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Effect of Including Glycaemic Index (GI) Nutrition Education, within the Conventional Healthy Dietary Recommendation Framework, on Body Weight and Composition of Women with Prior Gestational Diabetes Mellitus: Results from a One-Year Randomised Controlled Trial

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ABSTRACT

Introduction: Women with previous gestational diabetes mellitus (GDM) have increased risks for obesity and its metabolic consequences. Conventional diets have limited success in achieving weight loss in this population. Lowering dietary glycaemic index (GI) is known to facilitate weight loss in insulin-resistant women. This study evaluated the effects of including GI education within the conventional healthy dietary recommendation (CHDR) framework, on body weight and composition of women post-GDM. **Methods:** Seventy-seven, non-diabetic, women with previous GDM (aged 20-40y, mean BMI: 26.4±4.6kg/m^2) were randomised into two groups: subjects who received CHDR only (CHDR, n=38) and those who received low-GI education in addition (LGI, n= 39). The outcome of these interventions on body weight, waist circumference (WC), waist-to-hip-ratio (WHR), body fat and dietary intakes were assessed after one year. Clinically significant weight loss was defined as achieving a minimum of 5% weight loss from the baseline body weight. **Results:** After one year, as compared to CHDR, a significantly greater proportion of LGI subjects had 7% (28.2% vs. 5.3%, p =0.01) and 10% (15.4% vs. 0%, p =0.025) weight loss from baseline. WC significantly reduced in both groups (*p*< 0.004); however, only LGI subjects had significant WHR reduction (-0.02± 0.04, p=0.035). One-year mean increases in total (1.2±2.4kg, p= 0.008) and trunk fat (0.65±1.4kg, p= 0.019) were significant only within the CHDR group, although the changes were not significantly different between the groups. After intervention, LGI as compared to CHDR diets, had lower GI (58±4 vs.64±7, *p*<0.001) and higher dietary fibre (17±4 vs. 13±4g, *p* <0.001). **Conclusion:** Including GI education within the CHDR framework for

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women with prior GDM, increases their likelihood of achieving ≥7% weight loss and significant WHR reductions in one year.

Key words: Diet, gestational diabetes mellitus, glycaemic index, glycaemic load, prevention, type 2 diabetes

INTRODUCTION

Gestational diabetes mellitus (GDM) increases risk for metabolic syndrome and type 2 diabetes mellitus (T2DM) (Metzger *et al.*, 2007). To attenuate these risks, a moderate body weight loss of 5-10% through lifestyle interventions are recommended for post-GDM women (Metzger *et al.*, 2007). However, when compared to subjects with similar metabolic risks and glucose tolerance, women with previous GDM achieve lower weight loss in response to standard recommendations and regain the weight lost rapidly (Ratner *et al.*, 2008).

Meanwhile, subjects with hyper-insulinaemia, a condition commonly accompanying GDM; have a greater weight loss when on low glycaemic index (GI) diets (Pittas *et al.*, 2005; Sichieri *et al.*, 2007). Among iso-energetic meals, low-GI options are associated with greater satiety compared to high-GI meals. This is because low-GI foods increase secretion of anorexic signals such as cholecystokinin and glucagon-like peptide-1 (Lavin *et al.*, 1998). Also, low-GI foods, characterised by slower rates of digestion and absorption of carbohydrate in the small intestine, stimulate the nutrient receptors in the gastrointestinal tract for a longer period of time, resulting in prolonged feedback through these gut peptides that induce satiety (Lavin *et al.*, 1998).

Furthermore, postprandial glycaemic and insulinaemic spikes after consumption of high-GI foods inhibit lipolysis. This metabolic state could be physiologically interpreted as a "fasting state" that triggers the release of glucagon and hunger signals (Ludwig, 2000). On the contrary, low GI meals reduce voluntary energy intake for the rest of the day through increased satiety and delayed hunger (Ludwig, 2000). Therefore low-GI diets theoretically can improve adherence to reduced calorie diets and result in successful weight loss (Brand-Miller *et al.*, 2002). Based on this understanding, we tested the hypothesis that a greater proportion of prior-GDM subjects will achieve clinically significant weight loss on receiving nutrition education to lower their diet GI in addition to standard recommendations. We also analysed the effect of the intervention on body weight and body fat of post-GDM subjects one year post-intervention.

METHODS

The study was approved by the research ethics and review committees of the institutions involved, in line with Malaysian national regulations (approval no: IMU 199/2009 and FF-115-2010). The trial was registered with a research ID of NMRR-10-96-5183 at the Malaysian National Medical Research Registry (*https://www.nmrr.gov.my*). Informed consent was obtained from all subjects.

Participants

Women with prior-GDM (diagnosed as per WHO criteria) were identified from the delivery register of Universiti Kebangsaan Malaysia Medical Centre in Cheras, Kuala Lumpur and invited for screening. Seventy-seven of the eligible post-GDM subjects, aged 20-40, without a diagnosis of diabetes at the time of recruitment, were included. Subjects were screened at a minimum of two months postpartum and the median duration since the last GDM delivery to the time of screening.

Dietary intervention

Subjects were block randomised in the ratio of 1:1 into two diet groups as per pre-generated computerised allocation. One group of subjects only received conventional dietary recommendations (CHDR, n=38) and the second group received low-GI-education in addition to CHDR (LGI, n=39). Due to the nature of the intervention, blinding was not feasible. A detailed account of the educational intervention, including sample menus used in this study has been published earlier (Ghani *et al.*, 2014; Shyam *et al*; 2013a; b). In brief, the aim was to achieve ≥ 5% body weight loss if BMI>23 and maintain current weight if BMI<23 during the one-year trial period. This objective was achieved by establishing two diets that were similar in energy and macronutrient content but with varying dietary GI. CHDR education emphasised moderate intake of energy, fat, sugar and salt while encouraging an increase in intake of dietary fibre. Subjects were encouraged to indulge in moderate physical activity for 30 min, at least five times a week. LGI education in addition to the above, taught subjects to choose low-GI options for high GI staples like bread, rice etc and swap them with lower GI choices such as spaghetti, noodles or multi-grain bread, based on previous successful Asian interventions (Amano *et al.*, 2007; Nisak *et al.*, 2010). Subjects were encouraged to restrict rice intake to once per day as most local rice varieties are high in GI (Nisak *et al.*, 2010). Subjects were also provided a list of foods that classified foods as high, moderate or low GI to aid making choices. They were not required to memorise numerical GI values of foods but recommended to include one low GI food at each meal. Vouchers for low-GI bread were made available to LGI subjects to increase dietary adherence by allowing subjects to receive up to three loaves of low-GI multigrain bread per week (with tested GI value of 42) from pre-assigned shops (Nisak *et al.*, 2010).

Nutrition education was provided once at the baseline and take-home reference booklets were provided. Quarterly follow up visits were scheduled. Fortnightly reminders reinforcing concepts of healthy living and motivating subjects to comply with the intervention were sent using email or short messaging services. Frequency of subject contact was kept similar between groups. Compliance was monitored through assessments of dietary intake, and physical activity and nutrition knowledge assessment pertaining to the group-specific concepts.

Measurement of outcomes

Body weight was measured in light clothing without footwear using digital weighing scales (Model: BWB-800A, Tanita Corporation, Tokyo, Japan). Clinically significant weight loss was defined as achieving a minimum of 5%, weight loss from the baseline body weight (Metzger *et al.*, 2007). The percentage of subjects achieving 7% and 10% weight loss were also investigated (Tuomilehto, 2009). Waist (WC) and hip circumference was measured as per WHO guidelines (World Health Organisation, 2008) and waist-to-hip ratio (WHR) was calculated. Body fat was measured using the Dual-emission X-ray absorptiometry (DEXA, Model: Delphi, Hologic Systems; Bedford, USA).

Dietary intake was assessed with 3-day dietary records collected at baseline, three and six, nine and twelve months after intervention. Efforts were made to ensure submission of data and completeness and legibility of entries. Dietary analysis including diet GI (glucose scale) and glycaemic load (GL) estimation was performed using Malaysian diet intake calculator (Shyam, Kock Wai &Arshad, 2012). Data on self-reported adherence to dietary recommendations was obtained as previously described (Shyam *et al.*, 2013b). Validated international physical activity questionnaire (short form) was used to monitor subjects' physical activity levels (International Physical Activity Questionnaire (IPAQ) Research Group, 2005).

Anthropometric measurements, dietary intake, self-reported adherence, and physical activity levels were monitored quarterly. Body fat was measured at baseline and after the completion of the one-year trial period. Measurements were carried out by the same researcher or technician throughout the study period.

Statistical analysis

The sample size of 77 was found to be sufficient to detect a significant difference between groups, if the proportion of LGI subjects achieving clinically significant weight loss was 2.5-fold of that observed in the CHDR group (Sealed Envelope Ltd, 2001). Since prior data in our population was unavailable, it was assumed that 18% of the subjects would lose weight in the CHDR group (Stage, Ronneby & Damm, 2004). This sample size also provided 80% power to detect significant differences in body weight and body fat changes between the groups, if the true difference between them was 0.65 times the SD at 5% level of significance.

Statistical analyses were performed using IBM SPSS (version 19, Somers, NY, USA). The statistical significance standard was set at 5%. Data normality was tested using the Shapiro-Wilks test. If data points were not normally distributed, statistical analysis was attempted on the natural logarithm of the values. If the transformation was not successful, statistical analysis was carried out using non-parametric tests. Differences in proportions between groups were tested using the Chi-square test or Fischer's Exact as required. Repeated measures ANOVA was used to test the difference in body weight over time. Complete analysis and intent to treat (ITT) approaches were used. There were no significant differences in these results. This paper therefore presents the results of ITT. All dietary and IPAQ records obtained were included in the analysis.

To study the magnitude of changes and compare the effects of different treatments, a sole focus on *p*-values was found inadequate (Durlak, 2009). Therefore effect size (ES) statistics were computed. ES reported in this study was calculated as the "standardised" mean difference, i.e. as ratio of the mean change and standard deviation of change (Durlak, 2009). Individual ES values were calculated for changes in outcomes for each of the two diet groups and compared. ES between 0.2-0.5, 0.5-0.8 and >0.8 were taken to denote "small", "moderate" and "large" changes in outcomes.

RESULTS

Baseline characteristics of the subjects have been published previously (Shyam *et al.*, 2013a). In brief, the majority (74%) of the subjects were of Malay ethnicity, followed by Chinese (17%), Indians (6%) and others (3%). Subjects had a mean age of 30.5±9 years. Fifty-two percent of the subjects had tertiary degrees, and the majority (78%) were pursuing their careers at the time of recruitment. The majority (96%) of the subjects had sedentary occupations. About 48% of the subjects had family incomes ranging between RM 1500 and 3500 and another 32% had an average monthly family income of above RM3000. At baseline, 57% of the subjects had low levels of physical activity.

The median duration since last GDM delivery to the time of screening was 4 months (IQR 2). At baseline, mean BMI (26.4±4.6kg/m^{2}), body fat (38.4±5.3%) and WC (83.2±8.8 cm) of the subjects were above recommended healthy limits for Asian women. All parameters of interest, including confounding characteristics such as a lapse since delivery and prevalence of breastfeeding were comparable between groups at baseline (Shyam *et al.*, 2013a). The flow of the subjects through the trial is shown in Figure 1.

Changes in anthropometric measures:
There was a significant reduction in body weight in both groups with time (GLM repeated measure analysis, *p*-value for time = 0.033, group = 0.245 and group*time=0.145, refer Figure 2). Mean (±SD) weight loss in LGI and CHDR groups were 1.05±4.1 and 0.16±2.8 kg respectively (*p*-value between groups = 0.280). Accordingly, mean (±SD) percentage weight loss in the LGI and CHDR groups were 1.62±6.6 and 0.31±4.2% respectively (*p*-value between groups = 0.304).

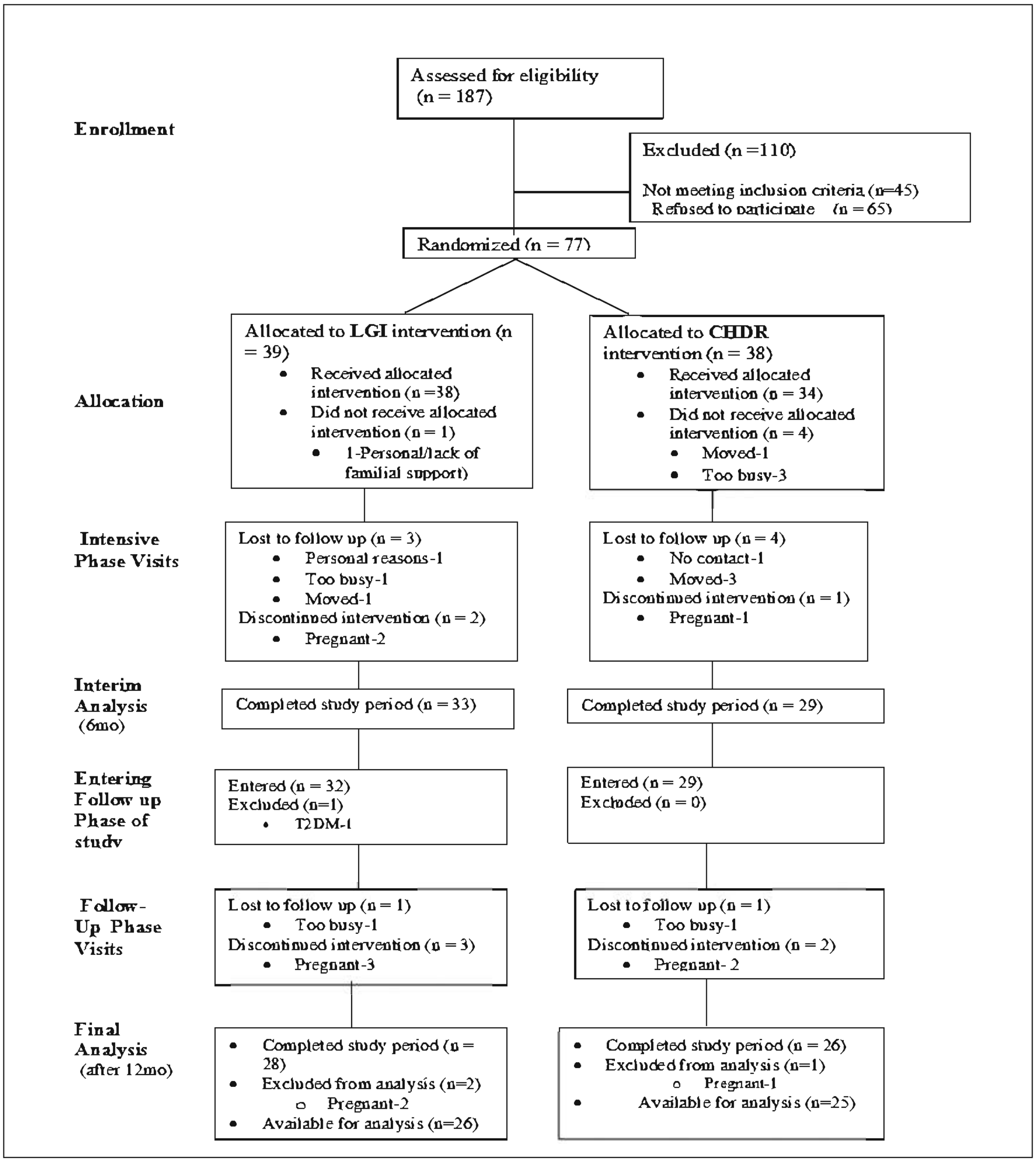
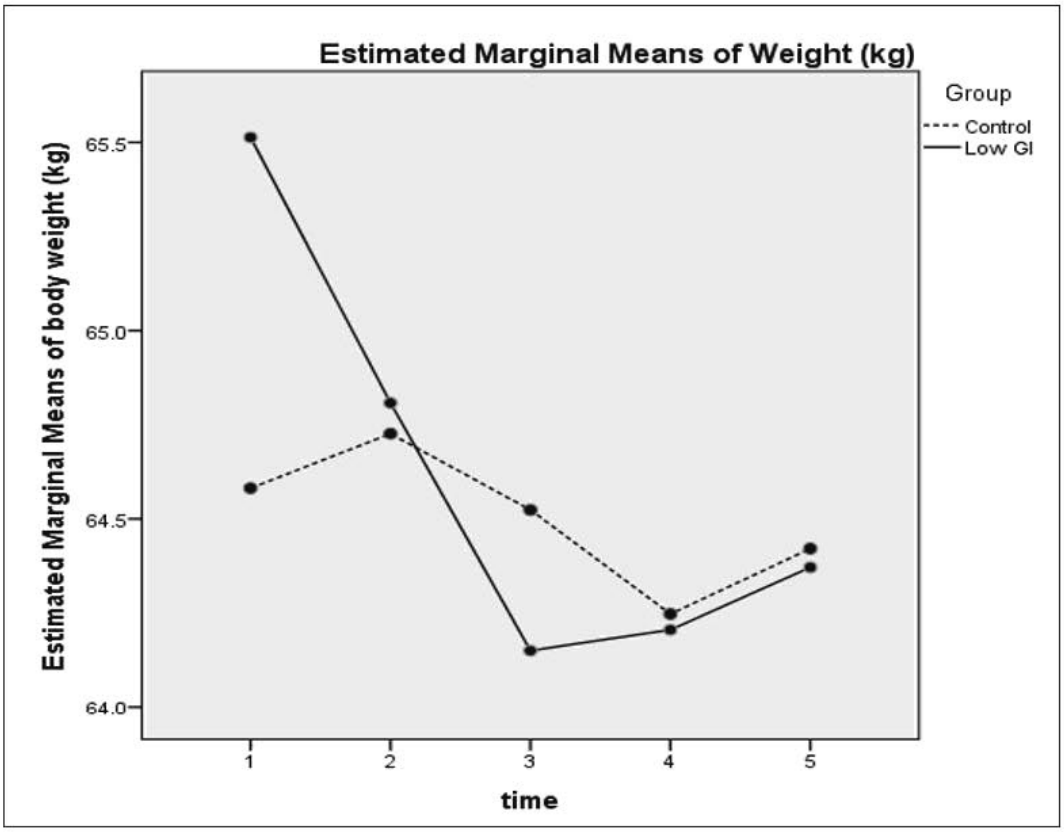


Figure 1. CONSORT diagram showing the flow of participants through this randomised trial
Legend: LGI: low GI group, CHDR: Conventional healthy dietary recommendation group



	LGI	CHDR
Time point (0) = Baseline Weight (kg) (mean±SD)	65.5±11.5	64.6±1.9
Changes from baseline (mean±SE) (kg)		
Time point (2) = 3 mo	-0.71±0.37	0.14±0.23
Time point (3) = 6 mo	-1.25±0.51	-0.06 ±0.39
Time point (4) = 9 mo	-1.21±0.53	-0.33±0.45
Time point (5) = 12 mo	-1.05±0.66	-0.16±0.45

Figure 2. Body weight changes in the diet groups during the one-year study period
Legend: LGI - low GI group; CHDR - Conventional healthy dietary recommendation group

WC remained significantly lower than baseline in both groups at one-year post-intervention (p < 0.005, see Table 1). Only LGI subjects had significantly lower WHR values after one year as compared to baseline (p =0.035). Though ES of WHR reductions after 1 year were greater in LGI as compared to CHDR subjects, these changes were statistically comparable between groups (-0.02±0.04 vs. -0.01±0.04, ES 0.5 vs. 0.3, p = 0.347).

Proportion of subjects achieving clinically significant weight loss

More subjects in LGI, as compared to CHDR group, attained 7% (28.2 vs. 5.3%, p= 0.01) and 10% (15.4 vs. 0%, p= 0.025) weight loss after 12 months (Figure 3).

Table 1. Anthropometric outcomes at baseline and at one year post intervention (Mean±SD)

	LGI			*CHDR*		
	Baseline	*End (1y)*	*p value*	*Baseline*	*End (1y)*	*p value*
Weight (kg)	65.5±11.5	64.3±12.2	0.12	64.6±12.5	64.4±13.0	0.781
BMI (kg/m2)	25.5±4.2	25.0±4.7	0.079	26.9±4.2	26.8±4.6	0.519
WC (cm)	83.2±8.5	80.4±9.9	<0.001	82.7±9.6	81.0±10.9	0.004
WHR	0.81±0.05	0.79±0.05	0.035	0.80±0.05	0.79±0.05	0.235

Legend: LGI - Low GI Group, CHDR - Conventional healthy Dietary Recommendation Group
BMI - Body mass index; WC - waist circumference; WHR - waist hip ratio
p-value calculated using paired tests of significance

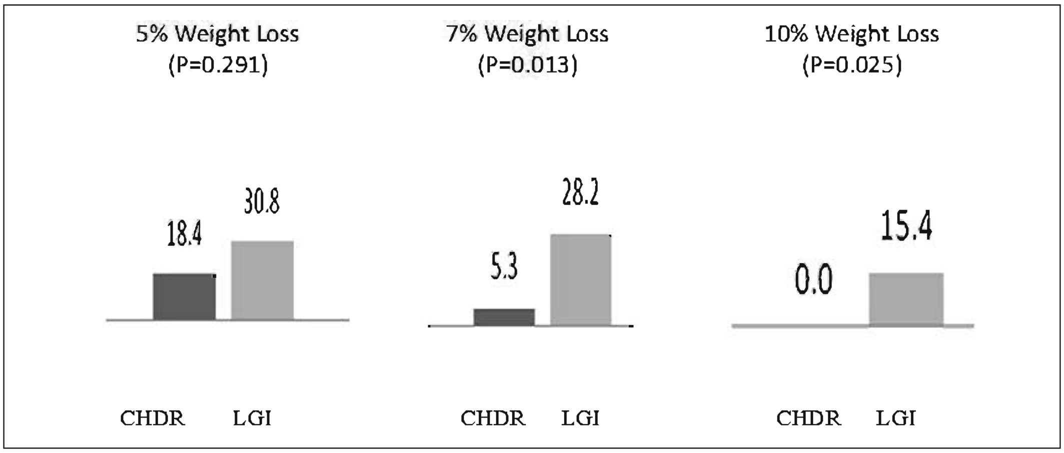


Figure 3. Percentage weight loss in study groups
Legend: LGI- Low GI Group; CHDR - Conventional healthy Dietary Recommendation Group
p-values shown are calculated for difference in proportion of subjects between groups using Fischer's Exact test.

Table 2. Changes in total body and trunk fat

	LGI			*CHDR*		
Mean±SD	*Baseline*	*End (1y)*	*p value*	*Baseline*	*End (1y)*	*p value*
Total Body Fat (kg)	24.8±7.3	25.6±7.6	0.054	24.9±7.7	26.1±8.4	0.008
Trunk Fat (kg)	11.1±3.9	11.7±4.4	0.052	11.7±4.5	12.4±4.7	0.019

Legend: LGI- Low GI Group; CHDR -Conventional healthy Dietary Recommendation Group
p-value calculated using paired tests of significance

None of the subjects in CHDR group were able to achieve 10% weight loss.

Changes in body fat

Changes in total body fat and trunk fat are presented in Table 2. Average total body fat (kg) increased significantly only in the CHDR group. However, changes in total body fat were not significantly different between the groups (LGI vs. CHDR: 0.87±2.7 vs. 1.2±2.4 kg, p= 0.58). Similarly mean increase in trunk fat (kg) was statistically significant only in the CHDR group. Although changes in trunk fat (kg) were not significantly different between the groups (LGI vs. CHDR: 0.56± 1.9 vs. 0.65 ±1.4 kg, p= 0.591), the magnitude of increase in trunk fat in the CHDR group was ~ 1.5-fold of that seen in LGI group (ES: 0.29 vs. 0.46).

However, body weight loss among subjects was significantly associated with loss in total body and trunk fat. Therefore subjects who lost weight also lost body fat (refer Table 3).

Changes in dietary intake

Over 95% of the subjects who completed the quarterly visits submitted their dietary records in both the groups. Mean diet GI and fibre intakes were the only significantly different dietary outcomes between the groups throughout the course of the one-year trial period (Table 4). Dietary GI was significantly lower in the LGI group at all visits (p<0.001, Table 4). With respect to diet GI classification (Barclay *et al.*, 2008), the average diet GI of CHDR subjects remained in the "high" range throughout the study period. However, for the LGI Group, while baseline diet GI was in the high "range", diet GI at 3, 6 and 12 months after intervention was in the intermediate range. At nine months post-intervention, the average diet GI of LGI subjects was at 60 (Figure 4).

Dietary fibre intake after intervention was consistently higher in the LGI as compared to CHDR group (mean absolute difference of 4g, p=0.002, Table 4). Intake of carbohydrates in both groups was similar during the trial period. (p= 0.992, Table 4), with no significant difference in absolute carbohydrate intake (g) at any of the visits. Throughout the one-year study period, the LGI group on an average consumed an additional 4g of fat as compared to CHDR and that was not statistically significant (p=0.059). Percentage of energy from protein increased in both groups of subjects as seen in Table 4 with no difference between groups. No time or group effects or group and time interactions were observed for absolute protein intake (g).

Dietary adherence and physical activity

Mean self-reported adherence did not change in either group with time (p = 0.465, see Figure 5) and was not significantly different between groups during the one -year period (p > 0.067). Physical activity levels remained comparable between the groups throughout the course of the trial (p > 0.143).

DISCUSSION

Anthropometric changes

The difference in mean weight loss after one year was not significantly different between the diet groups in this study. This observation is in agreement with previous similar long-term weight loss trials (Ebbeling *et al.*, 2005; Marsh *et al.*, 2010; Sichieri *et al.*, 2007). Irrespective of the diet, GI difference between the groups

Table 3. Correlation between changes in total body and trunk fat with other metabolic outcomes

Changes in	*Changes in total body fat (kg)*		*Changes in trunk fat (kg)b*	
Spearman's rho	*Correlation coefficient*	*p-value*	*Correlation coefficient*	*p -value*
Weight (kg)	0.782	<0.001	0.588	<0.001
BMI (kg/m2)	0.769	<0.001	0.654	<0.001
Waist circumference (cm)	0.375	0.001	0.351	0.002

Legend: BMI- Body Mass Index

Table 4. Changes in daily dietary intake of the study groups (Mean ± SD)

Dietary outcome	*LGI*			*CHDR*			p^2		
	Baseline	*Study (avg) δ*	p^1	*Baseline*	*Study (avg) δ*	p^1	*Time*	*Group*	*Time*Group*
Energy (kcal)	1804± 495	1661± 338	0.106	1721± 491	1595± 363	0.189	0.136	0.772	0.227
CHO (g)	245± 75	210± 52	0.008	225± 68	215± 51	0.638	0.362	0.992	0.477
CHO en%	55± 9	52± 5	0.318	53± 7	54± 5	0.333	0.720	0.097	0.372
Protein (g)	66± 21	68± 14 *	0.427	70± 26	63± 21*	0.091	0.223	0.059	0.350
Protein en%	15± 4	20± 4	0.329	16± 5	19± 5	0.798	0.006	0.059	0.031
Fat (g)	62± 23	57± 16	0.153	60± 20	53± 15	0.038	0.223	0.059	0.350
fat en%	29± 8	28± 5	0.729	30± 6	28± 5	0.082	0.006	0.059	0.031
Dietary fibrer (g)	13± 5	17± 4***	0.004	13± 5	13± 4***	0.894	0.130	0.002	0.106
Glycaemic index	62± 5	58± 4***	0.003	62± 7	64± 5***	0.426	0.380	<0.001	0.058
Glycaemic load	152± 41	125± 32	<0.001	142± 42	137± 36	0.610	0.364	0.067	0.316

Legend: LGI - Low GI Group; CHDR- Conventional Healthy Dietary Recommendation Group. δ- Study average was calculated as a mean of the values measured after intervention (i.e mean of values reported at 3, 6, 9 and 12 months).
p1- p values for changes within groups; p2- p values for repeated measure analysis using baseline, 3 and 6 months data
Values significantly different between groups:* (p<0.05), *** (p=<0.001)

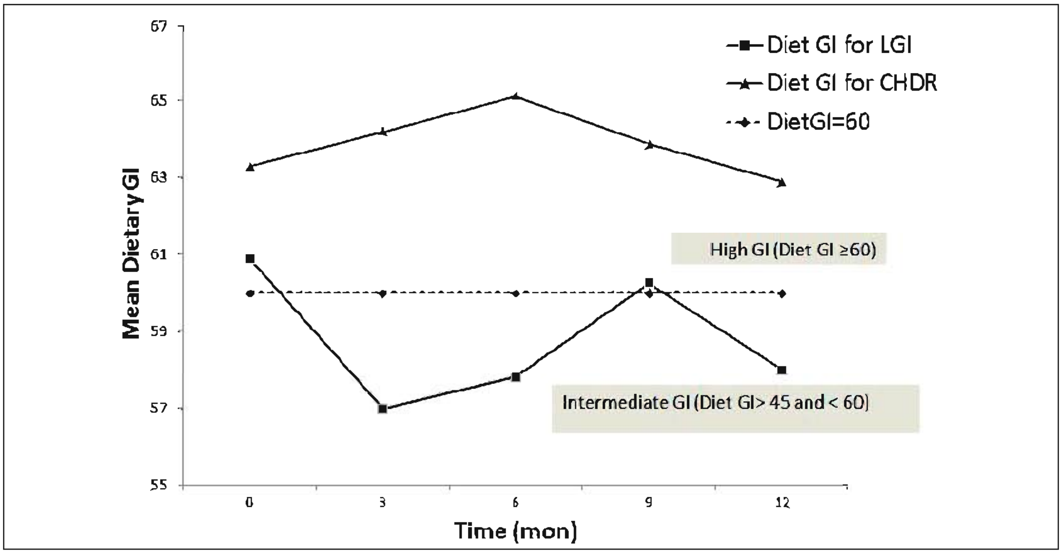


Figure 4. Dietary Glycaemic Index in the groups during the one year study period
Legend: LGI- Low GI Group; CHDR - Conventional Healthy Dietary Recommendation Group. The horizontal dotted line shows a dietary GI of 60 (above which it is considered "high"; diet GI >45 but <60 is considered intermediate; as per dietary GI categorization (Barclay *et al.*, 2008)

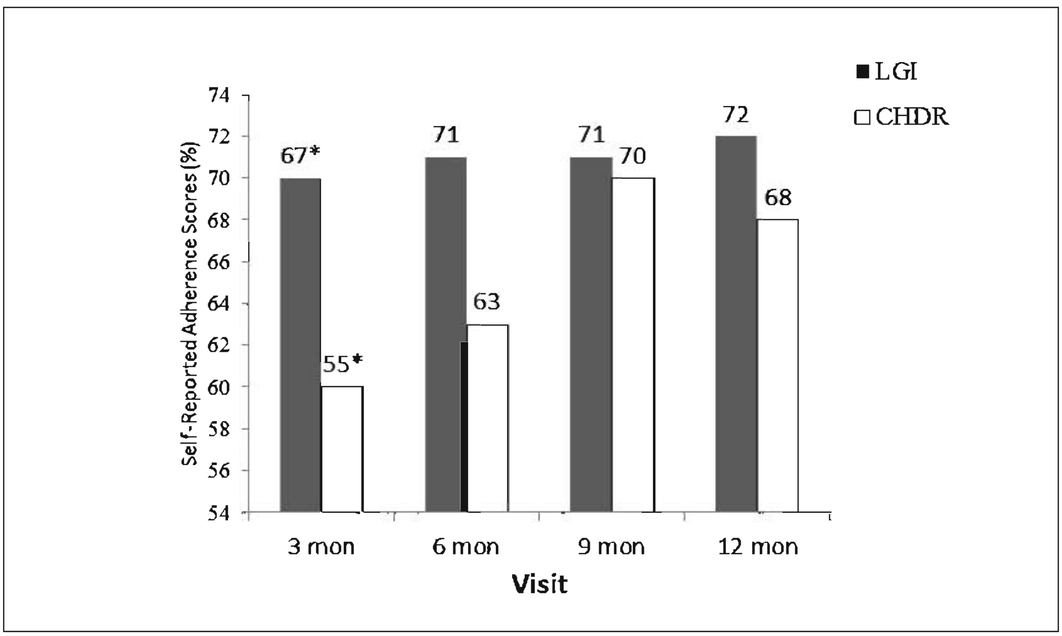


Figure 5. Self-reported adherence to dietary recommendations
Legend: LGI- Low GI group; CHDR- Conventional Healthy Dietary Recommendation Group. The higher the score, the greater the adherence.
****p* values were significantly different between groups for individual visits.**
Overall adherence scores during the trial were not significantly different between groups.

(6 units in the current trial to 39 units in the Brazilian feeding trial (Sichieri *et al.*, 2007)), none of these trials documented a significant weight loss difference between groups. However, it is possible that the modest sample size limits the power of this study to detect small differences in weight loss observed between the groups.

Similarly, we observed statistically comparable changes in body fat between groups in this study. These results are in concordance with the findings from a year-long study comparing low and high GL diets among women with polycystic ovaries (Marsh *et al.*, 2010) and the "Pounds Lost Trial" that evaluated four popular weight loss diets varying in macronutrient composition (de Souza *et al.*, 2012). These findings seem to reinforce the hypothesis that diets varying in macronutrient quality or quantity result in similar weight loss, with the energy content and dietary adherence being the major determinant of sustained weight loss over time (Dansinger *et al.*, 2005, de Souza *et al.*, 2012).

However, mean diet GL after intervention was the single significant predictor of one-year weight loss in the stepwise regression model that included all dietary variables in this study. Accordingly, the LGI group had an additional 1.31% weight loss (≈ 0.9kg absolute value) as compared to CHDR. The magnitude of weight loss occurring in the LGI group was also ~ four times that observed in CHDR group (ES: 0.25 vs. 0.06). The ES comparison which is not influenced by sample size consideration, suggests the modest benefits in weight loss afforded by small diet GI reductions. Every 1kg reduction in body weight is known to reduce the incidence of diabetes by 16% (Tuomilehto, 2009). Therefore in women with a history of GDM, small reductions in dietary GI of conventional healthy diets, with negligible changes to the amount of carbohydrate foods, may accrue benefits in terms of diabetes risk reduction. However, it is important to note that since GL (∑ available carbohydrate amount X GI) primarily determines the effectiveness of a diet in ensuring weight loss. Therefore, careful management of the portion sizes of carbohydrate foods should necessarily be emphasised in low GI dietary counselling. This also suggests that concurrently measuring dietary GL (apart from energy and macronutrient intake) in low GI dietary trials allows a more complete evaluation of the dietary manipulation and enables comparison with other similar trials.

Significantly, more subjects in the LGI group in this study achieved 7% and 10% weight loss after 12 months of intervention. These findings concur with results that showed that more women with polycystic ovarian syndrome (also associated with insulin resistance) achieved 7% weight loss goal within 12 months when on low GI diets, as compared to conventional healthy diets (Marsh *et al.*, 2010). Hence, moderately lowering the GI (as low as 6 units) of conventional diets, enables more women with insulin resistance tendencies to achieve and sustain clinically significant weight loss in the range of 7-10% of initial body weight, at least for one year. Such moderate weight loss is associated with improved cardio-metabolic risk profile in high-risk subjects (Tuomilehto, 2009). Therefore, lowering dietary GI of conventional healthy diets may be more suited for lowering cardio-metabolic risks among women post-GDM.

Additionally, a decline in central obesity as indicated by significant WHR reduction at the end of the trial, was seen only in the low GI group ($p = 0.035$); although changes in WC and WHR between groups were not significantly different ($p > 0.278$). These anthropometric findings were corroborated by the higher effect sizes for increases in total body and trunk fat in the CHDR group. These findings can be explained by the vulnerability of visceral fat to high insulin responses of high GI foods compared with subcutaneous fat (Du *et al.*, 2009). Thus lowering dietary GI may be successful in managing central obesity in women with a history of GDM.

Both diet groups experienced regain of body weight lost during the earlier phase of the trial. This tendency for regain of weight has been noted in many earlier weight loss trials (Franz *et al.*, 2007) including rigorously controlled trials (Shai *et al.*, 2008). The tendency for weight regain is of special interest when dealing with post-GDM women, a group known to steadily regain the weight lost (Ratner *et al.*, 2008). Results from the Diabetes Prevention Program showed that women post-GDM lost less weight and sustained the weight loss for a shorter time as compared to other populations at simialr risk for diabetes, but without a history of GDM (Ratner *et al.*, 2008). Specifically, post-GDM women had "no weight loss plateaus" and regained weight immediately after weight loss (Ratner *et al.*, 2008). We have earlier shown that this trend for immediate weight gain was apparent among CHDR subjects, with LGI subjects showing a better trend for long-term maintenance of weight loss, especially if they had higher fasting insulin levels (Ghani *et al.*, 2014). Given that maintenance of the reduced weight is vital to accrue the beneficial effects of weight loss (Johansson *et al.*, 2012), LGI diets could afford better risk management. These observations demonstrate the suitability of adding low-GI nutrition education to the conventional dietary framework for Malaysian women post-GDM, for long-term weight management. However longer trial periods may be necessary to verify the findings for periods ranging over a year.

Dietary adherence and retention rates

Dietary adherence, a major factor implicated in usual failure to sustain weight loss, is a challenge to monitor in clinical trials due to problems with documenting and interpreting patient adherence (Roberts, Barnard & Croymans, 2008). Dietary records though capable of ascertaining general qualitative dietary patterns, lack precision in quantitatively determining energy or macronutrient intake (Roberts *et al.*, 2008). Therefore dietary records by themselves may not sufficiently capture adherence. Meanwhile studies have successfully used subjects' self-reported adherence scores towards documenting adherence (Dansinger *et al.*, 2005). Median self-reported adherence rates among LGI and CHDR in this current study were 71% and 63% respectively. These are well above the self-rated adherence rates of 30-40% reported in the A to Z study that assessed four commercially popular diets for weight loss for a similar study period (Dansinger *et al.*, 2005). Also, no trend for reduction in self-reported adherence with time was noted in either trial group, as opposed to those reported in the West (Dansinger *et al.*, 2005).

Retention of subjects in the trial is viewed as another surrogate endpoint to document adherence (Roberts *et al.*, 2008). The ~70% retention rate (similar in both arms) documented in this trial exceeds those reported for comparable trials, including those that provided material rewards to subjects who returned for follow-up sessions (Sichieri *et al.*, 2007). Low GI diets encourage satiety and are hypothesised to enhance compliance to hypo-caloric diet prescriptions (Brand-Miller *et al.*, 2002). Evidence from the current trial, however, does not support the above theory. Furthermore, energy intakes and self-reported adherence were also similar between the diet groups. Nevertheless, adherence to low GI diets in the context of this trial was no more difficult than adhering to conventional healthy diets. Moreover, even with similar dietary adherence, low GI diets afforded better weight management as compared to iso-caloric conventional diets.

Concerns about the possible higher fat content of low GI diets are commonly voiced (Kalergis, 2005). In this trial however, there were no significant differences in macronutrient intakes between the diet groups (except for GI and dietary fibre). Subjects in the LGI group consumed greater amounts of dietary fibre as compared to those in the CHDR group, throughout the period after intervention, even when adjusted for energy restriction. Low-GI diets are often associated with higher fibre intake in clinical trials, including those conducted in the Asian context (Nisak *et al.*, 2010). In the Malaysian scenario, increasing dietary fibre to WHO recommended levels of 25-30g/day is acknowledged as a challenge (Ng *et al.*, 2010). However, adding GI education to CHDR improved dietary fibre intakes among our subjects as in the other previous Malaysian trial (Nisak *et al.*, 2010). Such improvements in dietary fibre intake could not be achieved with CHDR in isolation. Hence, GI education has the added value of enabling increased dietary fibre intake in the Malaysian population.

Interestingly, low GI diets were found to be more beneficial to subjects who had hyperinsulinaemia in sub-group analysis of our data based on fasting insulin levels (Ghani *et al.*, 2014). Viewed together, the findings from this study establish a scope for individualisation of Malaysian diets by lowering dietary GI, without compromising on the dietary quality or ease of adherence.

Strengths and limitations of this study

This is the first long-term Asian study to compare the effects of CHDR and LGI nutrition education in preventing cardiovascular risks, to the best of our knowledge. We acknowledge certain limitations that would suggest caution in generalising the study results to other populations. The nutrition intervention employed in this study reduced the GI in the experimental group to around 58 units, which while below the average Malaysian diet GI of 63 units (Shyam *et al.*, 2012), still remained in the intermediate GI range (Barclay *et al.*, 2008). Therefore the LGI diets in this trial cannot be referred to as "low-GI diets" *per se*. Moreover, the 15% difference in dietary GI between groups (i.e. ≈ 9 units), thought to have clinical significance (Goff *et al.*, 2003), could not be achieved after 12 months of intervention. This study achieved only a difference of 6 units between the groups and it is therefore possible that treatment differences shown here are restricted by this limitation. However, it is encouraging to observe that even a moderate reduction in GI can be beneficial to this population. We also realise that these results cannot be generalised to other populations due to the limited sample size. Furthermore dietary intakes, including GI and GL, were estimates calculated on the basis of subject self-reported data as is common in dietary research. Longer studies involving larger sample sizes are needed to confirm these findings in other high-risk populations.

In conclusion, in women with prior GDM, moderate reductions in GI of standard diets increases their odds of achieving ≥7% weight loss, after one year. Additionally, LGI diets also facilitate significant reductions in WHR. Therefore, low GI nutrition education delivered within the CHDR framework may be clinically useful to optimise the management of body weight and central obesity in Asian women with prior-GDM.

Abbreviations:

CHDR-Conventional Healthy Dietary Recommendation Group
ES- Effect size
GDM- Gestational Diabetes Mellitus
GI-Glycaemic Index
GL-Glycaemic Load
IPAQ-International Physical Activity Questionnaires
LGI-Low Glycaemic Index group
WC- Waist circumference

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