ORIGINAL ARTICLE

Medical Nutrition Therapy Administered by a Dietitian Yields Favourable Diabetes Outcomes in Individual with Type 2 Diabetes Mellitus

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SUMMARY

Aim: This prospective, single-group, pre-post design trial was conducted to evaluate the effect of individualised Medical Nutrition Therapy intervention administered by a dietitian in individuals with type 2 diabetes mellitus on glycaemic control, metabolic parameters and dietary intake. Methods: Subjects (n=104; age=56.4 ±9.9 years; 37% male; years of diagnosis = 6.3 ±4.9 years) treated with diet and on a stabile dose of oral anti-diabetic agents were given dietary advice by a dietitian for a 12 week period. Individualised dietary advice was based on Malaysian Medical Nutrition Therapy for adults with type 2 diabetes mellitus. The primary outcome measure was glycaemic control (fructosamine and HbA1c level) and the secondary outcome included measures of anthropometry, blood pressure, lipid profile, insulin levels dietary intake and knowledge on nutrition.

Results: At week 12, 100 subjects completed the study with a dropout rate of 3.8%. The post-Medical Nutrition Therapy results showed a significant reduction of fructosamine (311.5 ±50 to 297 ±44 umol/L; p< 0.001) and HbA_{1c} (7.6 ±1.2 to 7.2 +1.1 %, p<0.001) with pronounced reduction for subjects who had very high HbA_{1c} levels of >9.3% at baseline. Waist circumference (90.7 ±10.2 to 89.1 ±9.8 cm, p<0.05), HDL-cholesterol (1.1 ±0.3 to 1.2 ±0.3 mmol/L, p<0.05), dietary intake and nutrition knowledge score (42 ±19 vs. 75 ±17%; p< 0.001) were significantly improved from the baseline.

Conclusions: Individualised Medical Nutrition Therapy administered by a dietitian resulted in favourable diabetes outcomes, which were more apparent for individuals with higher than optimal HbA_{1c} levels at the start of the study.

KEY WORDS:
Type 2 Diabetes, Medical nutrition therapy, Dietitian, Malaysia

INTRODUCTION

Intensive glycemic control is necessary to prevent or minimize the development of diabetes-related complications in individual with type 2 diabetes (UKPDS) [1]. While there is mounting evidence to show that good glycemic control is important to decrease the risk of diabetes-related complications [1], the prevalence of inadequate glycemic control remains high (>75%) among Malaysian diabetics [2].

Medical Nutrition Therapy (MNT) is the cornerstone of effective diabetes management [3]. MNT describes the process of providing individualised nutrition recommendations, preferably by a dietitian which taking into account personal, cultural, and lifestyle preference to achieve the target treatment goals [3]. The effectiveness of MNT interventions has been well documented [3-5], nonetheless data on experience and nutrition-related outcomes among Malaysian diabetics is relatively scarce. This is particularly important, as non-adherence to lifestyle measures which include diet and exercise were highly prevalent among our diabetics [2]. Individual with diabetes did better in taking their medications rather than for lifestyle changes, making optimal glycemic control even difficult to attain [6].

Therefore, this study was conducted to evaluate the impact of MNT intervention administered by a dietitian in individuals with type 2 diabetes mellitus. We hypothesized that individual's clinical outcomes (glycaemic control, metabolic parameters), dietary intake and nutrition knowledge would improve after the MNT intervention compared to the baseline levels.

MATERIALS AND METHODS

This prospective, single group pre-post design trial was conducted to determine the efficacy of MNT intervention administered by a dietitian for a 12-week period in individuals with type 2 diabetes. The Clinical Research and Ethics Committee of our Institution approved the protocol and all the subjects were given their written consent prior to entry into the study.

Eligible subjects were men or non-pregnant women with poorly controlled type 2 diabetes (fasting, glucose < 15 mmol/L and HbA_{1c} < 12%) who were treated with diet and oral anti-diabetic agents (Metformin < 1650 mg/day and/or first generation sulfonylurea such as Glibenclamide; 5-15 mg/day) on a stable dose over the previous 3 months. Subjects were not using insulin and none of them had clinically significant cardiovascular, renal or liver disease.

This article was accepted: 7 November 2012
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A total of 150 subjects were screened out of which 114 were eligible. Ten subjects were excluded because they did not turn up for the subsequent visits and the remaining 104 subjects participated in this study. The sample size of 100 subjects was based on the power calculation to obtain a statistically significant (α= 0.05) HbA_{1c} of 0.4% between pre and post intervention study with 80% power and allowing for a 15% dropout rate.

Dietary intervention carried out was in the form of individualised dietary counselling, given on a one-to-one basis by a single dietitian over a 12-week period. All subjects received the MNT intervention at baseline and emphasized at week 4 and 12. The primary goals of the intervention were to achieve reduction in HbA_{1c} and improvement in metabolic parameters.

Nutritional prescriptions were based on the Malaysian MNT Guidelines for Type 2 Diabetes [7] and Malaysian Clinical Practice Guidelines for Type 2 Diabetes Mellitus [8]. Accordingly, the distribution of macronutrients aimed to provide 15-20%, 25-30% and 50-60% of total energy from protein, fat and carbohydrate intake, respectively. We targeted in achieving fibre intake of 25-30 g/day by promoting whole grain products, oats specifically during breakfast, and legumes, fruits and vegetables. Cholesterol intake was restricted to less than 200 mg/day, in view of reducing risks of cardiovascular diseases.

Nutrient and energy prescriptions were made according to individual energy requirements, which was derived from the Quick Method formula as follows: $Energy_{requirement}$ = weight (kg) x quick method factor [7,9]. Values of the quick method factor were determined based on the subject's body mass index and physical activity level. In principle, the higher the BMI, the lower the values of the quick method factor selected, so that the goal for weight loss could be attained.

Dietary intake assessments were carried out by the primary investigator at baseline (used as the basis for individualised dietary counselling), week 4 and 12 of the study using three day food records. Two weekdays and one weekend-day were specified in the record to account for the variation in food intake data. Subjects were asked to record all food and beverages consumed in the three 24-h periods. These food records were returned at each visit and were reviewed together with the subjects before being analysed. All food records obtained were checked for discrepancies and omissions, including food preparation, cooking method, food brand, portion size and ingredients to ensure completeness of the records and improve their validity.

Nutrient analyses were performed using a computerised dietary analysis program (Nutritionist Pro Version 2.0; First Data Bank, The Hearst Corp, NY USA). The results were presented as mean daily intake of energy, protein, total carbohydrate, fat, cholesterol, fibre, sodium and calcium.

The dietitian assessed adherence to dietary instruction at each visit. Similarly, the validity of the food records were scrutinised with the use of specific criteria [10]. Adherence was rated using categorical scores that ranged between 1 and 3. Category 1 was for the subjects who adhered closely to the advice given (good), category 2 was for those subjects who adhered generally to the advice given and dietary intake was acceptable to diabetes management (medium) and category 3 for those subjects who did not adhere to the advice and dietary intake was unacceptable for diabetes management (poor).

The knowledge assessment questionnaire was based on the content of the counselling session. It was designed to include questions on the importance of dietary aspects to manage diabetes, the role of specific nutrients on blood glucose level and the food myths practices in achieving good glycemic control. A total of 15 questions was developed and pre-tested prior to the intervention. It was written in true/false format (n=10) and multiple choice option (n=5).

Measurements were performed in the morning after the subjects had fasted for at least 10 hours at baseline, week 4 and 12 of the study. Body weight was measured using a digital weighing scale (SECA; London British Indicators, UK) to the nearest 1 kg in light clothing with empty pockets, without shoes, watch and other accessories. Height was measured with the height attachment on the same weighing scale (SECA; London British Indicators Ltd) to the nearest 0.1 cm with the subjects not wearing shoes. Body weight and height measurements were used to calculate the body mass index (BMI). Waist circumference was measured to the nearest 0.1 cm at the midway between the lowest rib and the iliac crest. Blood pressure was measured with the use of a fully automatic blood pressure monitor (Omron M4-I; Omron Healthcare Europe BV, Hoofdorp, Netherlands). Subjects rested in a supine position with the head slightly elevated for 5 min before the blood pressure was measured and a mean of two measurements was used.

Fasting blood samples were drawn through the antecubital arm vein for glucose, fructosamine, HbA_{1c}, insulin levels and lipid profiles. Blood was centrifuged for 10 min at 1006 x g and serum or plasma was stored frozen at -20 °C until they were analysed, except for HbA_{1c}. The blood for HbA_{1c} was kept refrigerated at 4 °C and was analysed in a batch within a week of collection. Serum fasting glucose, plasma fructosamine, HbA_{1c} and plasma lipid components (triglyceride, total and HDL-cholesterol) were measured using the COBAS Integra(R) 800 automated analyser (Roche Diagnostic, Basel, Switzerland) with specific enzymatic assay. Serum LDL was calculated using the Friedewald *et al.*[11] equation. Plasma insulin was determined by a solid-phase, two-site chemiluminescent enzyme-labelled immunometric assay (Immulite(R) 1000 Analyser; Diagnostic Company Procedure, Deerfield IL USA). Estimate of relative insulin resistance introduced as a homeostasis model assessment (HOMA-IR) were calculated according to Matthews *et al.*[12]

An intent to treat analysis was performed on the assumption that subjects adhered to the dietary advice and had baseline and endpoint values of HbA_{1c}. All data were normally distributed except for the insulin values. These values were log transformed to improve symmetry and homoscedasticity of the distribution. However, values displayed in the table were in the original scale of measurement. Descriptive

Table I: Baseline characteristics of the study patients (n=100)

Characteristics	Mean ± SD	95% CI
Age (years)	56.4 ± 9.9	54.4, 58.4
Duration of diabetes (years)	6.5 ± 4.9	5.4, 7.3
	n	**%**
Gender (female)	63	63.0
Ethnicity		
Malay	53	53.0
Chinese	30	30.0
Indian	15	15.0
Others	2	2.0
Marital Status		
Single	8	8.0
Married	74	74.0
Widowed/Divorced	18	18.0
Education Level		
No formal education	10	10.0
Primary	31	31.0
Secondary	39	39.0
Tertiary	20	20.0

Table II: Glycaemic and metabolic parameters of the patients (n=100) over 12 weeks study period (mean + SD)

Variables	Baseline	Week 4	Week12	[i]p value
Glycemic control				
Fasting blood glucose (mmol/L)	7.18 ± 2.0	6.96 ± 2.1[a]	7.52 ± 2.1[a]	< 0.05
Fructosamine (umol/L)	311.5 ± 49.5	297.0 ± 44.0	NM	< 0.001
HbA_{1c} (%)	7.60 ± 1.2	NM	7.20 ± 1.1	< 0.001
HbA_{1c} categorizationiv				
Optimal (n=26)	6.37 ± 0.3	-	6.49 ± 0.9	NS
Moderate (n=24)	7.04 ± 0.2	-	6.77 ± 0.5	< 0.01
High (n=22)	7.70 ± 0.2	-	7.14 ± 1.2	< 0.001
Very High (n=28)	9.25 ± 0.7	-	8.36 ± 1.2	< 0.001
Anthropometric measurements				
Body weight (kg)	68.0 ± 12.5	67.8 ± 12.6	67.6 ± 12.4	NS
BMI (kgm-2)	26.9 ± 4.8[a]	26.8 ± 4.8	26.8 ± 4.8[a]	NS
Waist circumference (cm)				
Men	94.0 + 8.7[a,b]	92.6 ± 8.8[a]	92.3 ± 8.0b	< 0.05
Women	88.6 ± 10.5[a,b]	87.7 ± 10.4[a]	87.3 ± 10.3b	< 0.05
Blood Pressure (mmHg)				
Systolic	133.2 ± 18.2	131.3 ± 16.9	132.2 ± 16.2	NS
Diastolic	78.0 ± 9.2	76.7 ± 9.0	77.2 ± 9.0	NS
Lipid profile (mmol/L)				
Triglyceride	1.43 ± 0.5	1.48 ± 0.8	1.52 ± 0.6	NS
Total cholesterol	4.55 ± 0.8	4.59 ± 0.9	4.67 ± 1.0	NS
LDL-cholesterol	2.78 ± 0.7	2.75 ± 0.7	2.80 ± 0.9	NS
HDL-cholesterol	1.12 ± 0.3[a,b]	1.16 ± 0.3[a]	1.18 ± 0.3[b]	< 0.05
Insulin level (umol/L)[ii, iii]				
Fasting insulin	12.08 ± 3.4	NM	11.35 ± 2.1	NS
HOMA-IR	3.68 ± 0.9	NM	3.74 ± 0.6	NS

[i]Repeated measure procedure using within-patients design
[ii]Mean + SE; iiiStatistical analyses were performed on log-transformed data
[a,b] Means in a row with like superscript letters are significantly different
[iv]Categorization was based on baseline HbA1c quartiles
BMI, body mass index; HOMA-IR, homeostasis model assessment;
NM, not measured; NS, Not significant

Table III: Dietary intake of the patients (n=100) over 12 week period (mean + SD)

Variables	Baseline	Week 4	Week 12	[i]p value
Energy (kcal/day)	1658.3 ± 348	1522.4 ± 338	1518.0 ± 325	NS
EI:BMR	1.2 ± 0.3	1.1 ± 0.3	1.1 ± 0.3	
Protein				
Gram	68.0 ± 15.0	69.7 ± 15.5	68.3 ± 15.1	NS
% energy	16.6 ± 2.6	18.3 ± 2.7	17.9 ± 2.7	
Carbohydrate				
Gram	229.16 ± 50.3 [a,b]	205.4 ± 50.2 [a]	203.4 ± 46.7 [b]	< 0.01
% energy	55.6 ± 4.4	53.4 ± 4.4	53.1 ± 4.4	
Fat				
Gram	51.5 ± 14	48.4 ± 13	50.7 ± 17.7	NS
% energy	27.7 ± 4.1	28.4 ± 4.1	28.8 ± 4.3	
Cholesterol(mg)	248.8 ± 70.9 [a,b]	230.1 ± 73.4 [a]	222.2 ± 70.7 [b]	< 0.001
Fibre (g)	10.6 ± 5.8 [a,b]	18.7 ± 10.6 [a]	17.4 ± 10.6 [b]	< 0.001
Calcium (mg)	626.8 ± 320.1 [a,b]	729.8 ± 291 [a]	697.0 ± 311 [b]	< 0.001
Sodium (mg)	2134.2 ± 834.5	2056.9 ± 712.5	2132.3 ± 859.8	NS

[i]Repeated measure procedure using within-patients design
[a,b] Means in a row with like superscript letters are significantly different

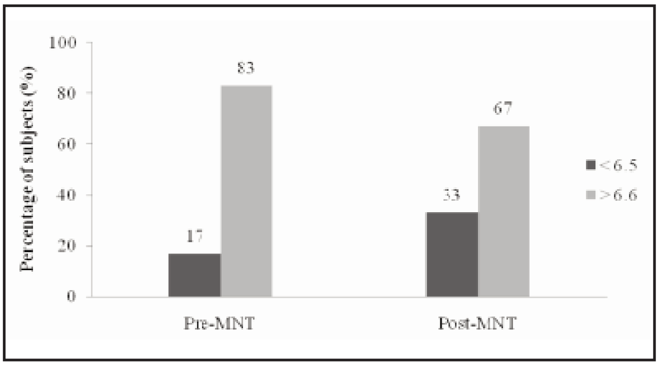

Fig. 1: Percentage of patients achieving target HbA1c levels before and after MNT Intervention.

statistics was used to describe the baseline demographic characteristics. Comparisons between pre-post analyses were made by using a student T-Test analysis. To determine whether the changes in HbA_{1c} level were greater for subjects who started with optimal-to-moderate or high levels of glycemic control, subjectswere categorised based on the quartiles of baseline HbA_{1c} levels: optimal (<6.7%), moderate (6.71-7.29%), high (7.30-8.29%) and very high (> 8.30%). The significance level for all tests was set at $p < .05$ and all statistical analyses were performed by using the latest version of SPSS software at that time (SPSS Inc. Chicago, USA).

RESULTS

Of the 104 eligible subjects recruited, 100 subjects completed the 12 week study (3.8% dropout rate). The key characteristics of the subjects are presented in Table I. With respect to treatment modalities, only a small percentage (10%) of the subjects was treated with diet alone. The remaining subjects were on either single (29%) or dual (61%) oral diabetic agents. Hyperlipidemia was the most common co-morbid condition, with 76% of the subjects on lipid lowering drugs (statin and/or fibrate). More than half of the subjects (60%) were taking anti-hypertensive drugs, which include B-blockers, angiotensin converting enzyme (ACE) inhibitors, anti-diuretics and/or calcium antagonist.

The average fasting blood glucose and HbA1c of the subjects were higher than the target treatment goals (Table II) [8]. More than half (62%) of the subjects were either overweight or obese, with a majority of them manifesting abdominal obesity with waist circumference measures exceeding 90 cm and 80 cm for men and women, respectively [8]. On average, systolic blood pressure and LDL-cholesterol were also higher as compared to the recommended value[8].

Significant improvement in glycaemic control was indicated by a reduction of fructosamine (311.5 ±49.5 to 297.0 ±44.0 umol/L, p<0.001) at week 4 and HbA_{1c} level at week 12 (7.6 ±1.2 to 7.2 ±1.1%, p<0.001); with an absolute change of 0.4% compared to the pre-MNT level (Table II). Subjects who started on the intervention with a very high HbA_{1c} level had a larger reduction in HbA_{1c} (-0.93%) at the end of the study (p< 0.001) and these changes were significantly different with their counterparts who had moderate (-0.3%) and optimal HbA1c levels (+0.1%) at the start of the study. Interestingly, the proportion of subjects who had achieved the target treatment goal for HbA_{1c} level of less than 6.5% after the MNT intervention had increased significantly compared to the baseline levels (p< 0.001; Figure 1). Nevertheless, despite an improvement in glycaemic control, there was a significant increment in fasting blood glucose at post MNT visit (p< 0.01; Table II). Body weight, BMI and waist circumference showed significant reduction over time at post MNT intervention (Table II). Lipid profile remained unchanged over the study with the exception for serum HDL-cholesterol, which had increased significantly by 5% at week 12.

At the end of week 12, majority of the subjects were able to achieve satisfactory knowledge scores with mean total scores at the end of intervention (74.6 ±17%) increasing significantly compared to baseline levels (41.9 ±18; p< 0.001). There was no significant decrease in energy intake from the baseline. Nevertheless, about 54% of the subjects were under reporting their energy intake at pre and post MNT intervention based on the Goldberg *et al.* criteria[13]. The proportions of macronutrients intake were still within the recommended range [7]. Dietary carbohydrate reduced (pre-MNT = 55.6 ±4.4; post-MNT = 53.1 ±4.4%, p< 0.001) while protein (pre-MNT = 16.6 ±2.6; post-MNT = 17.9 ±2.7 %, p< 0.001) and fat (pre-MNT = 27.7 ±4.1; post-MNT = 28.8 ±4.3%) increased after the MNT intervention as compared to the baseline levels. In terms of other nutrients, the mean intake of dietary cholesterol was reduced while dietary calcium and fibre increased significantly throughout the study period (p< 0.001).

At each visit, subjects generally adhered to the advice given (medium). Peak of adherence were observed at week 4 with majority of them had good adherence rate (good). However, towards the end of intervention, most of them were only at the level of generally adhered to the advice given (medium). There were no significant association between level of HbA_{1c} and adherence rate of the subjects. In terms of subjects' characteristics, those from the older age group and either being Chinese or Indian ethnicity were the one who responded well to MNT.

DISCUSSION

Individualised MNT administered by a dietitian resulted in favourable diabetes outcomes in individuals with type 2 diabetes. Subjects in this study were overweight and presented with poor glycemic control and metabolic outcomes (high waist circumference, blood pressure, and LDL-cholesterol) at entry into the study. However, after the 12-week of MNT intervention, subjects achieved significant reduction in glycemic control (measured by fructosamine at week 4 and HbA_{1c} level at week 12) and improvement in waist circumference and HDL-cholesterol after the 12-week intervention. Interestingly, approximately 70% of the subjects were able to achieve the target treatment goal of HbA_{1c} <6.5% - an increment of 94% from the pre-intervention level.

The overall improvement in HbA_{1c} (0.4%) however, may seem to be small as compared to 0.9-1.9% documented by Pastor *et al.*[14] in her review on the use of MNT-based intervention among individuals with type 2 diabetes in the U.S. Nonetheless, it is important to note that the relationship between HbA_{1c} and diabetes complications is continuous as suggested in UKPDS findings. Hence, no matter how small it is, improvements in HbA_{1c} will improve the prognosis of diabetes [15].

Another notable finding is that HbA_{1c} levels before the intervention affected the magnitude of change MNT could have on glycemic control in individuals with type 2 diabetes. This was consistent with Sigurdardotti *et al.*[16], who identified that pre-intervention HbA_{1c} is one of the important factors in predicting magnitude of changes in glycaemic control in response to patient education. In this study, the greatest HbA_{1c} reduction (-0.9%) was found in individuals with very high HbA_{1c} at the start of the study than the individuals who started with optimal (+0.1%) to moderate (-0.3%) levels of HbA_{1c}.

The improvement in waist circumference is a proxy measure of visceral fat reduction [17]. This is important as an excess in visceral adiposity has been associated with more difficult to control glycaemia and diabetes related complications among diabetics [18]. A small increment in HDL cholesterol at post-intervention visit can be clinically important and relevant to the management of diabetes. This is because a low HDL level elicits clinical fatalism which has been highly associated to the increased risk of CVD mortality among individuals with diabetes [19].

Despite all the above-mentioned improvements, a significant deterioration of fasting blood glucose (FBG) at the end of 12-weeks was an unexpected finding. However, fasting blood glucose should not be solely used to assess glycemic control, as fasting glucose has wide variability within individuals [20]. Indeed, in view of its impact on diabetes related complications, HbA_{1c} could be perceived as a better predictor of glycemic control as against fasting glucose level [21, 22].

In terms of dietary intake assessments, subjects were able to increase fibre and calcium while reducing dietary cholesterol significantly as compared to the pre-intervention consumption. However, the changes still fell short of achieving recommended intakes for these dietary components [7]. Furthermore, ensuring patient adherence to diabetes regimen is recognized as a challenge in diabetes management [6,22-23]. In this context, it is interesting to note that majority of the subjects were able to adhere to the prescribed diet and improved their nutrition knowledge at the end of the intervention. Nonetheless, good adherence to the MNT intervention was not sustained until the end of the study. This phenomenon is common in most dietary interventions with maximal effect usually seen early followed by a waning of compliance [24].

Age and ethnicity were also identified as an important factor of adherence to diet in the study subjects. Those from the older age group and either being Chinese or Indian ethnicity were the one who responded well to MNT. In terms of age and dietary adherence, Ingersoll *et al.* [25] have seen that patients who were more mature, perceived themselves to have better control over their self management of diabetes. On the other hand, ethnic inequalities and dietary adherence remain uncertain and warrant future study. However, previous study have documented that Malay ethnicity were associated with poor glycemic control in Malaysia [26] and similar finding was also observed in neighbouring Asian countries with similar multi-ethnic populations of Malays, Chinese and Asian-Indians [27].

While improvement in glycemic control and diabetes-related outcomes seems intriguing, the authors nonetheless caution against over interpretation of the results given the facts that this was a small, non-randomised, pre-post design without a control arm. Although such design may suffer from threat to internal validity, it can still provide preliminary evidence for intervention effectiveness. Second, the high prevalence of dietary intake under-reporting leads to uncertainty in terms of reliability of the dietary data. However, the high retention rate throughout the study is also strength, as dietary intervention has been previously perceived to be the most difficult aspect of management. The successful retention of subjects could be due to individualized dietary approach by a dietitian and frequent visits as opposed to the routine care.

CONCLUSION

This study provides additional evidence to support the positive impact of individualized MNT intervention administered by a dietitian in improving diabetes outcomes among subjects with type 2 diabetes, with the impact being most apparent for subjects with very high HbA_{1c} levels at the start of the study. For the future, randomised clinical trials are warranted to further explore the long term intervention specifically for those individuals with poor control glycemic level. The need to explore various approaches to adopt and maintain dietary changes among Malaysian diabetics over long periods is also widely recognized.

ACKNOWLEDGEMENTS

We would like to thank all the subjectsand medical laboratory technologists of the Endocrine Unit of Universiti Kebangsaan Malaysia Medical Centre for their participation in the study.

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