# Voranuch Lomsoonthorn<sup>1, 2, \*</sup>, Daruneewan Warodomwichit<sup>1</sup>, Kulapong Jayanama<sup>1</sup>

<sup>1</sup> Faculty of Medicine Ramathibodi Hospital, Mahidol University, Bangkok, 10400, Thailand <sup>2</sup> Institute of Nutrition, Mahidol University, Salaya, Phutthamonthon, Nakhon Pathom, 73170, Thailand

#### **ABSTRACT:**

**Background:** Overweight and obesity are two major public health problems that affect health of people both short term and long term. Controlling energy from diet and modification ratio of nutrient intake are alternative choices for reducing weight. This study aimed to compare high and normal protein diet intake which results in changing the anthropometric assessment and biochemical assessment of the body.

**Methods:** This was randomized controlled clinical trials design. The recruitment of research participants were officers of the Ramathibodi Hospital. All the participants were both male and female (73 participants), aged 25 – 50 years, and had BMI 23.0 – 39.9 kg per square meter. They were divided into two groups (normal and high protein group). In the first five months, all participants received the supplement with energy of 150 kilocalories; and the next 5 months the researcher introduced the meal suggestions. They were assessed the nutritional status (measured anthropometric, biochemical and dietary surveys).

**Results:** Forty three participants who completed the 10 months weight reduction were statistically significant difference between time at the same group (P<0.05). Body Mass Index (BMI), Body Fat Mass (BFM), Percent Body Fat (PBF) and Visceral Fat Area (VFA) dropped similarly to weight loss. There was no change in biochemical ( $P \ge 0.05$ ) throughout the study period. However, HDL–Cholesterol increased overtime in both groups (P<0.05).

**Conclusion:** The ratio of the amount of protein intake had no effect on weight loss including the anthropometry assessment and biochemistry assessment.

Keywords: Obese; Normal protein; High protein; Energy restriction diet; Supplement

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## **INTRODUCTION**

In the present scenario, the number of people with overweight (BMI  $\geq 25 \text{ kg/m}^2$ ) and obesity (BMI  $\geq 30 \text{ kg/m}^2$ ) is likely to rise in both male and female in almost every country around the world [1]. The obesity is the effect of the imbalance between energy intake and requirement of the body, resulting in the accumulation of fat in various parts of the body. Moreover, other factors that promote obesity

Correspondence to: Voranuch Lomsoonthorn E-mail: sesamae4@gmail.com, voranuch.lom@hotmail.com are economy, society, genetics and environment. Obesity is also the risk factor that cause chronic Non communication Diseases (NCDs) related to the metabolic consequences; such as, depression, diabetes, cancer, cardiovascular disease and high blood pressure etc. [2]. Also, it is a leading cause of death [1, 3, 4].

Presently, there are various methods for losing weight [5, 6]. However, each of them has the weak point.

To reduce fat and maintain muscular mass both dietary therapy (by energy control with adequate protein consumption) and exercise for increase the

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energy of the body incorporating (with behavioral modification), the long term condition is very essential. The dietary protocols containing high protein seem to be the interesting methods because 1) protein increases satiety more than carbohydrate (CHO) and fats since, it increases serum amino acid level, stimulates hormones relating the satiation (glucagon-like peptide-1 (GLP-1), Diet-induced thermogenesis (DIT)) and reduces hormone (Ghrelin) that decreases appetite [7, 8]; 2) protein promotes muscle synthesis and maintenance as a result, the more oxygen consumption by increase of muscle mass raises the body temperature and increases the Total Energy Expenditure; especially, Resting Energy Expenditure [9]; 3) protein needs more energy for the digestion and absorption of food (Thermic Effect of Food) [8, 10]. Furthermore, decrease of carbohydrate intake reduces the secretion of insulin which stimulates the breakdown of fat (lypolysis) for energy instead of carbohydrate, which resulted in losing weight.

Therefore, the objective of this study was to assess the effect between High Protein (HP) and Normal Protein (NP) diet on body compositions and metabolic profiles in obese people.

# MATERIALS AND METHODS

## **Research method**

The randomized controlled clinical trials were

designed for this study. The sample size calculation was determined followed the study by Due, et al [11]. A total of 74 participants were recruited from the intranet of Ramathibodi Hospital and posted poster. The participants were divided into two groups of 37 people (Normal Protein (NP) and High Protein (HP) group), with expected 30% of participants withdrawn from the study [12]. All participants received isocaloric having similar caloric values of (1,200-1,500 kcal) [13]. In the first 20 weeks, both groups received the supplement with 150 kcal of energy (Table 1) and next 20 weeks the researcher introduced the meal plan (Table 2 and 3).

All participants were (1) apparently healthy aged > 20 years old with BMI > 23 kg/m<sup>2</sup>; (2) no underlying disease including cancer, heart disease, liver disease, kidney disease, endocrine disorders; (3) no pregnancy and/or lactation; (4) no drugs or supplements such as steroids and antidepressant; (5) No recently significant weight change; (6) did not engage in research that affects body weight during the same period; and (7) signed a written inform consent.

The study assessment of "Anthropometry (Body Composition) Assessment [Body weight, Height, and Bioelectrical Impedance Analysis (BIA)]" were done by Inbody 720 (InBody, Co.,Ltd, Cerritos, CA, USA). While, the "Biochemical Assessment" were focused on the Lipid profiles,

Supplement	Grams	Protein	СНО	Fat	Kcal
NP	30	7	11	8	150
HP	40	31	6	1	150

Table 2 Distribution of nutrient for NP group and HP group throughout the study period

Nutrients	Group 1 (NP)	Group 2 (HP)	
Protein	0.8-1.2g/kg IBW/day [14]	1.3-2g/kg IBW/day [15]	
Fat	25-30 %	25-30 %	
Carbohydrate	55-65 %	40-50 %	

IBW: Ideal Body Weight

#### Table 3 Distribution of nutrient for the meal plan

Portion	0-5 Months		6-10 Months	
	NP	HP	NP	HP
Supplement	1	1	0	0
Fruit	2	2	2	2
Rice (CHO)	6	6	6	6
Meat/Milk	4	4	8	5
Fat	4	4	4	4

Donomotor		NP	HP n=36	
Parameter		n=37		
Sex	Male	3	3	
	Female	34	33	
Age	years	$32.6 \pm 7.1$	$34.9\pm7.1$	
Weight	kg	$74.2\pm12.0$	$73.9 \pm 12.9$	
Height	cm	$159.5 \pm 5.6$	$158.9\pm6.8$	
BMI	kg/m <sup>2</sup>	$29.2 \pm 4.4$	$29.2 \pm 4.1$	
BFM	kg	$30.4 \pm 8.9$	$30.1 \pm 8.2$	
PBF	%	$40.3 \pm 5.9$	$40.4\pm6.5$	
LBM	kg	$43.9\pm4.9$	$43.9\pm8.3$	
SMM	kg	$24.0 \pm 3.0$	$24.0\pm5.0$	
TBW	L	$32.2 \pm 3.6$	$32.2 \pm 6.1$	
VFA	cm <sup>2</sup>	$109.2 \pm 24.2$	$108.4\pm24.0$	
BMR	kcal	$1,316.3 \pm 106.8$	$1,316.5 \pm 180.0$	
Glucose	mg/dL	$92.1 \pm 7.0$	$100.1 \pm 34.8$	
Cholesterol	mg/dL	$199.0 \pm 35.7$	$207.4 \pm 34.8$	
HDL-C	mg/dL	$48.1 \pm 8.6$	$48.3\pm10.7$	
LDL-C	mg/dL	$131.1 \pm 35.4$	$135.8\pm38.6$	
TG	mg/dL	$98.7 \pm 37.2$	$130.1 \pm 86.9$	
BUN	mg/dL	$10.2 \pm 2.5$	$9.9 \pm 2.3$	
Cr	mg/dL	$0.70 \pm 0.14$	$0.69\pm0.13$	
eGFR	ml/min/1.73 m^	$112.0 \pm 14.3$	$110.8\pm13.8$	
Total Energy	kcal	$1,323.5 \pm 465.6$	$1,386.0 \pm 414.0$	
Protein	g	$52.7 \pm 20.4$	$55.3 \pm 18.4$	
Carbohydrate	g	$189.6\pm89.5$	$193.3 \pm 14.4$	
Fat	g	$39.4 \pm 22.2$	$44.3\pm20.8$	
Protein	%cal	$16.6 \pm 5.0$	$16.3 \pm 5.0$	
Carbohydrate	%cal	$57.0 \pm 12.7$	$55.4 \pm 13.1$	
Fat	%cal	$26.4 \pm 10.3$	$28.3\pm10.8$	

Table 4 General characteristics of the participants at Baseline

No statistically significant difference between study periods without superscript

Fasting plasma glucose and renal function and the "Dietary Compliance" were on the 24 hr-recall and 3-day food record (record 2 day works and 1 day off).

## Statistical analysis

All statistical analyses were performed using SPSS version 23.0 (SPSS Inc., Chicago, IL, USA). Mean  $\pm$  SD for variables with distribution nonnormal (skewed); such as, age, sex, weight, height were presented. BMI was displayed as a number (%). Comparison on the differences between 2 groups (NP and HP content) of anthropometry, biochemistry and dietary characteristics analyzed were performed using the unpaired t-test. While, the comparisons on the difference of anthropometry, biochemistry and dietary characteristics (at baseline the 5<sup>th</sup> and 10<sup>th</sup> month of the study) were analyzed using the repeated measures ANOVA.

The INMUCAL-Nutrients V.3 (DB Version : NB.2) was used on all data dietary assessment (24 hour dietary recall and 3 day diet record) for

calculation of total energy from diet.

## **Ethical considerations**

This study was approved by the Ethical Clearance Committee on Human Rights related to Research Involving Human Subjects of the Faculty of Medicine Ramathibodi Hospital, Mahidol University, on December 30, 2014, the registration ethical approval number: MURA2014/643 Np  $Dec_{14}$  (Protocol number ID 11 - 57 - 41).

## RESULTS

#### **General characteristics**

There were no statistically significances between groups on age, anthropometry assessment, biochemistry assessment and dietary assessment of NP and HP group ( $P \ge 0.05$ ) (Table 4).

## Anthropometry assessments

After the trials ended, the body weight loss of both groups were statistically significant (P < 0.05) but there were no statistical significance between the

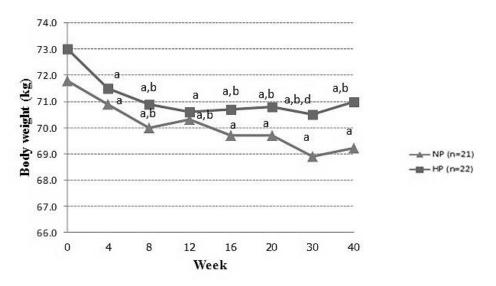


Figure 1 Alteration of body weight during the study

<sup>a, b, d</sup> Statistically significant difference between Week 0 4 8 12 16 20 and Week 30, respectively at the same group (P < 0.05). No statistically significant difference between study periods without superscript

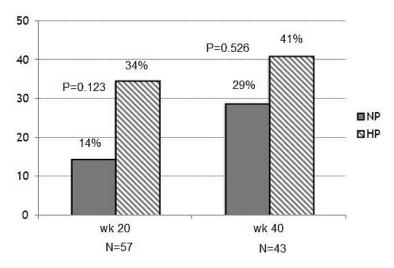


Figure 2 Percentage of participants with significant weight loss more than 5%

two groups' ability to lose weight according to their energy intake ( $P \ge 0.05$ ) (Figure 1).

In addition, the percentage of participants in HP group with significant weight loss more than 5% trend to be higher than the NP group (Figure 2).

BMI, Body Fat Mass (BFM), Percent Body Fat (PBF) and Visceral Fatty Acid (VFA) values reduced of both groups were statistically significant overtime within the same group (P < 0.05). Lean Body Mass (LBM), Skeletal Muscle Mass (SMM), Total Body Water (TBW) and Basal Metabolic Rate (BMR) of both groups were not statistically significant overtime within the same group ( $P \ge 0.05$ ).

## **Biochemistry assessments**

Glucose, cholesterol, Low-Density Lipoprotein-Cholesterol (LDL-C), Triglycerides (TG), Creatinine (Cr) and estimated Glomerular Filtration Rate (eGFR) of both groups were not statistically significant overtime within the same group ( $P \ge 0.05$ ).

High-Density Lipoprotein- Cholesterol (HDL-C) of both groups increased significantly overtime within the same group (P < 0.05).

## **Dietary assessments**

Daily total energy, of both groups, was lower towards the end of study, when compared to the beginning (Figure 3 and Figure 4).

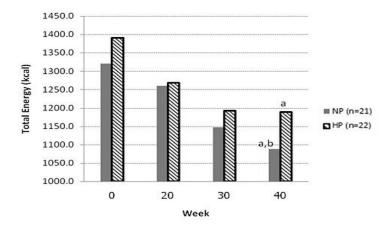


Figure 3 Alteration of daily total energy during the study

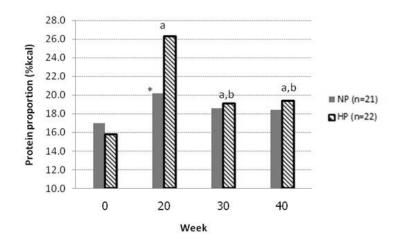


Figure 4 Alteration of daily total protein during the study

\* Statistically significant difference between groups at the same time period (P < 0.05). <sup>a, b</sup> Statistically significant difference between Week 0 20 and Week 30, respectively at the same group (P < 0.05)

#### DISCUSSION

In both groups, there were no significantly differences ( $P \ge 0.05$ ) on anthropometry, biochemistry and dietary assessments at the beginning and the end of the study in between groups.

After 10 months, all participants were able to lose weight, with statistically significance, as demonstrated on the anthropometry and biochemistry assessments. These results were consistent with the previous studies by Truby, et al. [16], Frestedt, et al. [17] and Clifton, et al. [18] because the participants received similar total energy intake from their diet, as well as similar lifestyles.

Since these two groups did not do any exercises, protein intake did not affect their weight, a similar result was found by Meckling, et al. [19]. Furthermore, the SMM of the participants in both groups did not change and but remained the same which it was suggested by Miller, et al. [20] that HP intake along with exercise can help improve body composition [21].

The result in this study showed similar finding as reported by Clifton, et al. [12] that the long term high protein intake can aid in weight loss and fat mass loss, if dietary restrictions was done continually.

While, the VFA decreased significantly over time, it also reduced the risk of various diseases such as metabolic syndromes, hypertension, and insulin resistance. Also, increasing levels of VFA played a role in building free fatty acids (more resist in hormone which resulted in the interference of insulin function [22].

Cholesterol and LDL-C of the both groups were no statistically significant difference. Our result concurred with the study by Schwingshackl, et al. [23] which found that high protein intake has no effect to blood lipids and a rather higher standard, which was the main cause leading to the risk factor of Heart Disease [24]. The HP gr had cholesterol and LDL-C slightly higher than NP gr.

The HDL-C of both groups were increasing statistically significant difference between time at the same group (P < 0.05) in long term, while the TG of both groups were decreasing due to decrease intake CHO. The Blood Urea Nitrogen (BUN) of both groups had slightly increased when compared to the baseline data. The total energy intake of two groups was no statistically significant difference between groups at the same time. However, when compared to the BMR (the basic energy needs of the body in resting time) it showed that the total energy intake was slightly higher. This could be contributed to the maintaining of weight [25].

There were a few limitations of this study: (1) we were not be able to collect the 24 hr-Urine urea nitrogen (UUN) and 24 hr-Cr, because the participants did not feel comfortable in complying; therefore, protein consumption could not be confirmed; (2) the duration of data collection in this study was long term; therefore, participants could not control their diet continuously and experiencing some contact lost. Therefore, for the future research study, we would recommend the combining of the exercise and diet restriction (controlled protein diet) in order to assess the anthropometry biochemistry and satiety.

## CONCLUSION

Regulating energy intake from diet without exercise can cause weight loss, which in turn, it could help maintaining weight. In addition, the ratio of the amount of protein intake had no effect on weight loss, including the anthropometry assessment, biochemistry assessment and satiety assessment. Lastly, the HP diet did not impair renal function from biochemistry assessment.

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