

# INTRODUCTION

Nutrition therapy (NT) is essential in managing patients with type 2 diabetes (T2D) and obesity. While it aims to improve glycemia and induce weight less, it is often associated with depletion of essential micronutrients.

## AIM

This study evaluates the effect of NT implemented in 2 different models on macro- and micronutrient dietary intake in patients with T2D and are overweight/obese.

# METHODS

We randomized 108 participants (ratio 1:2) to receive individualized dietary plan (IDP) or structured dietary plan (SDP) (fig. 1); that includes specified menus, diabetesspecific meal replacements and snacks (fig. 2). SDP were further randomized to receive additional weekly phone coaching or not. Participants had 3 visits and 2 follow-up phone calls with a registered dietitian (RDN) over 16 weeks. They were asked to provide a 3-day dietary log at each visit. We analyzed data from 81 participants (75%) who completed 16 weeks of follow-up and had completed 3-day dietary records. Their baseline characteristics are listed in Table 1.

# Improved Intake of Essential Nutrients Following Structured Nutrition Therapy versus Individualized Dietary Plan for Overweight and Obese Patients with Type 2 Diabetes: A Randomized Clinical Study

Barakatun-Nisak Mohd-Yusof, PhD<sup>1,2</sup>; Adham Mottalib, MD<sup>1</sup>; Veronica Salsberg, MS RDN<sup>1</sup>; David Pober, PhD<sup>1</sup>; Wael Mohamed, MD<sup>1</sup>; Joanna Mitri, MD<sup>1</sup>; Osama Hamdy, MD, PhD<sup>1</sup> <sup>1</sup>Joslin Diabetes Center, Harvard Medical School, Boston, MA and <sup>2</sup>Universiti Putra Malaysia, Selangor, Malaysia

**Dietary Plan** 

(n=33)

57 ± 10

66.7

 $10.8 \pm 9.3$ 

 $8.19 \pm 1.04$ 

 $100.4 \pm 21.3$ 

35.2 ± 7.2

**1916 ± 675** 

**212 ± 86** 

43 ± 8

**15 ± 6** 

85 ± 39

**38 ± 6** 

12 ± 2

**81 ± 22** 

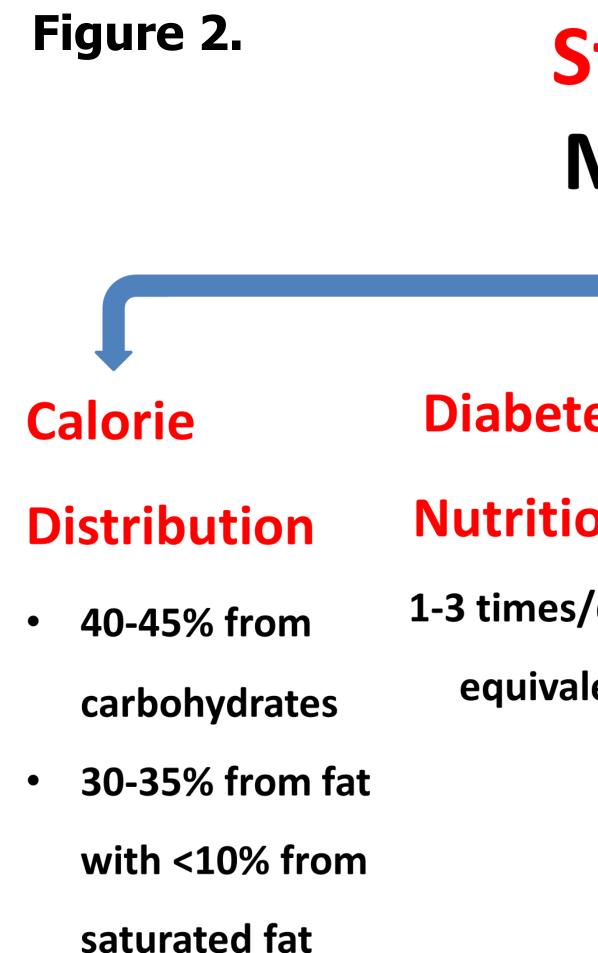
17 ± 4

Figure 1.

Individualized **Dietary Plan** 



Under RDN supervision



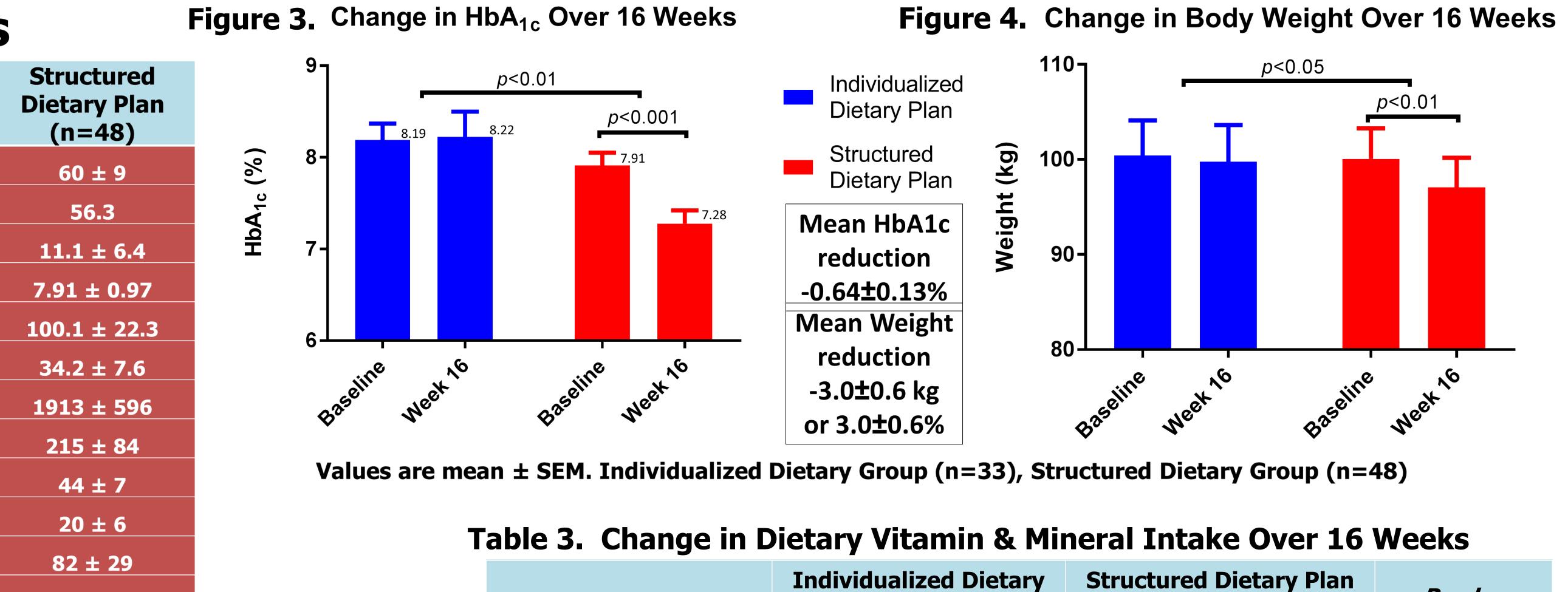
- 1-1.5 gm/kg of body weight from protein
- 14g fiber/1000 Kcal

## **Baseline Characteristics** Table 1 Nutrition Therapy Age (years) Sex (Female %) **Diabetes Duration (years)** Structured HbA1c (%) **Dietary Plan** Body weight (kg) BMI (kg/m²) Energy intake (kcal/day) **Carbohydrate intake (g/day)** % of energy Under RDN Fiber intake (g/day) supervision Total fat intake (g/day) % of energy 50% of subjects in this group Saturated fat intake (% of energy) were randomized to receive Protein intake (g/day) weekly coaching % of energy Values are mean $\pm$ SD. Groups were not significantly different at baseline Table 2. Change in Energy, Macronutrient & Fiber Intake Over 16 Weeks

Structured Meal Plan					
es-Specific on Formula	Dinner Menus	Snack Lists			
/day to replace lent calories	17 choices with detailed ingredients, cooking instructions and nutrition facts	<section-header></section-header>			

	Individualized Dietary Plan (n=33)		Structured Dietary Plan (n=48)		<i>P value</i> difference between
	Baseline	Week 16	Baseline	Week 16	groups over time
Energy intake (kcal/day)	1916 ± 118	1727 ± 83*	1913 ± 104	1624 ± 68***	NS
Carbohydrate intake (g/day)	211.8 ± 14.9	182.1 ± 9.9*	<b>215.0 ± 14.6</b>	175.2 ± 9.0***	NS
% of energy	43 ± 1	42 ± 2	44 ± 1	<b>41 ± 1</b>	NS
Fiber intake (g/day)	15.3 ± 1.0	17.0 ± 1.3*	19.8 ± 1.1	22.9 ± 1.0**	<0.01
Total fat intake (g/day)	84.9 ± 6.8	75.1 ± 5.1	81.8 ± 5.0	66.5 ± 3.2***	NS
% of energy	<b>38 ± 1</b>	<b>38 ±1</b>	<b>38 ± 1</b>	36 ± 1**	NS
Saturated fat (% of energy)	12 ± 1	12 ± 1	12 ± 1	9±1***	<0.01
Protein intake (g/day)	81.1 ± 3.9	83.2 ± 4.6	86.0 ± 3.9	92.5 ± 3.2*	NS
% of energy	17 ± 1	19 ± 1	18 ± 1	23 ± 1***	NS

The Usual Care cohort received care from an endocrinologist.



Week 16 Baseline 633.9 ± 177.7 461 ± 49.3 487.3 ± 43.7 Vitamin A (RAE/day) 0.93 ± 0.08 0.86 ± 0.07 0.93 ± 0.06 Vitamin B<sub>1</sub> (mg/day)  $1.1 \pm 0.1$ 1.3 ± 0.1  $1.4 \pm 0.1$ Vitamin B<sub>2</sub> (mg/day) 15.3 ± 1.0 15.5 ± 1.3 16.5 ± 1.3 Vitamin B<sub>3</sub> (mg/day) 1.3  $\pm$  0.1 1.3  $\pm$  0.1 2.2 ± 0.3 Vitamin B<sub>6</sub> (mg/day) 4.7 ± 1.4 2.5 ± 0.3 3.9 ± 0.5 Vitamin B<sub>12</sub> (mcg/day) 183.2 ± 108.5 88.9 ± 10.3 84.0 ± 7.3 Vitamin C (mg/day) **2.2 ± 0.3 2.3 ± 0.4**  $4.0 \pm 1.4$ Vitamin D (mcg/day) **4.5 ± 0.7 12.3 ± 8.3** 4.9 ± 0.5 Vitamin E (mg/day) 240.3 ± 26.5 228.2 ± 24.9 263.0 ± 24.0 Folate (mcg/day) 121.5 ± 31.9 91.7 ± 16.9 122.4 ± 19.2 Vitamin K (mcg/day) 3.6 ± 0.3 3.2 + 0.2 3.9 ± 0.2 Pantothenic acid (mcg/dav) 656.1 ± 50.0 552.3 ± 38.5 681.8 ± 42.8 Calcium (mg/day) 0.9 ± 0.3 0.6 ± 0.1 4.9 ± 4.1 Copper (mg/day) 13.5 ± 1.433.2 ± 19.718.4 ± 5.3 Iron (mg/day) 147.9 ± 15.4 139.8 ± 10.5 173.6 ± 12.2 Magnesium (mg/day) 754.8 ± 53.6 700.7 ± 51.8 754.8 ± 44.4 Phosphorous (mg/day) L680.8 ± 115.5 1607.9 ± 93.9 1852.3 ± 89.5 Potassium (mg/day) 62.9 ± 6.3 197.7 ± 136.6 65.8 ± 4.1 Selenium (mcg/day) 3301.1 ± 296.6 2798.7 ± 206.4 2977.6 ± 174.9 Sodium (mg/day)

**Plan (n=33)** 

Values are mean ± SEM. \* p<0.05, \*\* p<0.01, \*\*\* p<0.001 compared to baseline. N=68 in each cohort. The Why WAIT cohort was enrolled in a 12-week intensive lifestyle intervention program.

Zinc (mg/day)

6.5 ± 0.6 6.0 ± 0.6

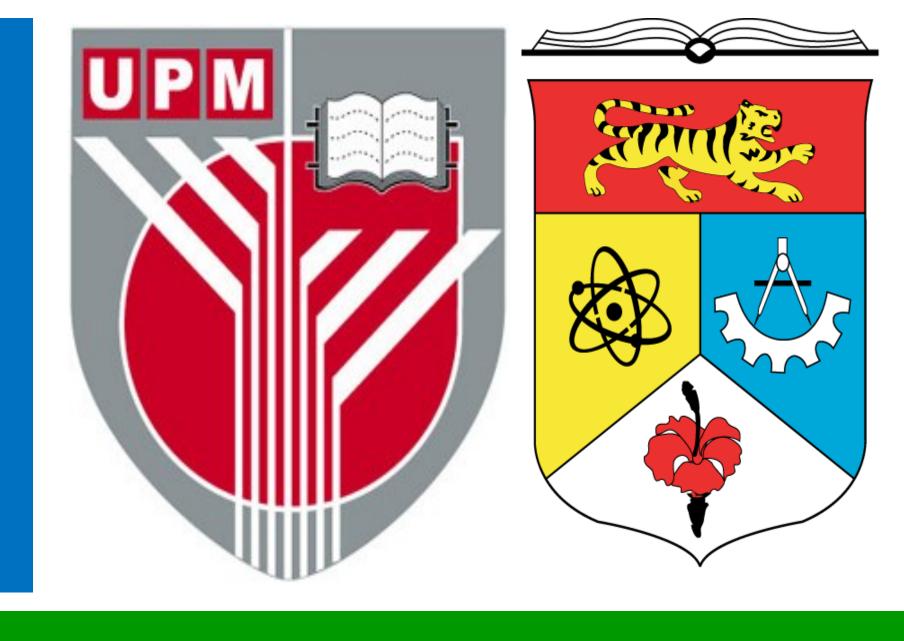
7.5 ± 0.9

**18 ± 4** 

**38 ± 6** 

12 ± 3

86 ± 23



ietary Plan 18)	<i>P value</i> difference between		
Week 16	groups over time		
502.4 ± 88.8	NS		
1.42 ± 0.06**	<0.001		
1.7 ± 0.1*	<0.01		
23.8 ± 1.1	<0.01		
<b>2.2 ± 0.1</b> *	NS		
5.9 ± 0.4**	NS		
121.4 ± 8.0	NS		
10.3 ± 5.5	NS		
3.8 ± 0.3	NS		
354.8 ± 23.1	<0.05		
118.0 ± 18.1	NS		
10.4 ± 2.0**	<0.01		
09.2 ± 31.3***	<0.001		
4.0 ± 0.1	NS		
18.8 ± 0.6	NS		
59.0 ± 18.5***	<0.001		
.087.8 ± 41.7**	<0.001		
2288.8 ± 117.3**	<0.01		
172.7 ± 6.0***	NS		
2232.4 ± 130.9	NS		
40.5 ± 1.3***	<0.001		

# RESULTS

Both interventions reduced energy, carbohydrate and fat intake compared to baseline with no difference between groups. HbA1C and weight decreased in SDP compared to IDP (HbA1c  $-0.64 \pm 0.13\%$  vs  $0.01 \pm 0.19\%$ , p < 0.01; weight  $-3.0 \pm 0.6$  kg vs  $-0.9 \pm 0.5$  kg, p<0.05) (fig 3 & 4). Dietary fiber intake increased while saturated fat intake decreased in SDP compared to IDP (p<0.01) (table 2). Energy intake from protein was higher in SDP compared to baseline (p<0.001) (table 2). Participants in the SDP significantly increased intake of vitamins B1, B2, B3, B9, B12, pantothenic acid (B5), dietary calcium, magnesium, phosphorus, potassium and zinc compared to IDP (table 3). No difference in micro- or macronutrients between SDP with or without weekly RDN phone support.

# CONCLUSION

For overweight and obese patients with T2D, a structured nutrition plan provided by RD reduces A1C, body weight and improves level of 11 essential nutrients compared to current recommendation of individualized meal plan despite providing similar caloric level and macronutrient composition.