorrhage; and fetal outcomes included mean gestational age, mean birth weight, shoulder dystocia and Apgar Score.

Results

A total of 120 women were randomized into two groups of 60, the dietary counseling and routine prenatal care groups. Baseline demographic characteristics were similar between the

EFFECTS OF DIETARY COUNSELING ON GESTATIONAL WEIGHT GAIN AND PREGNANCY OUTCOMES IN OBESE PREGNANT WOMEN PROSPECTIVE RANDOMISED CONTROLLED TRIAL IN HOSPITAL SULTANAH BAHIYAH, ALOR SETAR, KEDAH

Dr Sharifa Azlin Hamid

MMed Obstetrics and Gynaecology

Department of Obstetrics and Gynaecology

School of Medical Sciences, Universiti Sains Malaysia

Health Campus, 16150 Kelantan, Malaysia

Introduction: Obesity is a serious and increasing health problem in the Western World and also in Malaysia. Prevalence of obesity in Malaysia is 7.5% and estimated prevalence of obesity in women in Malaysia was 16.6%. The numbers keep increasing each year and it gives a significant impact to the reproductive age women. Obese women who get pregnant carried higher maternal morbidity and perinatal morbidity and mortality. Pregnancy complications such as Gestational Diabetes Mellitus(GDM), Pre-Eclampsia(PE), Caeserean Section, infections and thromboembolic disease significantly associated with obese mother.

Observational studies indicate that the rate of pregnancy complications among obese pregnant women can be limited if weight gain during pregnancy is restricted. Heavier women may benefit from avoiding high and very high gestational weight gain (GWG), which brings only a slight increase in the risk of growth restriction for the infant.On recent data, especially in Asian

population, there is no evidence-based prenatal counseling protocol available to prevent excessive gestational weight gain.

Objective: To evaluate the effects of dietary counseling in obese pregnant women on gestational weight gain and pregnancy outcomes in Hospital Sultanah Bahiyah, Alor Setar, Kedah

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Results: A total of 120 women were randomized into two groups of 60, the dietary counseling and routine prenatal care groups. Baseline demographic characteristics were similar between the study groups. The dietary counseling group gained significantly less gestational weight gain than did the routine prenatal care group 7.6 kg (SD 1.54) compared with 9.1kg (SD 1.86), $p<0.001$ with 95% CI: 0.83-2.07. In a multiple logistic regression, statistically significant variables in the maternal outcome include gestational age, GDM and spontaneous labour. Fetal outcome with significant variables include Apgar score in 1 minute, 5 minutes, 10 minutes and diagnosis of pneumonia.

Conclusions: The study shows dietary counseling in obese pregnant women has significant benefit in reducing gestational weight gain and improving pregnancy outcomes in maternal side such as prolonged gestational age of delivery, reducing occurrence of GDM and higher proportion goes into spontaneous labour. Fetal outcomes also significantly improved in term of Apgar Score and reducing number of fetus develop pneumonia.

Prof Dr Mohd. Shukri Othman: Supervisor

Dr Ahmad Amir Ismail: Co-Supervisor

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ABSTRAK (BAHASA MELAYU)

Objektif

Untuk memastikan samada kaunseling pemakanan dalam wanita hamil yang mengalami masalah obesiti memberi kesan terhadap pertambahan berat badan semasa hamil dan hasil kehamilan.

Kaedah

Kajian perbandingan secara prospektif dan rawak ini telah dilaksanakan pada 1hb Disember 2013 dan berakhir pada 30hb Disember 2014. Kajian ini telah dijalankan di Hospital Sultanah Bahiyah, Alor Setar, Kedah.Seramai 120 orang pesakit dengan julat Jisim Badan obesiti ; Kelas I,II and III dipilih dalam kajian ini secara sama dan rawak kepada dua kumpulan ; ibu hamil yang yang menerima kaunseling pemakanan dan dalam kumpulan kawalan dengan rawatan susulan biasa.Ibu hamil yang obese mendapat diet kaunseling daripada hanya seorang pakar nutrisi sekurang-kurangnya sekali dalam setiap semester kehamilan. Kaunseling pemakanan yang utama adalah tentang pemakanan dan penyekatan kalori. Hasil utama yang diukur adalah perkadaran pesakit yang pertambahan berat badan semasa hamil adalah dalam saranan panduan dari Institute of Medicine(IOM). Hasil kedua yang diukur adalah komplikasi pada ibu seperti kejadian kencing manis, darah tinggi, cara kelahiran dan pendarahan selepas bersalin. Keadaan bayi juga dianalisa seperti usia kandungan, purata berat semasa lahir, ‘dystocia’ bahu dan Skor Apgar.

Keputusan

Secara keseluruhannya, 120 ibu hamil yang mengalami masalah obesiti secara rawak telah dibahagikan kepada dua kumpulan dalam kajian ini iaitu 60 orang pesakit menerima kaunseling pemakanan dan 60 orang lagi menerima rawatan susulan biasa. Ciri-ciri

demografi adalah sama dalam setiap kumpulan. Kumpulan yang menerima kaunseling pemakanan menunjukkan pertambahan berat badan yang sedikit berbanding kumpulan rawatan secara biasa (7.6 kg (SD 1.54) berbanding 9.1kg (SD 1.86), $p<0.001$) dengan 95% CI 0.83-2.07. Dalam 'multiple logistic regression' analisa, didapati terdapat hasil yang signifikan secara statistik untuk keadaan ibu seperti usia kehamilan, perkadaran kencing manis semasa hamil dan proses kelahiran spontan. Bagi keadaan bayi pula, terdapat signifikan secara statistik pada Skor Apgar dalam 1 minit, 5 minit, 10 minit dan jumlah bayi yang mendapat diagnosa radang paru-paru.

Kesimpulan

Kajian ini menunjukkan bahawa kaunseling pemakanan kepada wanita hamil yang mengalami masalah obesiti dapat mengurangkan peningkatan berat badan semasa hamil dan memberi kesan baik kepada ibu seperti usia kehamilan yang lebih panjang semasa bersalin, kadar kencing manis semasa hamil yang berkurang dan proses kelahiran spontan yang tinggi. Bayi pula mempunyai Skor Apgar yang baik dan jumlah yang mendapat diagnosa radang paru-paru yang sedikit.

1.0 INTRODUCTION

1.1 Obesity, gestational weight gain & pregnancy outcomes –an overview

Obesity is a serious and increasing health problem in the Western World and also in Malaysia. Prevalence of obesity in Malaysia is 7.5% by Khoo et al, 2000. Rampal et alin 2007 estimated prevalence of obesity in women in Malaysia was 16.6%. The numbers keep increasing each year and it gives a significant impact to the reproductive age women. Obese women who get pregnant carried higher maternal morbidity and perinatal morbidity and mortality. Pregnancy complications such as Gestational Diabetes Mellitus(GDM), Pre-Eclampsia(PE), macrosomic fetus, Caeserean Section, infections and thromboembolic disease significantly associated with obese mother.

Observational studies indicate that the rate of pregnancy complications among obese pregnant women can be limited if weight gain during pregnancy is restricted.Heavier women may benefit from avoiding high and very high gestational weight gain (GWG), which brings only a slight increase in the risk of growth restriction for the infant(Nohr *et al.*, 2008).On recent data, especially in Asian population, there is no evidence-based prenatal counseling protocol available to prevent excessive gestational weight gain.

Excessive gestational weight gain is common with about one third of women gaining more weight in pregnancy than what is recommended. Unfortunately, the prevalence of excessive gestational weight gain is increasing. Gestational weight gain greater than that recommended by the Institute of Medicine (IOM) is associated with increased risk of gestational complications (hypertension, diabetes, and preeclampsia), macrosomic fetus and

complications in delivery including increased risk of cesarean delivery(Rasmussen *et al.*, 2010).Mamun A.A 2011 suggests that excess GWG as another indicator of adverse pregnancy outcomes.

Dennedy et al(2011)reported that management of diet, gestational diabetes and gestational and inter-gestational weight may improve outcomes in women who are obese during pregnancy. There is not enough evidence to recommend any intervention for preventing excessive weight gain during pregnancy, due to the significant methodological limitations of included studies and the small observed effect sizes(Muktabhant *et al.*, 2012).

In one recent systemic review and meta-analysis by Eugene Oteng-Ntim et al, 2012 concluded that antenatal lifestyle intervention is associated with restricted gestational weight gain and a trend towards a reduced prevalence of gestational diabetes in the overweight and obese population. These findings need to be interpreted with caution as the available studies were of poor to medium quality.

There are only eight randomized controlled trials on dietary counseling and their cumulative results showed that dietary counseling more effective in reducing the risk of GDM, however the data was not statistically significant (Oostdam N *et al* 2012). Data on other interventions such as behavioral therapy, recurrent Motivational Interviewing(MI)and prescribing physical activities / aerobic exercise were very sparse and only one small RCT, one observational study and one retrospective study in which yielding conflicting results (Phelan *et al.*, 2011).

Aim of this trial is to study the effect of dietary counseling in achieving recommended gestational weight gain by IOM and reducing adverse pregnancy outcomes among obese parturients in Hospital SultanahBahiyah, Kedah, Malaysia.

For the purpose of this study the following definitions are used (Viswanathan *et al.*, 2008).

1. **Gestational weight gain** was classified according to the new Institute of Medicine Gestational Weight Gain Guideline 2009 -Increament of body weight from that measured at first prenatal visit (at baseline) to last body weight measurement before delivery with precision of 0.5kg
2. **Obesity** was classified using WHO classifications with BMI> or equal to 30 kg/m^2
3. **Gestational Diabetes Mellitus -** carbohydrate intolerance resulting in hyperglycaemia with onset or first recognition during pregnancy.
4. **Infant macrosomia -** infant birthweight>4.0 kg

The article from newspaper quoting statement made by our Minister of Health -Datuk Seri Liow Tiong Lai. He mentioned that 16.8 million Malaysians are suffering from obesity which is “kegemukan” and from these 8.4% are categorized as obese. Adapted from Kosmo newspaper 16/11/2010.

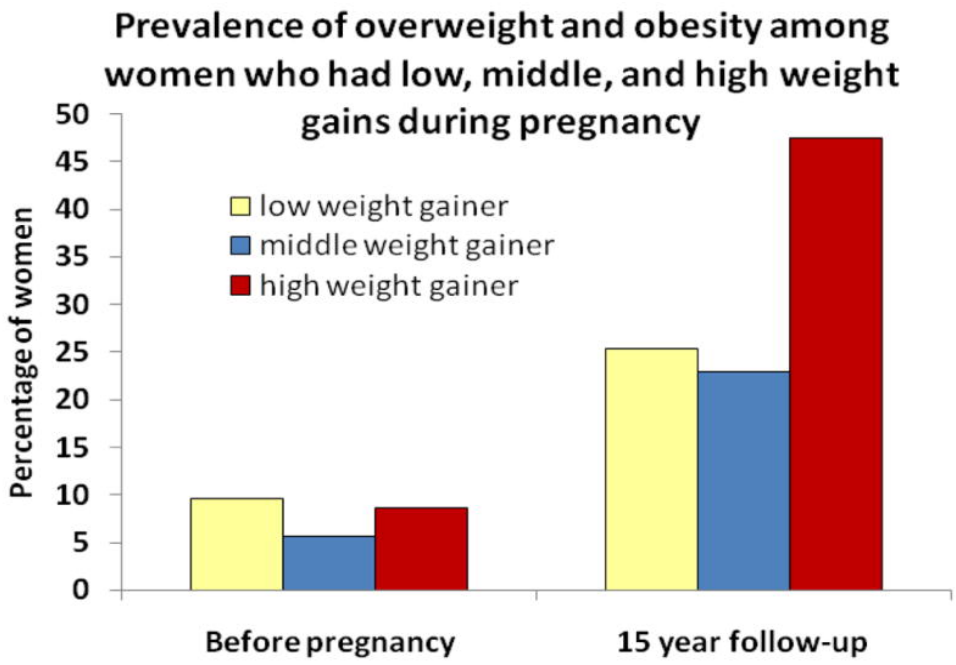

Figure 1 Prevalence of overweight and obesity among woman who had low, middle and high weight gains during pregnancy(Guelinckx,2010).

The above table by Guelinckx et al (2010)demostrate the 15 year follow up of different weight gainer in pregnancy. Significant increase in weight gain after 15 years noted in group with excessive weight gainer during pregnancy. Thus, this will give more implications to future pregnancy itself. In recent study by Crane J.M, 2009 stated that by restricted gestational weight gain to advisable recommendation will save 6400 obese pregnant women from adverse pregnancy outcome.

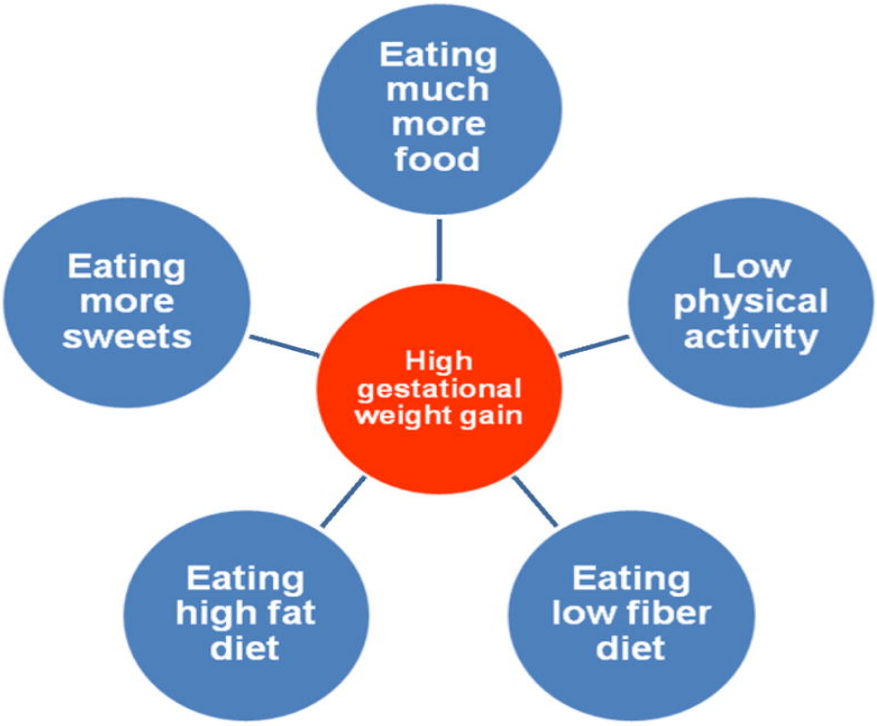

Figure 2 Factors affecting high gestational weight gain(Guelinckx *et al.*, 2010).

The above schematic mapping illustrated the factors influence high gestational weight gain. Noted most of the causes depend on dietary management. Thus, comprehensive and systematic dietary management includes all aspects of food intake and dedicated patients are indeed important factors in achieving recommended gestational weight gain.

1.2 Introduction To The State Of Kedah

State of Kedah also known by its honorific, Darul Amanor "Abode of Peace" is a state of Malaysia. It is located in the northwestern part of Peninsular Malaysia. It consists of the mainland and Langkawi. The mainland has a relatively flat terrain, which is used to grow rice. Langkawi is an archipelago of islands, most of which are uninhabited. Kedah was called Kadaram by ancient and medieval Tamil people and Syburiby the Siamese when it was under their influence.

Kedah borders the state of Perlis to the north and shares an international boundary with the Songkhla and Yala provinces of Thailand. It borders the states of Perak to the south and Penang to the southwest.

The state's capital is Alor Setar and the royal seat is in Anak Bukit. Other major towns include Sungai Petani, and Kulim on the mainland, and Kuah on Langkawi.

Kedah is the 8th largest state by land area and 8th most populated state in Malaysia, with a total land area of 9,500 km^2 (3,700 sq mi) and a population of 1,890,098. Kedah has a relatively heterogeneous population constituted by the three major ethnic groups; the Malays, Chinese and Indians, similar to most of the other Malaysian states. Kedah is considered the "rice bowl" (*Jelapang Padi*) of Malaysia, accounting for about half of Malaysia's total production of rice. In 2008, the state government banned the conversion of paddy fields to housing and industrial lots to protect the rice industry.Tourism, particularly on the island of Langkawi is of growing importance.

1.3 The Department Of Obstetrics And Gynaecology, Hospital Sultanah Bahiyah (HSB), Alor Setar, Kedah

Hospital SultanahBahiyah (HSB) is a new building officially operated in 2008 located at Jalan Langgar, AlorSetar Kedah. It is a tertiary center for northen region; received a referral from whole Malaysia especially from Kedah, Perlis, Perak and Penang. Obstetrics and Gynaecology (O & G) Department is one of the branches in HSB that provides various fields of managing women's health. HSB also fully computerized hospital in which data of patients will be key in e-HIS system.

There are 4 subspecialities in O & G Department; Reproductive and Fertility Unit, Gynae-Oncology Unit, Maternal Fetal Medicine Unit and Urogynaecology Unit.O&G Department consist of 3 consultants, 12 specialists, 20 Medical Officers and House Officer training.We have one labour room suite (13 beds), CMR (5 beds), 3 antenatal + postnatal wards (2A,2C,2D) with 36 beds/ward, 1 gynae / gynae-onco ward with 36 beds, 1 PAC with 8 beds, 2 Maternity OT (1 for elective cases , 1 emergency / IVF cases) and specialists clinics.

Total number of deliveries in HSB kept increasing each year for the past 4 years, approximately 900-1000 deliveries per months.

2008 :10,235 deliveries 2009 :10,847

2010 :10,894 2011 :11,385

2012 : 12,403

Table 1 Daily Activities- Specialists Clinics Obstetrics & Gynaecology Department, Hospital Sultanah Bahiyah

Day	**8.00 am-1.00 noon**	**1.00-2.00 pm**	**2.00 pm-5.00 pm**
Sunday	• Menopause / HRT Clinic • MFM Clinic • OSCC(once per month) • IVF/ICSI Gynae OT	R	• **EPAU Clinic** • Obstetric audit
Monday	• General Gynae • Gynae Cancer Clinic • UroGynae • MFM Clinic • ART Clinic • IVF/ICSI	E	• Dept Meeting(1st week every month) • Gynae Oncology(PM) • Pre-op discussion
Tuesday	• **Antenatal Clinic** • Combine Clinic (2x per month) • MFM Clinic • ART Clinic • Gynae Cancer Clinic • Urogynae • IVF/ICSI	H	• **EPAU Clinic** • Colposcopy • Obstetric audit • Gynae Oncology(PM)
Wednesday	• Infertility Clinic • ART Clinic • MFM Clinic • Postnatal Clinic • Gynae OT, IVF/ICSI	A	• **EPAU Clinic** • Pre Pregnancy Clinic (Twice Per-Month) • HO teaching
Thursday	• **Antenatal Clinic** • MFM Clinic • Menstrual Disorder Clinic (MDC) • Molar/DVCC Clinic • IVF/ICSI Tumour Board Meeting	T	• Obstetric audit • Essay writing (Master students)

Table 2 Antenatal Clinic Outpatients (New Case / Follow Up) Statistics O&G Clinic HSB 2009 -2012

MONTHS	2009	2010	2011	2012
TOTAL	5969	5383	5378	5420

Table 3 EPAU Clinic (First Visit And Follow Up Statistics In O&G HSB 2009 -2012)

2009		2010		2011		2012	
First Visit	Follow Up	First Visit	Follow Up	First Visit	Follow Up	First Visit	Follow Up
948	611	1037	827	1156	2000	860	947

2.0 LITERATURE REVIEW

Gestational weight gain during pregnancy still a controversial issue since different country and ethnicity had their own special characteristics towards weight gain. In 2009, the Institute of Medicine (IOM) of the National Academy of Sciences published a revised recommendations on gestational weight gain (GWG) during pregnancy and highlighted major gaps in knowledge, including lack of understanding of the extent to which GWG guidelines should vary among subgroups of women. In recent study by Maamun A.A (2011) committed that excess GWG as one of independent indicator for adverse pregnancy outcomes.

Viswanathan M et al (2008) systematically reviewed studies on outcomes of maternal weight gain from 1990 to 2007 in which they found strong evidence supported an association between gestational weight gains and the following outcomes: preterm birth, total birthweight, low birthweight (<2500 g), macrosomia, large-for-gestational-age (LGA) infants, and small-for-gestational-age infants; moderate evidence supported an association for cesarean delivery and intermediate-term weight retention (3 months to 3 years postpartum).

During the 20th century, recommendations for maternal weight gain in pregnancy were controversial, ranging from rigid restriction to encouragement of ample gain.For more than 20 years, it has been recognized that optimal GWG varies by prepregnancy body mass index (BMI; weight (kg)/height $(m)^2$) , yet very little is known about other maternal factors.

Carmichael S.L and Abram B (1997) reviewed 13 studies in which eleven studies reported a significant association between maternal weight gain and risk of preterm delivery, and most reported that inadequate rate of maternal weight gain was associated with an increased risk (approximately 50-100%) of preterm delivery. Studies examining pattern of gain noted that a

low rate of gain during the latter part of pregnancy (but not early pregnancy) was associated with an increased risk of preterm delivery (also approximately 50-100%).

Abrams et al (2000) in systemic review of all observational studies showed that pregnancy weight gain within the IOM's recommended ranges is associated with the best outcome for both mothers and infants. However, weight gain in most pregnant women is not within the IOM's ranges. Thus, an experimental data are required for better understanding of good gestational weight gain in pregnancy.

However, in this study we only focused on obesity subgroup in achieving recommended gestational weight gain by IOM 2009. Since, obesity is a chronic and pandemic disease worldwide including Malaysia, this group of women need careful intervention to reduce adverse pregnancy outcomes carried by both obesity and excessive gestational weight gain.Prevalence of obesity in Malaysia is 7.5% by Khoo et al, 2000. Rampal et al in 2007 estimated prevalence of obesity in women in Malaysia was 16.6%.

Being obese pregnant women, theycarry a higher maternal morbidity and perinatal morbidity and mortality. These obesity-related health issues extend to pregnancy where they are responsible for producing a variety of medical and obstetric complications resulting in an increased incidence of maternal and fetal adverse outcomes (Dennedy and Dunne, 2010). One local case control study in Alor Gajah, Malacca, in 30 antenatal mother recruited, there were statistically significant obese women and housewife will get pregnancy induced hypertension (Adinegara and Razzak, 2004).

Obese pregnant women also at risk of developing GDM, Pre Eclampsia and caeserian section. Furthermore, the neonates also at risk of macrosomia or large for gestational age. This may put the women at double risk not only to herself but also the baby into morbidity and mortality.

Recent observations indicate that GDM may be associated with increased incidence of fetal malformation and perinatal mortality. Such poor outcome is likely confined to a subset of GDM patients in whom diabetes was present but unrecognized before pregnancy. The most frequent and significant morbidity is fetal macrosomia, which in turn is associated with increased risk of birth injuries and asphyxia (Persson and Hanson, 1998).However, Catalano et al (2001) found that there was a positive correlation between weight gain in mother and birth weight in control subjects but a negative correlation in subjects with gestational diabetes mellitus. Obesity and pregestational diabetes are independently associated an increased risk of LGA delivery(Ehrenberg *et al.*, 2004).

Callaway L.K et al (2010) in one RCT evaluate the feasibility of an individualized exercise program to prevent gestational diabetes mellitus (GDM) in 50 obese pregnant women. Average weekly energy expenditure (MET hours per week and kilocalories per week) of exercise-specific activity was assessed during pregnancy using the Pregnancy Physical Activity Questionnaire. Fasting glucose and insulin and homeostasis model assessment of insulin resistance (HOMA-IR) were assessed at baseline and 20, 28, and 36 weeks' gestation. 73% achieved more than 900 kcal/week of exercise-based activity at 28 weeks compared to only 42% women in the control group. This study is feasible however do not ensure reduction in GDM cases.

High gestational weight gain contributed by eating much more food, eating low fiber diet, eating high fat diet, eating more sweets and low physical activity. >80% of high GWG caused by dietary intake. Thus, an approach towards dietary counseling provides an effective intervention towards reducing GWG and indirectly other adverse maternal and fetal outcomes.

Recent systemic review and meta-analysis by Oostdam N et al (2012) review different interventions for preventing gestational diabetes mellitus. Overall, there were eight clinical trials comparing dietary counseling versus usual care. They found that dietary counseling alone was more effective in reducing the risk of GDM (RD -0.05, 95% CI -0.10 to -0-01; 7 trials, I2=41%). There were no statistically significant differences in maternal fasting glucose or risk of macrosomic infant.

Three trials studied on intervention of low glycemic index diet versus high glycemic index/ low fat diet advice. The result suggested that low glycemic index was more effective in reducing the risk of LGA infant, but no difference was found for maternal fasting glucose.

Han et al in Cochrane Database (2012) found that limited randomised controlled trial evidence available on the effect of exercise during pregnancy for preventing pregnancy glucose intolerance or GDM. Results from three randomised trials with moderate risk of bias suggested no significant difference in GDM incidence between women receiving an additional exercise intervention and routine care. However, meta- analysis by Oostdam N et

al (2012) reviewed that exercise was more effective in reducing the risk of macrosomial infants.

Based on the limited data currently available, conclusive evidence is not available to guide practice. Standardised behavioural interventions are needed to assess the effects of exercise on preventing GDM and other adverse pregnancy outcomes including large-for-gestational age and perinatal mortality(Han *et al.*, 2012).

Obese pregnant women also benefited from gestational weight gain during pregnancy in post-partum period. Evidence suggests that dieting and exercise together appear to be more effective than diet alone to help women to lose weight after childbirth, as the former improves maternal cardiorespiratory fitness level and preserves fat-free mass, while diet alone reduces fat-free mass (Amorim *et al.*, 2007).

One randomized controlled trial of lifestyle intervention in 360 obese pregnant women was published in 2011 by Vinter CA et al. They compared behavioral, physical activity and dietetic counseling and found that combination of dietary management and physical exercise improved adverse pregnancy outcome compare in control group.

Long term measurement and consistent in managing obese pregnant women are required in order to optimize maternal and fetal health since their health will determine the future generations.Greater maternal prepregnancy weight and GWG up to 36 weeks of gestation are associated with greater offspring adiposity and adverse cardiovascular risk factors(Fraser *et al.*, 2010). In this study, greater prepregnancy weight was associated with greater offspring adiposity and more adverse cardiovascular risk factors at age 9 years. GWG in early

pregnancy (0 to 14 weeks) was positively associated with offspring adiposity across the entire distribution but strengthened in women gaining >500 g/wk. By contrast, between 14 and 36 weeks, GWG was only associated with offspring adiposity in women gaining >500 g/wk. GWG between 14 and 36 weeks was positively and linearly associated with adverse lipid and inflammatory profiles, with these associations largely mediated by the associations with offspring adiposity.

In conclusion, any interventions need specific measure, standardization and commitment by both patients and health professionals. Dietary management can be used as an easy, cheap, uncomplicated, safe and cost-effective in managing adverse pregnancy outcomes. The gestational weight gain may differ in different region of the world and a protocol in developed countries may not applicable in developing countries. Thus, adherence to IOM recommendations may be controversial. However, there were studies to recommend the IOM recommendation is useful in preventing GDM and macrosomic infant.

Large, schematic management and maybe combinations of different interventions may benefit more to the patients and their health outcomes. More randomizes trial in different regions in the world need to be conducted in order to achieve significant results and guidance in future.

Most importantly, is prepregnancy optimization of body weight may make a different in managing obese pregnant women. With ideal body mass index, indirectly will reduced the obstetric complications to mother and and fetus. In long term, dietary management may be beneficial to all population before embark into pregnancy.

3.0 CONCEPTUAL FRAMEWORK

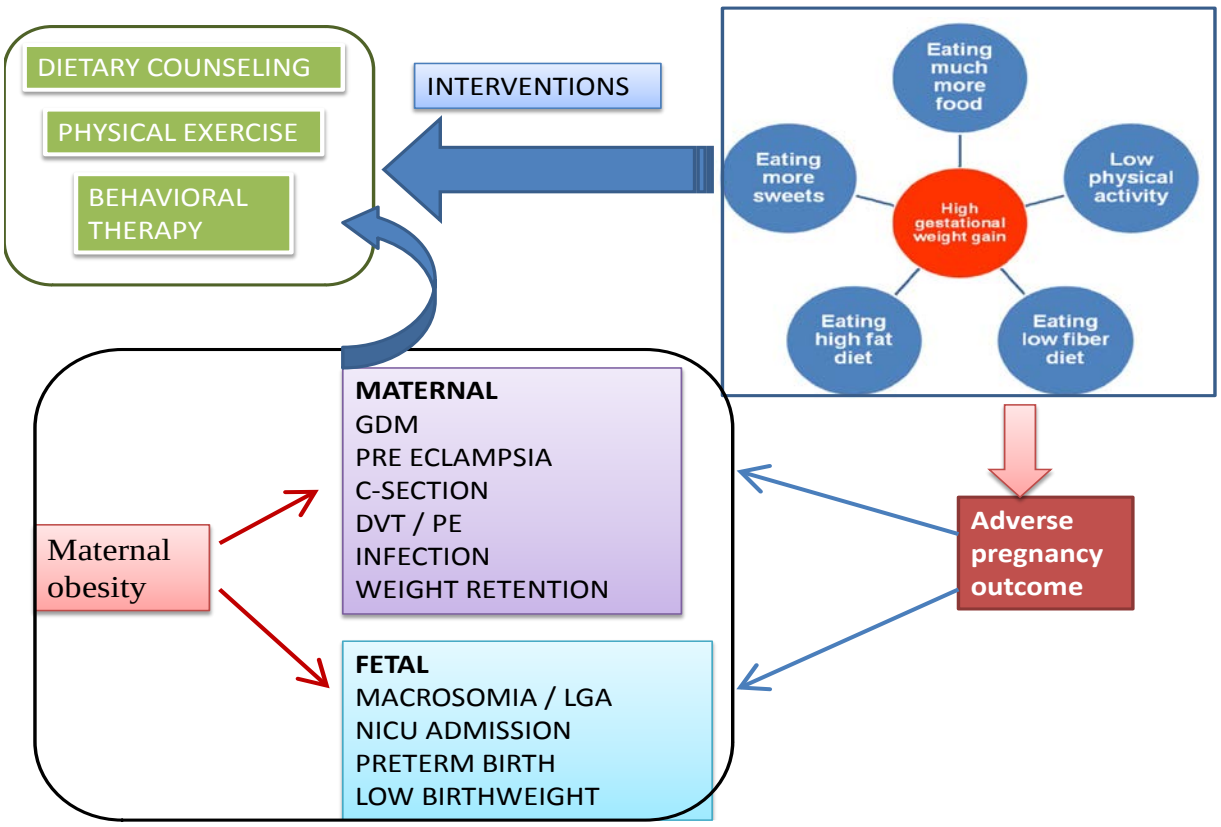

Figure 3 Conceptual Framework of the study

3.1 Justification

Most of the studies done noted that recommended weight gain in most pregnant women is not within the IOM's ranges, however very few data available to guide us regarding the best gestational weight gain in pregnancy especially in obese women.

There are few intervention studies aiming at weight management during pregnancy have been performed and most of these interventions were not as successful as expected(Althuizen *et al.*, 2006; Amorim *et al.*, 2007).In one systemic review and meta-analysis by Oostdam N et al 2012 found that dietary counseling was more effective in reducing the risk of GDM.

There are also lacking of studies regarding effects of dietary counseling on gestational weight gain and pregnancy outcomes particularly in multi-ethnic and different types of food intake in Malaysia. Up to date, there was limited data on gestational weight gain and maternal and fetal outcomes of obese parturient.

3.2 Rationale

This study is an evaluation of effectiveness of dietary counseling to obese parturient and reducing adverse maternal and fetal outcome. The results obtained from the effects of dietary counseling can be used as a measures for improving maternal health in Malaysian population.

In the end, this study provides easy, cheap and effective measure to reduce adverse pregnancy outcomes with dietary counseling. The findings could help in providing an outline for standard gestational weight gain in obese parturient.

3.3 Benefit Of The Study

This research is essential to evaluate the effect of dietary counseling on gestational weight gain and pregnancy outcomes amongst obese patients. Since the adverse pregnancy outcome is much related to the obesity, thus it is beneficial to investigate the effectiveness of dietary counseling as a measure to reduce gestational weight gain and reduce the adverse pregnancy outcomes.

4.0 OBJECTIVES

4.1 General Objective

To evaluate the effects of dietary counseling in obese pregnant women on gestational weight gain and pregnancy outcomes

4.2 Specific Objectives

1) To determine the effectiveness of dietary counseling in reducing gestational weight gain
2) To determine the effects of dietary counseling on maternal outcome such as mean gestational age, GDM, Pre-Eclampsia, PIH, C-Section and PPH; and fetal outcome such as mean birth weight, shoulder dystocia and Apgar Score of both groups

Primary Outcome

1) The mean difference of gestational weight gain between the intervention group with dietary counseling and normal prenatal care group

Secondary Outcomes

1) Maternal complications which include GDM, PIH, PE, C-Section and PPH
2) The fetal outcomes which include mean birth weight, shoulder dystocia and Apgar Score

4.3 Research Question

Is there a significant reduction in gestational weight gain and adverse pregnancy outcomes in obese parturients in Hospital Sultanah Bahiyah(HSB) with dietary counseling?

4.4 Hypothesis

NULL HYPOTHESIS (HO)

There is no different in the proportion of observed gestational weight gain and adverse pregnancy outcomes in HSB between obese patients who received dietary counseling and who did not receive dietary counseling

ALTERNATIVE HYPOTHESIS (HA)

The proportion of observed gestational weight gain and adverse pregnancy outcomes in HSB is lower in patients who received dietary counseling than who did not receive dietary counseling

5.0 METHODOLOGY

5.1 Study design

Prospective Randomised Controlled Trial

Selection of subjects:

Reference population

All pregnant women attending antenatal follow up in Malaysia

Source of population

All pregnant women who are obese in Kedah state

Study population

All obese pregnant women, booking <12 weeks who presented to Hospital Sultanah Bahiyah, Alor Setar, Kedah

Study duration:

Twelve months period from December 2013 to December 2014

Study location:

Hospital Sultanah Bahiyah (HSB) Alor Setar, Kedah which is tertiary government hospital

5.2 Study participants:

Inclusion criteria

1. Women age 18 years old until 40 years old

2. Singleton pregnancy

3. Able to communicate in Malay or English

4. Willing and able to give informed consent

5. BMI > or equal to 30 and< or equal to 45

Exclusion criteria

1. Pregnant with diseases that require specific treatment at the onset of enrollment (as an example HIV, diabetes, hypertension, heart / renal disease, connective tissue disease and mental disorder)

2. Not able to communicate in Malay or English

3. Alcoholic or drug abuser

4. Previous preterm deliveries

5.3 Sample Size Calculation

Calculation of sample size for this study was based on the standard statistical approach, applied to a wide range of clinical trials. Computerized power and sample size program by Dupon WD and Plummer WD is used for the calculation.The difference in mean looked for in the study is7.5 (Wolff *et al.*, 2008)

n = required sample size

δ = 5.0, detectable mean difference of weight gain between patients without dietary counseling (control group) and patients with dietary counseling (intervention group)

σ = 7.5, the standard deviation of weight gain in the control group (Wolff *et. al*., 2008)

α= 0.05

Power = 0.8

m = ratio of placebo to intervention group = 1

n = 48

Dropped out rate is 20% = 10

Total sample size is 116 patients i.e 58 patients in control group and 58 patients in intervention group