EFFICIENCY OF 40G SACHET MEDICAL FOOD (GEN-DM®) FOR CONTROL BLOOD SUGAR AND SERUM LIPID PROFILE IN THE TRANSPORT CO., LTD EMPLOYEES

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ABSTRACT

This study examined efficiency of 40g sachet medical food (Gen-DM®) to control blood sugar and serum lipid profile in the Transport Co., Ltd employees aged 24-60 years. There were 50 subjects consisting of 13 males and 37 females. The experiment took 12 weeks to compare between the dietary advice for lowering blood sugar and serum LDL-C for 4 weeks with two meals of dietary advice for weeks 1-4 and replaced the rest of the meal with Gen-DM 1-2 sachets for 8 weeks. Follow-up and assessment of the body composition, blood pressure, blood chemistry and 24 hr. recall were investigated throughout the study every 4 weeks. Subjects who consumed average Gen-DM (98.2%) throughout the study. It was found that the energy received from food and physical activity did not change from baseline period and had no adverse effects throughout the study.

During the first 4 weeks (week 4) of only the dietary advice, changes of blood sugar and LDL-C were not evident, but the body weight and body fat were significantly lower than baseline. On week 8 of taking Gen-DM together with the dietary advice, the body weight and body fat were significantly lower than baseline and week 4, but the blood sugar and LDL-C were significantly lower than only week 4. On week 12 of taking Gen-DM together with the dietary advice for 8 weeks, it was found that blood sugar and LDL-C were significantly lower than baseline and week 4, and body weight and body fat did not decrease from week 8.

In conclusion, Gen-DM as a medical food could significantly reduce blood sugar and LDL-C. Therefore, Gen-DM sachet for the Transport Co., Ltd employees could be taken when dining outside as one meal replacement and had two meals of recommended regular diets for improvement of their diet-related chronic diseases.

KEY WORDS: MEDICAL FOOD / GEN-DM / BLOOD SUGAR / LDL-C /
TRANSPORT CO., LTD

104 pages

ประสิทธิผลของการดื่มอาหารทางการแพทย์ (GEN-DM®) ขนาดพกพา (40 กรัม) ต่อการควบคุมระดับน้ำตาลและไขมันในเลือดของพนักงานบริษัท ขนส่ง จำกัด

EFFICIENCY OF 40G SACHET MEDICAL FOOD (GEN-DM®) FOR CONTROL BLOOD SUGAR AND SERUM LIPID PROFILE IN THE TRANSPORT CO., LTD EMPLOYEES

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บทคัดย่อ

งานวิจัยนี้ศึกษาประสิทธิผลของการดื่มอาหารทางการแพทย์ (GEN-DM®) ขนาดพกพา 40 กรัม ต่อการควบคุมระดับน้ำตาลและระดับไขมันในเลือดของพนักงานบริษัท ขนส่ง จำกัด อายุระหว่าง 24-60 ปี จำนวน 50 คน ประกอบด้วยชาย 13 คน และหญิง 37 คน ศึกษานาน 12 สัปดาห์ โดยเปรียบเทียบระหว่างการควบคุมอาหารเพื่อลดระดับน้ำตาลและระดับแอลดีแอล-โคเลสเตอรอลในเลือดเพียงอย่างเดียวนาน 4 สัปดาห์ กับการดื่มเจ็น-ดีเอ็ม 1-2 ซองแทนอาหารมื้อหลัก 1 มื้อ พร้อมกับควบคุมอาหารเช่นเดียวกับ 4 สัปดาห์แรกอีก 2 มื้อ นาน 8 สัปดาห์ ติดตามและประเมินผลทุก 4 สัปดาห์ด้วย สัดส่วนร่างกาย ความดันโลหิต ชีวเคมีในเลือด และข้อมูลการบริโภคอาหาร 24 ชม. ซึ่งบันทึกตลอดการศึกษา พบว่ากลุ่มตัวอย่างสามารถดื่มเจ็น-ดีเอ็มได้ตลอดการศึกษา โดยมีค่าเฉลี่ย 98.2% ของปริมาณที่กำหนดให้ดื่ม ปริมาณพลังงานที่ได้รับจากอาหารและกิจกรรมต่าง ๆ ไม่มีการเปลี่ยนแปลงจากก่อนการศึกษา และไม่มีอาการข้างเคียงใด ๆ เกิดขึ้นจากเจ็น-ดีเอ็ม

ภายหลังการควบคุมอาหารอย่างเดียวนาน 4 สัปดาห์ไม่พบการเปลี่ยนแปลงของระดับน้ำตาลและระดับแอลดีแอล-โคเลสเตอรอลในเลือด แต่น้ำหนักตัว และเนื้อเยื่อไขมันลดลงอย่างมีนัยสำคัญทางสถิติ และเมื่อดื่มเจ็น-ดีเอ็มพร้อมกับการควบคุมอาหารนาน 4 สัปดาห์แรก พบว่า น้ำหนักตัว และเนื้อเยื่อไขมันยังคงลดลงได้ต่อเนื่องอย่างมีนัยสำคัญทางสถิติจากก่อนการศึกษาและสัปดาห์ที่ 4 สำหรับระดับน้ำตาลและระดับแอลดีแอล-โคเลสเตอรอลในเลือดเริ่มลดลงต่ำอย่างมีนัยสำคัญทางสถิติจากก่อนการศึกษา และเมื่อดื่มต่ออีก 4 สัปดาห์ พบว่าระดับน้ำตาลและระดับแอลดีแอล-โคเลสเตอรอลในเลือดยังคงลดลงได้ต่อเนื่องอย่างมีนัยสำคัญทางสถิติจากก่อนการศึกษาและสัปดาห์ที่ 4 แต่น้ำหนักตัว และเนื้อเยื่อไขมันไม่ลดลงอีกจากสัปดาห์ที่ 8

ดังนั้นการนำเจ็น-ดีเอ็มซึ่งเป็นอาหารทางการแพทย์ที่มีคุณสมบัติช่วยควบคุมระดับน้ำตาลและระดับไขมันในเลือดมาพัฒนาเป็นขนาดพกพาเพื่อให้พนักงานดังกล่าวสามารถนำติดตัวไปใช้รับประทานแทนอาหารหลัก 1 มื้อพร้อมกับการควบคุมอาหารอีก 2 มื้อทำให้มีประสิทธิภาพในการการบำบัดโรคเรื้อรังที่สัมพันธ์กับอาหารที่ประสบอยู่ในกลุ่มพนักงานที่ไม่สามารถเลือกซื้ออาหารที่เหมาะสมกับโรคประจำตัวของตนได้

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LIST OF ABBREVIATIONS

AHA	American Heart Association
AHEAD	Action for Health in Diabetes
ANOVA	Analysis of Variance
AUC	Area under the curve
BCAA	Branched chain amino acid
BMI	Body mass index
BMR	Basal Metabolic Rate
BP	Blood pressure
bpm	Beats per minute
BUN	Blood urea nitrogen
bw	Body weight
CE	Coronary events
cm	Centimeter
CHD	Coronary heart disease
CI	Confidence interval
Cr	Creatinine
CRP	C-reactive protein
CVD	Cardiovascular disease
DBP	Diastolic blood pressure
DCCT	Diabetes Control and Complications Trial
dL	Deciliter
DRI	Dietary Reference Intake
EFA	Essential fatty acid
Etc.	Et cetera
F	Fructose
FDA	Food and Drug Administration
FPG	Fasting plasma glucose

LIST OF ABBREVIATIONS (cont.)

g	Gram
GI	Glycemic index
Hb	Hemoglobin
HbA1c	Hemoglobin A1c
HDL-C	High-density lipoprotein cholesterol
HF	Heart failure
HR	Hazard ratio
iAUC	Incremental area under the curve
IDF	International Diabetes Federation
IFG	Impaired fasting glucose
IGT	Impaired glucose tolerance
IHD	Ischemic heart disease
kcal	Kilocalories
kg	Kilogram
L	Liter
LA	Linoleic acid
LDL-C	Low-density lipoprotein cholesterol
LMICs	Low- and middle-income countries
LNA	Linolenic acid
m	Meter
mg	Milligram
MI	Myocardial infarctions
mmHg	Millimeter of mercury
mmol	Millimole
mL	Milliliter
MRI	Magnetic resonance imaging
MRS	Magnetic resonance proton spectroscopy
MS	Metabolic syndrome

LIST OF ABBREVIATIONS (cont.)

n	Number
NCEP	National Cholesterol Education Program
NGSP	National Glycohemoglobin Standard Program
NHANES	National Health and Nutrition Examination Survey
NS	Not significant
OA	Oleic acid
OGTT	Oral glucose tolerance test
PG	Plasma glucose
PUFA	Polyunsaturated fatty acid
r	Pearson's correlation coefficient
RCTs	Randomised controlled trials
RDI	Recommended Daily Intakes
RR	Relative risk
SBP	Systolic blood pressure
SD	Standard deviation
SES	Socioeconomic status
SFA	Saturated fatty acid
SGOT	Serum glutamic-oxaloacetic transaminase
SGPT	Serum glutamic-pyruvic transaminase
SPSS	Statistical Package for the Social Sciences
SSBs	Sugar-sweetened beverages
TBW	Total body water
TC	Total cholesterol
TG	Triglyceride
TP	Transport Co., LTD
U	Unit
USDA	United States Department of Agriculture
VLDL	Very low-density lipoprotein

LIST OF ABBREVIATIONS (cont.)

vs	Versus
WHO	World Health Organization

CHAPTER I
INTRODUCTION

1.1 Background

Diabetes is a chronic disease and is a leading cause of cardiovascular disease, blindness, kidney failure and lower-limb amputation. Diabetes worldwide in 2015 found that the 415 million adults are estimated to currently have diabetes. There are 318 million adults with impaired fasting glucose, which puts them at high risk of developing the disease in the future. Estimated number of people with diabetes in 2040 is 642 million adults. From diabetes 2015 IDF found that adults who died from diabetes 5.0 million. The number of people with diabetes is increasing in every country in the world. In 2015, diabetes prevalence in Thailand was 4.1 million adults and 76,000 adults died from diabetes (1).

Cardiovascular disease (CVD) is the most common cause of death and disability among people with diabetes. The cardiovascular diseases that accompany diabetes include angina, myocardial infarction (heart attack), stroke, peripheral artery disease and congestive heart failure (1). It was found that a high prevalence of dyslipidemia, which might be playing a major role in the development of cardiovascular diseases among diabetic patients (2).

Obesity and overweight pose a major risk for chronic diseases, including type 2 diabetes, cardiovascular disease, hypertension and stroke. The key causes are increased consumption of energy dense foods high in saturated fats and sugars, and reduced physical activity (3).

The worldwide prevalence of obesity was more than doubled between 1980 and 2014. In 2014 more than 1.9 billion adults, 18 years and older, were overweight. Of these over 600 million were obese. In 2014 overall about 13.0% of the world's adult population, aged 18 years and over, (11.0% of men and 15.0% of women) were obese and 39.0% (38.0% of men and 40.0% of women) were overweight (4).

In 2009, Thailand national health surveys by physical examination nationwide reported that from 1991-2009 the prevalence of overweight (BMI $\geq$ 25.0 kg/m^2) in Thai people aged 15 years and over was a twofold increase whereas there was a threefold increase in obese (BMI $\geq$ 30.0 kg/m^2) prevalence (5).

Obesity and abdominal obesity were the cause of many chronic diseases and increased the risk of cardiovascular disease, type 2 diabetes, dyslipidemia and hypertension. In 2013, statistics from a survey of the Thai people reported that obese adults and/or adult with abdominal obesity have the following chronic diseases, dyslipidemia 25.5 million, hypertension 10.7 million, impaired fasting glucose 5.3 million, type 2 diabetes 3.5 million, paralysis 0.75 million, and cardiovascular disease 0.7 million (6).

Dowd et al. (7) examined how body mass index (BMI) at age 25 years predicts later obesity and test the importance of long-term obesity beyond obesity severity for adult cardiovascular, inflammatory, and metabolic risk. Data from adults aged 35–64 years from the 1999–2010 U.S. National Health and Nutrition Examination Survey were analyzed in 2013 to test how BMI at age 25 years predicts later adult BMI. Next, logistic regression models predicted the odds of elevated risk for blood pressure (BP), high-density lipoprotein cholesterol (HDL-C), total cholesterol (TC), triglyceride (TG), C-reactive protein (CRP), and glycosylated hemoglobin (HbA1c) by BMI at age 25 years and current BMI. The results showed men obese at age 25 years had a 23.1% estimated probability of class III obesity after age 35 years, compared to a 1.1% probability for men of normal weight at this age. For women, these probabilities were 46.9% and 4.8%, respectively. Those obese in both periods had higher odds of elevated BP, CRP, and HbA1c compared to those of normal weight at age 25 years, with no effects for lipids. After adjustment for current BMI, these associations were either eliminated (for BP and CRP) or greatly reduced (HbA1c). In conclusions, the biological risks of long-term obesity are primarily due to the risk of more severe obesity later in life among those obese early in life, rather than obesity duration. Current body weight rather than duration may be the best reflection of clinical cardiovascular and metabolic risk.

Qin et al. (8) examined the prevalence of obesity, abdominal obesity and associated factors in 17,656 Chinese hypertensive adults aged 45-75 years. A cross-

sectional investigation was carried out in Lianyungang, China. Overweight or obesity was defined as a BMI of 25.0 kg/m^2. Abdominal obesity was defined as a waist circumference ≥90 cm for men and ≥80 cm for women. The results showed the prevalence of overweight or obesity and abdominal obesity was 54.4% (women 59.3% and men 46.0%) and 59.4% (women 73.8% and men 35.1%), respectively. In the multivariable logistic regression models, higher hypertension grades and standard of living, greater red meat consumption, lower physical activity levels, and antihypertensive treatment were independently associated with overweight or obesity and abdominal obesity in both sexes. Inland residence (versus coastal) was an independent associated factor for abdominal obesity in both sexes. Furthermore, a positive family history of diabetes in both sexes, a positive family history of hypertension, men with a positive family history of coronary heart disease, and men with inland residence were all independently associated with overweight or obesity. In conclusions, they found a high prevalence of overweight or obesity and abdominal obesity in Chinese hypertensive adults, particularly in inland areas.

Butler et al. (9) assessed whether metabolic syndrome (MS) predicts a higher risk for cardiovascular events in older adults. They studied the impact of MS (38.0% prevalence) on outcomes in 3,035 participants in the health, aging, and body composition study (51.0% women, 42.0% black, ages 70 to 79 years). The results showed during a 6-year follow-up, there were 434 deaths overall, 472 coronary events (CE), 213 myocardial infarctions (MI), and 231 heart failure (HF) hospital stays; 59.0% of the subjects had at least one hospital stay. Coronary events, MI, HF, and overall hospital stays occurred significantly more in subjects with MS (19.9% vs. 12.9% for CE, 9.1% vs. 5.7% for MI, 10.0% vs. 6.1% for HF, and 63.1% vs. 56.1% for overall hospital stay; all $p<0.001$). No significant differences in overall mortality was seen; however, there was a trend toward higher cardiovascular mortality (5.1% vs. 3.8%, $p=0.067$) and coronary mortality (4.5% vs. 3.2%, $p=0.051$) in patients with MS. After adjusting for baseline characteristics, patients with MS were at a significantly higher risk for CE (hazard ratio [HR] 1.56, 95% confidence interval [CI] 1.28 to 1.91), MI (HR 1.51, 95% CI 1.12 to 2.05), and HF hospital stay (HR 1.49, 95% CI 1.10 to 2.00). Women and whites with MS had a higher coronary mortality rate. The CE rate was higher among subjects with diabetes and with MS; those with both had the highest

risk. In conclusions, overall, subjects over 70 years are at high risk for cardiovascular events; MS in this group is associated with a significantly greater risk.

Wilson et al. (10) studied a cohort of 3,323 middle-aged adults for the development of new Cardiovascular disease (CVD), coronary heart disease (CHD), and type 2 diabetes over an 8-year period. In persons without CVD or type 2 diabetes at baseline, the prevalence of the MS (≥3 of 5 traits) was 26.8% in men and 16.6% in women. There were 174 incident cases of CVD, 107 of CHD, and 178 of type 2 diabetes. In men, the MS age-adjusted relative risk (RR) and 95% CIs were RR=2.88 (95% CI 1.99 to 4.16) for CVD, RR=2.54 (95% CI 1.62 to 3.98) for CHD, and RR=6.92 (95% CI 4.47 to 10.81) for type 2 diabetes. Event rates and RRs were lower in women for CVD (RR=2.25, 95% CI 1.31 to 3.88) and CHD (RR=1.54, 95% CI 0.68 to 3.53), but they were similar for type 2 diabetes (RR=6.90, 95% CI 4.34 to 10.94). Population-attributable risk estimates associated with MS for CVD, CHD, and type 2 diabetes were 34.0%, 29.0%, and 62.0% in men and 16.0%, 8.0%, 47.0% in women. In conclusions, MS is common and is associated with an increased risk for CVD and type 2 diabetes in both sexes. The MS accounts for up to one third of CVD in men and approximately half of new type 2 diabetes over 8 years of follow-up.

In 2014, the Transport Co., Ltd (TP) Health Program by Leelahagul P. reported that 32 TP employees had 71.9% overweight, 84.4% excess body fat, 6.3% diabetes, 18.8% impaired fasting glucose, 78.1% hypertriglyceridemia, 68.8% high LDL-C and 53.1% hyperuricemia. After six months of nutritional therapy for weight reduction, high blood sugar, dyslipidemia, and hyperuricemia, most of them had improved nutritional status, 65.6% and 56.3% of them can reduce their body weight and body fat. Those with high blood sugar, hypertriglyceridemia, high LDL-C, and hyperuricemia had lower these abnormal levels, 50.0%, 68.2%, 52.0%, and 47.1%, respectively.

From reported of the TP Health program supports that appropriate nutritional therapy can prevent and reduce the severity of diet-related chronic diseases in the TP employees as well but the results should be more than this. Because of their job responsibility, they can not choose the appropriate food for their health status such as the drivers who have the uncertainty of mealtime and limited of food sources.

Therefore, researchers were interested in medical food sachet that used combined with the regular diet to treatment for diet-related chronic diseases in TP employees. From reported of TP was found that cost of healthcare for TP employees had more than thrity million baht/year. Thus appropriate nutrition therapy can reduce cost of healthcare, promote health of TP employees, and modify behavior correctly.

Researchers requested Thai Otsuka Pharmaceutical Co., Ltd to produce Gen-DM 40g sachet, a medical food, for nutrition therapy in the TP employees.

Gen-DM, a medical food, is a nutritionally complete formula appropriate for normal, diabetic, high blood sugar, and hypercholesterolemia people (11), and ones who need tube feeding.

Gen-DM has suitable energy distribution consisting of carbohydrate 55.0%, fat 30.0%, and protein 15.0% (12, 13). Important compositions of Gen-DM are dextrin, fructose, polydextrose, oligofructose, soybean oil, casein, soy protein isolate, carnitine, minerals, and vitamins.

Fructose, a monosaccharide, is 1.7 times sweeter than sugar, and it is only need in smaller amount to obtain the same level of sweetness. Fructose enters the bloodstream more slowly than glucose and its levels are much lower, but they persist longer in the circulation. Fructose stimulates only modest insulin secretion and does not require the presence of insulin to enter cells (14-16).

Polydextrose, a soluble fiber, is digested and catabolized by the gut microflora to short-chain fatty acid and carbon dioxide. Short-chain fatty acids supply 50.0-75.0% of the energy requirement of the colonocytes of humans, but only about 5.0% of the overall energy requirement of the animal itself. Soluble fibers tend to have little effect on fecal bulk. They decrease the rate of passage of material through the upper gastrointestinal tract and tend to delay the rate of absorption of nutrients, probably because of their ability to form viscous solutions. Soluble fibers may decrease the rate of absorption of glucose by the small intestine and may reduce the rate of rise of plasma glucose that follows a meal. Also, they may reduce plasma cholesterol levels. (17)

Oligofructose is a fiber-like substance that resists hydrolysis by human alimentary enzymes, but fermented by colonic microflora into short chain fatty acids, lactic acid, gases and some energy. Propionate, a byproduct of fermentation by

intestinal flora, affecting glucose and lipid metabolism. Its effect on controlling plasma glucose and lipid in human still needs further investigation (18).

Soybean oil consisting of linoleic acid and alpha-linolenic acid are essential fatty acid (EFA). Linoleic acid will be induced modified secretion of cholesteryl ester by liver and increased hepatic LDL-C receptor function. When soybean oil is consumed at 20.0% of total caloric intake it will provide 11.3 and 1.4% of total calories as linoleic and alpha-linolenic acids, these amounts of EFA intake are also adequate to prevent linoleate and alpha-linoleate deficiencies which require only 3.0 and 0.3% of total calories, respectively. Thus soybean oil consumption is not only appropriate for controlling serum LDL-C levels but also for preventing EFA deficiencies (13, 19).

Soy protein isolate is a protein good quality. The form of protein used in enteral solutions include intact proteins, hydrolyzed protein, and crystalline amino acids. Intact proteins are in their original natural form. Some examples are eggs, milk, and meat proteins. Intact proteins separated from the original food are termed “isolates.” Some examples are soy protein isolate, lactalbumin, casein or whey from milk, and albumin from egg white. Because of their size, they do not have a significant impact on the formula's osmolality, but they do require normal levels of pancreatic enzymes for complete digestion. The form of protein becomes important when a patient’s digestive or absorptive capacity is compromised (20).

Carnitine is an important metabolite which function is indispensable for intermediary metabolism in eukaryotic cells. Its prime function is to act as a carrier for the transport of activated long-chain fatty acids from the cytosol into the mitochondrial matrix where beta-oxidation takes place, and it is involved in the metabolism branched chain amino acid (BCAA) and glucose (21, 22).

Samaisong et al. (23) studied glycemic index (GI) of Gen-DM in normal people found that glycemic index was 50.2 that was appropriate level for diabetic patients. Diabetic patients receiving Gen-DM as two meal snacks/day for two weeks together with regular diet for diabetes. The results showed that the total energy received per day was not different from baseline. Body weight, body fat, and waist circumference and hip did not change during the study. Liver function, kidney function and blood biochemistry were normal during the study, but found that blood

glucose levels was significantly decreased. Insulin and fructosamine levels had tend to be decreased during the study. Total cholesterol, LDL-C, and TG levels were lower than from baseline. In conclusion, used of Gen-DM as two meal snacks for diabetic patients together with regular diet for diabetes can control blood sugar and serum lipid profile as well, can decrease insulin resistance, and improved function of insulin.

Therefore, Gen-DM was developed to be a sachet for TP employees could be taken when dining outside as one meal replacement and had the rest two meals of recommended regular diets for improvement of their diet-related chronic diseases.

1.2 Objectives

1.2.1 To study the efficiency of Gen-DM sachets for control

1.2.1.1 blood sugar and serum lipid profile

1.2.1.2 body weight and body fat

1.2.1.3 daily total dietary intake

1.2.2 To study the suitability and expediency of Gen-DM sachets for outside dining of TP employees.

CHAPTER II
LITERATURE REVIEW

2.1 Diabetes

Diabetes is a chronic condition that occurs when the body can not produce enough insulin or can not use insulin, and is diagnosed by observing raised levels of glucose in the blood. Insulin is a hormone produced in the pancreas; it is required to transport glucose from the bloodstream into the body's cells where it is used as energy. The lack or ineffectiveness, of insulin in a person with diabetes means that glucose remains circulating in the blood. Over time, the resulting high levels of glucose in the blood (known as hyperglycemia) causes damage to many tissues in the body, leading to the development of disabling and life-threatening health complications (1).

2.1.1 Classification of diabetes (1)

There are three main types of diabetes.

2.1.1.1 Type 1 diabetes

Type 1 diabetes is caused by an autoimmune reaction, in which the body's defense system attacks the insulin-producing beta cells in the pancreas. As a result, the body can no longer produce the insulin it needs. Why this occurs is not fully understood. The disease can affect people of any age, but onset usually occurs in children or young adults. People with this form of diabetes need insulin every day in order to control the levels of glucose in their blood. Without insulin, a person with type 1 diabetes can not survive.

Type 1 diabetes often develops suddenly and can produce symptoms such as: abnormal thirst, dry mouth, frequent urination, lack of energy, extreme tiredness, constant hunger, sudden weight loss, and blurred vision.

2.1.1.2 Type 2 diabetes

Type 2 diabetes is the most common type of diabetes. It usually occurs in adults, but is increasingly seen in children and adolescents. In type 2 diabetes, the body is able to produce insulin but becomes resistant so that the insulin is ineffective. Over time, insulin levels may subsequently become insufficient. Both the insulin resistance and deficiency lead to high blood glucose levels.

The symptoms of type 2 diabetes include frequent urination, excessive thirst, weight loss, and blurred vision.

2.1.1.3 Gestational diabetes

Hyperglycemia that is first detected at any time during pregnancy is classified as either: gestational diabetes mellitus and diabetes mellitus in pregnancy.

Less common types of diabetes including

1. Monogenic diabetes, the result of a genetic mutation. Examples of monogenic diabetes include maturity-onset diabetes of the young and neonatal diabetes mellitus. An estimated 4.0% to 13.0% of diabetes in children is due to monogenic diabetes.

2. Secondary diabetes, which arises as a complication of other diseases, such as hormone disturbances (e.g. Cushing's disease or acromegaly) or diseases of the pancreas.

2.1.2 Diagnostic tests for diabetes (24)

2.1.2.1 Criteria for the diagnosis of diabetes

1. Fasting plasma glucose (FPG) ≥126 mg/dL. Fasting is defined as no caloric intake for at least 8 hours.

2. 2-hours plasma glucose (PG) ≥200 mg/dL during an oral glucose tolerance test (OGTT). The test should be performed as described by the WHO, using a glucose load containing the equivalent of 75g anhydrous glucose dissolved in water.

3. Hemoglobin A1C (HbA1C) ≥6.5%. The test should be performed in a laboratory using a method that is NGSP certified and standardized to the DCCT assay.

2.1.2.2 Categories of increased risk for diabetes (prediabetes)

1. Fasting plasma glucose (FPG) 100 mg/dL to 125 mg/dL (impaired fasting glucose; IFG).

2. 2-hours plasma glucose (PG) in the 75g OGTT 140 mg/dL to 199 mg/dL (impaired glucose tolerance; IGT).

3. Hemoglobin A1c (HbA1c) 5.7-6.4%.

2.2 Dyslipidemia

2.2.1 Definition of dyslipidemia (13)

Dyslipidemia is a disorder of serum lipid profile which is a risk factor and the leading causes of atherosclerosis which is a chronic pathology and the leading cause of three types of disease is ischemic heart disease (IHD), ischemic stroke and peripheral arterial disease.

The disorders of serum lipid profile as a following:

2.2.1.1 High levels of total cholesterol (TC): this condition mainly caused by high levels of low-density lipoprotein cholesterol (LDL-C) which is a major risk factor and the leading causes of atherosclerosis.

2.2.1.2 Low levels of high-density lipoprotein cholesterol (HDL-C): this condition is an independent risk factor and the leading causes of atherosclerosis.

2.2.1.3 High levels of triglyceride (TG): this condition may be caused by high levels of very low-density lipoprotein-TG (VLDL-TG) and/or high levels of triglyceride in chylomicron (chylomicron-TG). Only VLDL-TG are the leading cause of atherosclerosis but high levels of chylomicron-TG are the leading cause of acute pancreatitis.

The lipid disorders are prevalent in diabetes mellitus because insulin resistance or deficiency affects key enzymes and pathways in lipid metabolism (25).

2.3 Medical food

2.3.1 Definition of medical food (26)

A medical food, as defined in section 5(b)(3) of the Orphan Drug Act (21 U.S.C. 360ee(b)(3)), is "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary based on recognized scientific principles, are established by medical evaluation."

FDA considers the statutory definition of medical foods to narrowly constrain the types of products that fit within this category of food (21 CFR 101.9(j)(8)). Medical foods are distinguished from the broader category of foods for special dietary use by the requirement that medical foods be intended to meet distinctive nutritional requirements of a disease or condition, used under medical supervision, and intended for the specific dietary management of a disease or condition. Medical foods are not those simply recommended by a physician as part of an overall diet to manage the symptoms or reduce the risk of a disease or condition. Not all foods fed to patients with a disease, including diseases that require dietary management, are medical foods. Instead, medical foods are foods that are specially formulated and processed (as opposed to a naturally occurring foodstuff used in a natural state) for a patient who requires use of the product as a major component of a disease or condition's specific dietary management.

2.3.2 Classification of medical foods (27)

The FDA classifies medical foods into four major categories.

2.3.2.1 Nutritionally complete products: usually contain a protein source, carbohydrate source, and fat source with possible vitamins, minerals or electrolytes. These are taken as a complete food, so do not need to be supplemented with other food sources, most commonly used for patients who are tube feeding.

2.3.2.2 Nutritionally incomplete products: these contain a single food group, such as carbohydrates only or vitamins only. It is necessary to

consume additional food sources for a complete diet. This food group may be taken by patients who are at home and still able to eat normal foods.

2.3.2.3 Formulas for metabolic (genetic) disorders: the majority of medical foods treat metabolic disorders, targeting signaling pathways. They are typically formulas with unique nutrients removed or added.

2.3.2.4 Oral rehydration solutions: these help the body absorb nutrients by shifting the osmolarity of an oral solution so that the gastrointestinal tract retains fluid. They typically contain sodium, chloride, potassium citrate, dextrose and water.

2.4 Diabetes and fructose

Fructose, a monosaccharide, is 1.7 times sweeter than sugar, and it is only need in smaller amount to obtain the same level of sweetness. Fructose enters the bloodstream more slowly than glucose and its levels are much lower, but they persist longer in the circulation. Fructose stimulates only modest insulin secretion and does not require the presence of insulin to enter cells (14-16). Fructose was found in fruit, honey, and table sugar. Sources of dietary fructose include agave, the richest natural source of fructose, with 85.0% of carbohydrate in this form; honey, with approximately 50.0%; and fruit juices (28).

Gallagher et al. (29) did a randomized crossover design, twenty-seven participants with a mean age of 44 years and a mean BMI (in kg/m^2) of 26 completed the study. Fructose (52g), sucrose (65g), and sucralose (0.1g) were delivered as sweet-taste–balanced muffins with a total fat load (66g). Blood samples were taken at baseline and every 30 min for 4-hours glucose, TG, and insulin concentrations, and the area under the curve (AUC) and the incremental area under the curve (iAUC) were analyzed. The results showed that no significant difference was shown between the 3 sweeteners for TG and glucose concentrations and the AUC. The glucose iAUC was lower for fructose than for sucrose and sucralose ($p<0.05$). Insulin concentrations differed significantly by the type of muffin ($p=0.001$), the interaction of time by type of muffin ($p=0.035$), the AUC ($p<0.001$), and the iAUC ($p<0.001$). Fructose had a

significantly lower insulin response than that of either sucrose (P-treatment=0.006) or sucralose (P-treatment=0.041). In conclusions, fructose, at a moderate dose, did not significantly elevate TG compared with sucrose or sucralose and lowered the glucose iAUC. These results indicate that these sweeteners, at an equivalent sweetness, can be used in normal solid meals. Fructose showed a lower insulin response, which may be beneficial in the long term in individuals at risk of type 2 diabetes.

Moore et al. (30) studied in 5 adults with type 2 diabetes underwent an oral glucose tolerance test (OGTT) on two separate occasions, at least 1 week apart. Each OGTT consisted of 75g glucose with or without the addition of 7.5g fructose (F) (OGTT+F or OGTT–F), in random order. Arterialized blood samples were collected from a heated dorsal hand vein twice before ingestion of the carbohydrate and every 15 minutes for 3 hours afterward. The results showed the area under the curve (AUC) of the PG response was reduced by fructose administration in all subjects; the mean AUC during the OGTT+F was 14.0% less than that during the OGTT–F ($p<0.05$). The insulin AUC was decreased 21.0% with fructose administration ($p=0.2$). Plasma glucagon concentrations declined similarly during OGTT–F and OGTT+F. The incremental AUC of the blood lactate response during the OGT –F was ~50.0% of that observed during the OGTT+F ($p<0.05$). In conclusions, low-dose fructose improves the glycemic response to an oral glucose load in adults with type 2 diabetes, and this effect is not a result of stimulation of insulin secretion.

Stanhope et al. (31) studied in a metabolic facility and gave the subjects consumed energy-balanced diets containing 55.0% of energy as complex carbohydrate for 2 weeks (GI=64). The subjects then consumed 25.0% of energy requirements as fructose- or glucose-sweetened beverages along with their usual ad libitum diets for 8 weeks at home and then as part of energy-balanced diets for 2 weeks at the metabolic facility (fructose GI=38, glucose GI=83). The 24-hours glucose and insulin profiles and fasting plasma glycated albumin and fructosamine concentrations were measured 0, 2, 8, and 10 weeks after beverage consumption. The results showed that consumption of fructose-sweetened beverages lowered glucose and insulin postmeal peaks and the 23-hours AUC compared with the baseline diet and with the consumption of glucose-sweetened beverages (all $p<0.001$, effect of sugar). Plasma glycated albumin concentrations were lower 10 weeks after fructose than after glucose

consumption ($p<0.01$, effect of sugar), whereas fructosamine concentrations did not differ between groups. In conclusion, the results suggest that the specific effects of fructose, but not of glucose and insulin excursions, contribute to the adverse effects of consuming sugar-sweetened beverages on lipids and insulin sensitivity.

Samaisong et al. (23) studied 25 adults with type 2 diabetes. Divided the studied by type of food eaten is 4 periods (1 period = 2 weeks). Period 1 (Week -2 - week -1); the participants had eaten a regular diet and record 24-hours recall for 2 weeks in order to calculate the energy received on a daily and proportional distribution of energy. Period 2 (Week 1 - Week 2); the participant had eaten a regular diet and record 24-hours recall together with intake Gen-formula® (mix fructose) 40g melted with boiled water 200 mL as a snack between meals, at 10.00 am. and 15.00 pm. for 2 weeks. Period 3 (Week 5 - Week 6); the participants had eaten controlled diet for diabetes which prepared by the researcher. This diet will set amount of energy equal the average energy from food in period 1 which recorded by the participants and optimized to maintain a steady weight. Proportional distribution of energy is protein 15.0%, fat 30.0% and carbohydrate 55.0% together with intake Gen-formula® (mix fructose) 40g melted with boiled water 200 mL as a snack between meals, at 10.00 am. and 15.00 pm. During the study, the participants will learn how to prepare the diet as required. Period 4 (Week 7 - Week 10); the participants prepare the diet as required had eaten at home together with intake Gen-formula® (mix fructose) 40g melted with boiled water 200 mL as a snack between meals, at 10.00 am. and 15.00 pm. The results showed the total energy received per day was not different from baseline. Body weight, body fat, and waist circumference and hip did not change during the study. Liver function, kidney function and blood biochemistry were normal during the study, but found that blood glucose levels was significantly decreased. Insulin and fructosamine levels had tend to be decreased during the study. Total cholestrol, LDL-C, and TG levels were lower than from baseline. In conclusion, intake Gen-formula® (mix fructose) which is a snack eaten two times between meals for diabetic together with eaten diet which appropriated to prepared for diabetic can control blood sugar as well. It also encourages the patient's insulin resistance is decreased. The function of insulin is better.

CHAPTER III
MATERIALS AND METHODS

3.1 Study Design

This study was a 12-week repeated measures designs in the TP employees who had high blood sugar (≥100 mg/dL) or high serum LDL-C (≥130 mg/dL). This study provided nutritional therapy as the following, first 4 weeks (weeks 1-4) subjects received dietary advice for lowering blood sugar and serum LDL-C, and weeks 5-12 subjects received the same dietary advice for weeks 1-4 and replaced one regular meal with 1-2 Gen-DM sachets (based on their total energy intake at baseline).

3.2 The research place

The Division of Medical Services, the Transport Co., Ltd 999 Kamphaengphet 2 Road, Chatuchak Sub-district, Chatuchak District, Bangkok Province 10900.

3.3 Duration of study period

July 2015 – July 2016

3.4 Subjects

3.4.1 Sample size calculations

This study used one sample group formula (32) to determine sample size. The formula was given below.

$$n = \frac{[(Z_{\alpha/2} + Z_{\beta})\sigma]^2}{(\mu_1-\mu_2)^2}$$

Samaisong et al. (23) studied the effects of diabetic diets supplemented with medical food fructose formula on nutritional status in patients with type 2 diabetes mellitus. This study provided nutritional therapy for 8 weeks found that the average of blood sugar at the end of this study was 131±30 mg/dL. Using statistically significant was 0.05 and power of the test was 0.2 to calculate the number of subjects was as follows.

μ_1 = 131 (the average of blood sugar at the end of samaisong study)

μ_2 = 117.9 (the average of blood sugar was expected at the end of our study 131 - (10.0% of 131)

σ = SD = 30

α = 0.05 (2-sided) $Z_{0.025}$ = 1.96

1- β = 0.20 $Z_{0.2}$ = 0.842

$$n = \frac{[(1.96 + 0.842)(30)]^2}{(131-117.9)^2}$$

= 42 subjects

The average of serum LDL-C at the end of samaisong study was 111±28 mg/dL. Using statistically significant was 0.05 and power of the test was 0.2 to calculate the number of subjects was as follows.

μ_1 = 111 (the average of serum LDL-C at the end of samaisong study)

μ_2 = 99.9 (the average of serum LDL-C was expected at the end of our study 111 - (10.0% of 111)

σ = SD = 28

α = 0.05 (2-sided) $Z_{0.025}$ = 1.96

1- β = 0.20 $Z_{0.2}$ = 0.842

$$n = \frac{[(1.96 + 0.842)(28)]^2}{(111-99.9)^2}$$

= 50 subjects

Expected drop out 5.0% of subjects thus the number of including subjects 50-53 subjects.

3.4.2 Inclusion criteria

3.4.2.1 Subjects were the TP employees.

3.4.2.2 Subjects had fasting plasma glucose ≥100 mg/dL (24).

3.4.2.3 Subjects had serum LDL-C ≥130 mg/dL (33).

3.4.2.4 Subjects did not use drug or supplements that affect blood sugar and serum LDL-C or use drug in stable dose throughout the study.

3.4.2.5 Subjects had no medical history of liver disease, kidney disease, thyroid disease, and infectious disease.

3.4.2.6 Subjects were able to participate throughout the study period.

3.4.3 Exclusion criteria

3.4.3.1 Liver disease, kidney disease, thyroid disease, and infectious disease were found in subjects from first blood examination.

3.4.3.2 Subjects were not able to participate throughout the study period.

3.4.3.3 Subjects reject or withdraw from study.

3.5 Diet for study (Appendix A)

Gen-DM, a medical food, is a nutritionally complete formula appropriate for normal, diabetic, high blood sugar, and hypercholesterolemia people (11), and ones who need tube feeding.

Gen-DM provide energy and nutrients complete without sugar and lactose, has carnitine which need for fat metabolism, and provide essential fatty acids such as linoleic acid and alpha-linolenic acid.

Table 3.1 Nutritional values of Gen-DM sachet (40g)

Ingredient	Amount per 40g	Food source	
Energy, kcal	180.0	Protein	15.0%
		Fat	30.0%
		Carbohydrate	55.0%
Protein, g	6.8	Soy protein isolate	4.3g
		Sodium caseinate	4.3g
Fat, g	6.1	Soybean oil	6.1g
Carbohydrate, g	24.6	Dextrin	16.3g
		Fructose	3.6g
		Polydextrose	2.0g
		Oligofructose	1.7g
		Other	1.4g
Dietary fiber, g	1.1		
Moisture, g	1.3		

3.6 Process of study

3.6.1 During first 4 weeks (weeks 1-4) subjects received dietary advice for lowering blood sugar and serum LDL-C.

They received documents for how to practice such as avoid the consumption of fatty meats, skin meats, organ meats, egg yolk, seafood such as shrimp and crab, saturated fatty acid such as palm oil, coconut oil, and animal sources such as lard and butter. (Appendix B)

3.6.2 Weeks 5-12 subjects received the same dietary advice for weeks 1-4 and replaced one regular meal with 1-2 Gen-DM sachets (one Gen-DM sachet mix with 200 mL water and stir until dissolved). (Appendix B)

During the study period their energy intake and physical activities should be kept constant, and not different from the baseline.

3.7 Nutritional assessment

3.7.1 General information

General information including three parts: primary information, socio-economic information, and health information were collected from questionnaire at week 0. (Appendix C)

3.7.2 Body composition and blood pressure

Body composition and blood pressure assessment were carried out at weeks 0, 4, 8, and 12. Body composition including height, body weight, body fat, fat free mass, muscle mass, total body water, bone mass, and visceral fat by Tanita Body Composition Analyzer SC-300 (34), and blood pressure measurement consisting of systolic blood pressure (mmHg), diastolic blood pressure (mmHg), and pulse (bpm).

3.7.3 Blood biochemistry assessment

Ten milliliters of 10-hours fasted blood samples were collected for biochemical assessment including total cholesterol (TC), high-density lipoprotein cholesterol (HDL-C), low-density lipoprotein cholesterol (LDL-C), triglyceride (TG), uric acid, fasting plasma glucose (FPG), hemoglobin (Hb), creatinine (Cr), blood urea nitrogen (BUN), serum glutamic-oxaloacetic transaminase (SGOT), and serum glutamic-pyruvic transaminase (SGPT) by using Roche Diagnostics Cobas C111 Clinical Chemistry Analyzer at weeks 0, 4, 8, and 12 (35).

3.7.4 Dietary assessment

3.7.4.1 24-hours dietary records were analyzed for energy and nutrient intakes by using INMUCAL-Nutrients version 3.0 throughout the study (36). (Appendix D)

3.7.4.2 Satisfaction and adverse effect of taking Gen-DM were evaluated by questionnaire at weeks 5-12. (Appendix E)

3.7.5 Physical activity assessment

Physical activities were recorded during the study by using questionnaire. (Appendix F)

3.8 Criteria for nutritional status (Appendix G)

3.8.1 Body weight status was classified by BMI, criteria of WHO (37).

3.8.2 Body fat status was classified by healthy percentage body fat ranges: an approach for developing guidelines based on body mass index (38).

3.8.3 Fasting plasma glucose status was classified by criteria of clinical practice guideline for diabetes 2014 (24).

3.8.4 Dyslipidemia was classified by criteria of American Herat Association and NCEP (33, 39, 40).

3.8.5 Anemia was classified by criteria of WHO 2011 (41).

3.8.6 Hyperuricemia was classified by criteria of Guideline for Management of Gout (42).

3.8.7 Blood pressure status was classified by Thai Guideline on The Treatment of hypertension 2012 update 2015 (43).

3.9 Ethic

The study was approved by the Ethical Clearance Committee on Human Rights Related to Research Involving Human Subjects Faculty of Medicine, Ramathibodi Hospital, Mahidol University (ID 06-58-29). Written informed consents were obtained from all subjects. (Appendix H)

3.10 Statistical analysis

All statistical analyses were performed with SPSS version 18.0 for window (44). Data analysis was divided into two parts.

3.10.1 Descriptive statistic

General data, socio-economic data, health data, and nutritional assessment were expressed as mean, percentage, standard deviation (SD) and 95% confidence interval.

3.10.2 Inferential statistic

Explain a correlation analysis between nutritional and nutrient parameters by using Pearson's correlation coefficient.

Compare the difference data in subjects by using Repeated Measures ANOVA and Wilcoxon Matched Pairs Signed-Ranks Test. The compared difference data were considered to be statistically significant when $p<0.05$ and 95% confidence interval.

CHAPTER IV
RESULTS

This study aimed to assess the effect of Gen-DM sachet for TP employees could be taken when dining outside as one meal replacement and had the rest two meals of recommended regular diets for improvement of their diet-related chronic diseases.

The results are presented as the following parts:

4.1 General information of TP employees (Questionnaire)

4.2 Effect of nutritional therapy on nutritional status

4.3 The suitability and expediency of medical food (Gen-DM®) (Questionnaire)

4.1 General information of TP employees (Questionnaire)

General information of 50 TP employees were presented in **Table 4.1**. Subjects were in young adulthood (18-44 years) 52.0%, in middle adulthood (45-64 years) 48.0%, and 96.0% of them are Buddhist. Most of subjects were born in central and live in central region.

Table 4.2 shows the education level of 50 TP employees. Most of the subjects completed bachelor's degree (46.0%). The highest educational level was master degree (18.0%) whereas the lowest educational level was primary school (4.0%).

They live together with their children (44.0%). Their income ranged from 10,000-100,000 Baht/month, 60.0% of them had monthly income 10,000-30,000 Baht, as well as 34.0%, 28.0%, and 20.0% had monthly family income 10,000-30,000 , 50,001-70,000 , and 30,001-50,000 Baht, respectively. **(Table 4.3)**.

Table 4.1 General information of 50 TP employees

General data	n	% of total
Number of sibling		
0-4	37	74
5-9	13	26
Birthplace		
Northern	5	10
Northeastern	10	20
Western	3	6
Central	21	42
Eastern	3	6
Southern	8	16
Present address		
Northeastern	2	4
Western	1	2
Central	45	90
Southern	2	4
Marital status		
Single	19	38
Married	27	54
Divorced	2	4
Widowed	2	4
Number of children		
0	23	46
1	7	14
2	15	30
3	3	10

Table 4.2 Education levels of 50 TP employees

Educational level	n	% of total
Primary school	2	4
Junior high school	2	4
Senior high school	6	12
Vocational certificate	5	10
High vocational certificate	3	6
Bachelor's degree	23	46
Master' degree	9	18

Table 4.3 Socio-economic information of 50 TP employees

Socio-economic data	n	% of total
Person who live with		
Father	8	16
Mother	13	26
Husband	17	34
Wife	10	20
Children	22	44
Relative	15	30
Others	4	8
Subjects income (Baht/month)		
< 10,000	2	4
10,000-30,000	30	60
30,001-50,000	5	10
50,001-70,000	12	24
70,001-100,000	1	2
Family income (Baht/month)		
10,000-30,000	17	34
30,001-50,000	10	20
50,001-70,000	14	28
70,001-100,000	5	10
>100,000	4	8

Table 4.4 Health information of 50 TP employees

Disease	n	% of total
Known underlying diseases		
No	28	56.0
Yes	22	44.0
Underlying diseases (n=22)		
Hypercholesterolemia	17	77.2
Hypertension	7	50.0
Gastritis/ peptic ulcer	3	13.6
Diabetes	2	9.1
Allergy	2	9.1
Gout	1	4.5
Dizziness	1	4.5
Genetic underlying diseases (n=22)		
No	17	77.3
Yes	5	22.7
Medications		
Diabetes	2	4.0
Hypertension	2	4.0
Hyperuricemia	1	2.0
Family medical history		
Hypertension	21	42.0
Diabetes	19	38.0
Hypercholesterolemia	9	18.0
Obesity	7	14.0
Gastritis/ peptic ulcer	5	10.0
Gout	4	8.0
Cardiovascular disease	4	8.0
Hypertriglyceridemia	2	4.0
Allergy	2	4.0
Migraine	1	2.0
Cancer	1	2.0
Thyroid	1	2.0
Hypotension	1	2.0
Meniere's disease	1	2.0
Do not know	6	12.0

Table 4.4 shows that 56.0% of subjects reported had no underlying diseases. The first five order of underlying diseases were hypercholesterolemia, hypertension, gastritis/peptic ulcer, diabetes, and allergy, whereas the first five orders of family medical history were hypertension, diabetes, hypercholesterolemia, obesity and gastritis/peptic ulcer. Five subjects had taken medicines for diabetes, hypertension, and hyperuricemia. Most of them who had underlying diseases thought that their underlying diseases were not caused by genetics (77.3%).

Seventy two percent of subjects had exercise, 69.4%, of them exercised less than 3 times/week, and 66.6% exercised less than 30 minutes/time. Subjects exercised by walking (52.7%), jogging (25.0%), aerobics (13.8%), cycling (11.1%), swimming (8.3%), yoga (8.3%) and others (30.1%). Housework that subjects always done were sweep/mop (78.0%), car wash (30.0%), gardening (26.0%), and others (12.0%). Most of subjects were seated work, and had 6-7 hours sleep a night **(Table 4.5)**.

Table 4.5 Activity information of 50 TP employees

Activity	n	% of total
Exercise		
No	14	28.0
Yes	36	72.0
Frequency of exercises (n = 36)		
< 3 times/week	25	69.4
3-5 times/week	7	19.4
> 5 times/week	4	11.1
Duration of exercises (n = 36)		
< 30 minutes/time	24	66.6
30-60 minutes/time	9	25.0
> 60 minutes/time	3	8.3
Type of exercises (n = 36)		
Walking	19	52.7
Jogging	9	25.0
Aerobics	5	13.8
Cycling	4	11.1
Swimming	3	8.3
Yoga	3	8.3
Fitness	2	5.5
Dancing	2	5.5
Hula Hoop	2	5.5
Swing arm	2	5.5
Football	1	2.7
Badminton	1	2.7
T25	1	2.7
Housework		
Sweep/mop the house	39	78.0
Car wash	15	30.0
Gardening	13	26.0
Wash the clothes	4	8.0
Child care	1	2.0
Cooking	1	2.0
Characteristics of works		
Seated work	22	44.0
Seated work and walking	21	42.0
Driving	7	14.0
Sleeping pattern		
Daytime	7	14.0
Nighttime	43	86.0

Table 4.6 shows dietary behavior of 50 TP employees. Most of subjects had three meals a day (82.0%), and 86.0% of them ate snack foods such as coffee, tea, soft drink, fruit juices, and fresh fruit. Subjects always ate the delicatessen, breakfast (72.0%), lunch (92.0%), and dinner (58.0%). Forty four percent of subjects always cooked by steaming/stew/boiling, and favorite seasoning were chilli powder, fish sauce, and sugar. Meat buffet were the first order (48.3%) that 56.0% of subjects had 1-2 times/month.

Details of beverage consumption are shown in **Table 4.7.** The favorite beverages of subjects were coffee (84.0%) and sweetened soft drink (62.0%) that more than tea (28.0%), and most of them did not drink alcohol (78.0%) and energy drink (90.0%). They drank soybean milk (72.0%) more than cow milk (66.0%), and 64.0% of them drank fresh water less than recommendation.

Seventy four percent of subjects always ate pork meat, and most of them ate some fatty meats (66.0%), skin meats (50.0%), and organ meats (60.0%) when they found in food. Most of subjects ate seafood 1-3 times/week (54.0%), and ate 1-3 eggs/week (60.0%) that ate only whole egg (88.0%). Most of subjects did not eat tofu (56.0%), whereas 44.0% of them ate tofu 3 times/week **(Table 4.8)**.

Table 4.9 shows most of subjects ate stir-fried vegetable (66.0%) more than steamed vegetable (62.0%), and salad (48%). Thirty two percent of them ate fresh fruit 3-4 times/week, and first three orders of fresh fruit that they ate, mango (26.1%), watermelon (19.6%), and guava (15.2%).

Yellow/orange curry (46.0%) was the most curry that subjects always ate, and 62.0% of them use soybean oil for cooking. Most of subjects did not add non-dairy creamer into coffee or tea (78.0%) **(Table 4.10)**.

Table 4.6 Dietary behavior of 50 TP employees

Dietary behavior	n	% of total
Meals		
< 3 meals/day	7	14.0
3 meals/day	41	82.0
> 3 meals/day	2	4.0
Eating snack foods		
Yes	43	86.0
No	7	14.0
Snack foods (n=43)		
Crispy snacks	11	25.6
Thai desserts	4	9.3
Bakery	12	27.9
Coffee, tea, soft drink, and fruit juices	30	69.8
Energy drinks	2	4.7
Fresh fruits	26	60.5
Tamarind mixed with sugar	1	2.3
Cooked foods		
Frying	10	20.0
Stirfrying	13	26.0
Steaming/stew/boiling	22	44.0
Roasting/grilling/baking	5	10.0
Seasonings		
Sugar	30	60.0
Fish sauce	33	66.0
Fish sauce with chilli	21	42.0
Vinegar	30	60.0
Chilli powder	42	84.0
Frequency of buffet eating		
No	21	42.0
1-2 times/month	28	56.0
3-4 times/month	1	2.0
Favorite buffet		
Meat buffet	14	48.3
Shabu shabu	6	20.7
Japanese food	9	31.0

Table 4.7 Beverage consumption of 50 TP employees

Amount of beverage consumption	n	% of total
Tea		
No	36	72
1-3 cups/week	11	22
≥ 7 cups/week	3	6
Coffee		
No	12	24
1-3 cups/week	8	24
4-6 cups/week	3	6
≥ 7 cups/week	27	54
Alcohol		
No	39	78
1-3 glasses/month	7	14
4-6 glasses/month	2	4
≥ 7 glasses/month	2	4
Energy drink		
No	45	90
1-3 bottles/month	2	4
≥ 7 bottles/month	3	6
Sweetened soft drink		
No	19	38
1-3 glasses/week	19	38
4-6 glasses/week	10	20
≥ 7 glasses/week	2	4
Cow milk		
No	17	34
1-3 boxes/week	7	14
4-6 boxes/week	2	4
7-9 boxes/week	17	34
10-12 boxes/week	1	2
> 12 boxes/week	6	12
Soybean milk		
No	14	28
1-3 glasses/week	33	66
4-6 glasses/week	3	6
Fresh water		
1-2 glasses/day	2	4
3-4 glasses/day	11	22
5-6 glasses/day	19	38
> 7 glasses/day	18	36

Table 4.8 Meat consumption of 50 TP employees

Meat consumption	n	% of total
Favorite meat		
Pork	37	74
Beef	1	2
Poultry	2	4
Fish	9	18
Seafood	1	2
Eating served fatty meat		
No	9	18
All	8	16
Not all	33	66
Eating served skin meat		
No	19	38
All	6	12
Not all	25	50
Eating served organ meats		
No	12	24
All	8	16
Not all	30	60
Eating served seafood		
1-3 times/week	27	54
4-6 times/week	2	4
1-2 times/month	21	42
Eating egg		
1-3 eggs/week	30	60
4-6 eggs/week	14	28
7-9 eggs/week	3	6
13-15 eggs/week	3	6
Eating egg, part		
Whole egg	44	88
Only egg white	6	12
Eating tofu		
No	28	56
3 times/week	22	44

Table 4.9 Vegetable and fruit consumption of 50 TP employees

Vegetable and fruit consumption	n	% of total
Eating salad		
No	26	52.0
1-2 times/week	23	46.0
3-4 times/week	1	2.0
Eating stir-fried vegetable		
No	17	34.0
1-2 times/week	16	32.0
3-4 times/week	16	32.0
5-6 times/week	1	2.0
Eating steamed vegetable		
No	19	38.0
1-2 times/week	16	32.0
3-4 times/week	14	28.0
5-6 times/week	1	2.0
Eating fresh fruit		
No	4	8.0
1-2 times/week	10	20.0
3-4 times/week	16	32.0
5-6 times/week	13	26.0
> 7 times/week	7	14.0
Favorite fresh fruits (n = 46)		
Mango	12	26.1
Watermelon	9	19.6
Guava	7	15.2
Orange	5	10.9
Durian	3	6.5
Papaya	3	6.5
Rambutan	2	4.3
Apple	2	4.3
Cantaloupe	2	4.3
Yong coconut	1	2.2

Table 4.10 Fat consumption of 50 TP employees

Fat consumption	n	% of total
Favorite Thai curry		
Curry with coconut milk	10	20
Spicy red curry	13	26
Sour yellow/orange curry	23	46
Thai spicy mixed vegetable soup	4	8
Non-dairy creamer added		
No	39	78
Yes	11	22
Cooking oil		
Soybean oil	31	62
Rice bran oil	5	10
Palm oil	5	10
Coconut oil	1	2
Lard	2	4.0
Sunflower oil	2	4.0
Olive oil	2	4.0
No	2	4.0

4.2 Effect of nutritional therapy on nutritional status

Nutritional status was assessed from body composition data and blood biochemistry data. Body composition and blood pressure data of 50 TP employees are shown in **Table 4.16-4.20**. Blood biochemistry data are shown in **Table 4.21-4.23.**

Table 4.11 shows mean ± SD of initial characteristic of 50 TP employees, aged 24-60 years, consisting of 13 males and 37 females.

At baseline we found that 32 subjects (64.0%) had BMI ≥24.9 kg/m^2, 41 subjects (82.0%) had high body fat (female; body fat ≥30%bw and male; body fat ≥20%bw), 22 subjects (44.0%) had high blood sugar (FPG ≥100 mg/dL), and 49 subjects (98.0%) had high serum LDL-C (LDL-C ≥130 mg/dL).

Table 4.11 Mean (±SD) of initial characteristic of 50 TP employees

Parameters	Mean ± SD	
Sex (n)		
Male	13	
Female	37	
Age (year)	43.2 ± 10.2	(24-60)
Height (cm)	161.8 ± 8.5	(140-180)
Weight (kg)	68.6 ± 13.7	(41.3-115.1)
BMI (kg/m^2)	26.1 ± 4.1	(17.2-37.0)
Body fat (%bw)	32.8 ± 7.6	(18.1-49.3)
Male	25.0 ± 3.9	(18.9-33.4)
Female	35.5 ± 6.6	(18.1-49.3)
FPG (mg/dL)	100.7 ± 16.1	(80-174)
LDL-C (mg/dL)	166.3 ± 27.8	(77-256)

During the second (weeks 5-8) and third (weeks 9-12) periods of this study, subjects drank Gen-DM (40-80g energy 180-360 kcal/day) replace one meal, and had the rest two meals of recommended regular diets to reduce blood sugar and serum lipid profile. At the end of this study found that 84.0% of subjects drank Gen-DM 2 sachets/day, and 16.0% of them drank Gen-DM 1 sachet/day. Compliances of Gen-DM consumption averaged 98.2% which is in the acceptable level. All subjects maintained their total energy intake and physical activity as the baseline period.

Mean (±SD) of energy and macronutrient intakes shows in **Table 4.12**. After the first 4 weeks (week 4) of the dietary recommendation, subjects received dietary advice for lowering blood sugar and serum LDL-C, total energy, energy distribution, and macronutrient intakes were not significant differences from baseline.

During weeks 5-12, 28.1% (week 8) and 28.3% (week 12) of the total energy intake was derived from Gen-DM. Energy distribution of Gen-DM at weeks 8 and 12 were carbohydrates 15.4% and 15.5%, protein 4.2% and 4.3%, and fat 8.6% and 8.6% of total energy intake, respectively.

At week 8 and at the last period of study (week 12), subjects received Gen-DM, and had the rest two meals of recommended regular diets, found that sugar,

saturated fatty acid and cholesterol intakes were significantly lower than those at baseline and week 4. However, there was no significant differences of the aforesaid parameters between week 8 and 12.

Table 4.13 shows mean (±SD) of mineral and vitamin intakes. The results found that at the first 4 weeks (week 4) of the dietary recommendation, mineral and vitamin intakes were no significant differences from baseline.

At week 8 and at the last period of study (week 12), subjects received Gen-DM, and had the rest two meals of recommended regular diets, found that most of vitamin and mineral intakes were significantly higher than those at baseline and week 4. However, there was no significant differences of the aforesaid nutrients between week 8 and 12.

Comparison of energy intake with estimated energy requirement which calculated from basal metabolic rate (45) multiply with activity factor (46). Energy requirement was higher than energy intake during the study **(Table 4.14)**.

Their mean (±SD) nutrient intakes compared with Thai Recommended Daily Intakes (Thai RDI) (47) shows in **Table 4.15**. Most of nutrient intakes of subjects during study were lower than the Thai RDI except vitamin C and sodium intakes were higher than Thai RDI.

Table 4.12 Mean (±SD) of energy and energy distribution intakes of 50 TP employees during the study*

Nutrient	Week 0	Week 4	Week 8	Week 12
Total energy (kcal)	1199 ± 285	1148 ± 276	1194 ± 296	1178 ± 272
Regular diet (%total energy)	100.0 ± 0.0	100.0 ± 0.0	71.9 ± 8.4	71.7 ± 8.2
Gen-DM (%total energy)	-	-	28.1 ± 8.4	28.3 ± 8.2
Carbohydrate (%total energy)	50.1 ± 5.4	50.8 ± 4.2	51.9 ± 4.0	51.3 ± 3.6
Regular diet (%total energy)	50.1 ± 5.4	50.8 ± 4.2	36.6 ± 4.6	35.8 ± 4.2
Gen-DM (%total energy)	-	-	15.4 ± 4.6	15.5 ± 4.5
Carbohydrate (g)	150.1 ± 39.0	145.3 ± 34.4	154.6 ± 38.5	150.6 ± 33.1
Sugar (g)	44.0 ± 24.0	43.8 ± 17.1	30.8 ± 14.1^{a1b1}	29.2 ± 13.0^{a1b1}
Sugar (%total energy)	14.2 ± 5.6	15.2 ± 4.2	10.1 ± 3.6^{a1b1}	9.7 ± 3.4^{a1b1}
Protein (%total energy)	18.7 ± 2.7	18.3 ± 2.3	17.7 ± 2.0	17.9 ± 1.8
Regular diet (%total energy)	18.7 ± 2.7	18.3 ± 2.3	13.5 ± 2.7	13.6 ± 2.6
Gen-DM (%total energy)	-	-	4.2 ± 1.3	4.3 ± 1.2
Protein (g)	55.7 ± 14.6	52.7 ± 14.5	53.3 ± 15.7	53.0 ± 15.0
Animal protein (g)	38.6 ± 12.8	34.4 ± 11.7^{a2}	27.2 ± 12.5^{a1b1}	27.6 ± 11.9^{a1b1}
Vegetable protein (g)	13.0 ± 3.6	12.3 ± 4.2	21.5 ± 4.6^{a1b1}	21.3 ± 4.0^{a1b1}
Fat (%total energy)	31.1 ± 4.5	30.7 ± 3.3	30.4 ± 2.9	30.9 ± 2.6
Regular diet (%total energy)	31.1 ± 4.5	30.7 ± 3.3	21.8 ± 4.5	22.2 ± 4.3
Gen-DM (%total energy)	-	-	8.6 ± 2.6	8.6 ± 2.5
Fat (g)	41.5 ± 11.9	39.4 ± 11.1	40.3 ± 10.8	40.5 ± 10.5
SFA (g)	12.4 ± 4.0	12.1 ± 3.8	8.7 ± 3.7^{a1b1}	8.6 ± 3.3^{a1b1}
SFA (%total energy)	9.4 ± 2.3	9.4 ± 1.9	6.4 ± 1.7^{a1b1}	6.5 ± 1.5^{a1b1}
Cholesterol (mg)	235.0 ± 97.6	223.7 ± 86.7	173.2 ± 73.2^{a1b1}	184.2 ± 81.2^{a2b2}
Fiber (g)	7.6 ± 3.9	7.7 ± 3.5	8.0 ± 2.9	7.7 ± 2.6
Regular diet (g)	7.6 ± 3.9	7.7 ± 3.5	6.0 ± 2.8	5.7 ± 2.5
Gen-DM (g)	-	-	2.0 ± 0.4	2.0 ± 0.4

*Week 0 = baseline

Week 4 = dietary recommendation for 4 weeks

Week 8 = dietary recommendation + Gen-DM for 4 weeks

Week 12 = dietary recommendation + Gen-DM for 8 weeks

Significant difference from week 0 $^{a1}p<0.001$, $^{a2}p<0.05$

Significant difference from week 4 $^{b1}p<0.001$, $^{b2}p<0.05$

Table 4.13 Mean (±SD) of micronutrient intakes of 50 TP employees during the study

Nutrient	Week 0	Week 4	Week 8	Week 12
Calcium (g)	361.45 ± 132.0	341.4 ± 103.7	405.8 ± 112.6^{b1}	402.0 ± 98.4^{b1}
Phosphorus (mg)	612.4 ± 173.4	575.8 ± 153.5	602.6 ± 159.9	604.1 ± 155.2
Iron (mg)	9.9 ± 3.0	9.2 ± 2.4	12.2 ± 2.8^{a1b1}	12.3 ± 2.7^{a1b1}
Animal iron (mg)	4.9 ± 2.2	4.3 ± 1.6	3.3 ± 1.6^{a1b1}	3.3 ± 1.4^{a1b1}
Vegetable iron (mg)	4.2 ± 1.9	3.7 ± 1.4	8.1 ± 1.8^{a1b1}	8.1 ± 1.6^{a1b1}
Vitamin A (RE)	368.5 ± 320.6	329.9 ± 155.6	479.5 ± 153.9^{b1}	479.1 ± 147.6^{b1}
Thiamin (mg)	1.0 ± 0.4	1.0 ± 0.4	1.3 ± 0.3^{a1b1}	1.3 ± 0.4^{a1b1}
Vitamin C (mg)	65.1 ± 47.0	73.6 ± 51.7	88.7 ± 56.1^{a1b2}	82.4 ± 49.1^{a2}
Sodium (mg)	3004.1 ± 971.3	2965.8 ± 944.3	2609.4 ± 1054.1^{a3b2}	2635.6 ± 906.1^{b3}

Significant difference from week 0 $^{a1}p<0.001$, $^{a2}p<0.01$, $^{a3}p<0.05$

Significant difference from week 4 $^{b1}p<0.001$, $^{b2}p<0.01$, $^{b3}p<0.05$

Table 4.14 Mean (±SD) of energy requirement and energy intakes of 50 TP employees during the study

Parameters	Week 0	Week 4	Week 8	Week 12
Energy requirement (kcal)*	1626.7 ± 324.7	1618.3 ± 321.9	1612.5 ± 324.2	1606.8 ± 319.4
Energy intake (kcal)	1199.6 ± 285.8	1148.0 ± 276.1	1194.1 ± 296.5	1178.8 ± 272.7

* energy requirement which calculated from basal metabolic rate (Tanita Technical Bulletin: Regression Formula for Basal Metabolic Rate) multiply with activity factor

Table 4.15 Mean (±SD) of energy and nutrient intake of 50 TP employees during the study compared with %Thai RDI

Nutrient	Week 0		Week 4		Week 8		Week 12	
	Amount/day	%RDI	Amount/day	%RDI	Amount/day	%RDI	Amount/day	%RDI
Saturated fatty acid (g)	12.4 ± 4.0	62.2 ± 20.1	12.1 ± 3.8	60.4 ± 19.1	8.7 ± 3.7	43.4 ± 18.6	8.6 ± 3.3	43.2 ± 16.4
Cholesterol (mg)	235.0 ± 97.6	78.3 ± 32.5	223.7 ± 86.7	74.6 ± 28.9	173.2 ± 73.2	57.7 ± 24.4	184.2 ± 81.2	61.4 ± 27.1
Calcium (g)	361.45 ± 132.0	45.2 ± 16.5	341.4 ± 103.7	42.7 ± 13.0	405.8 ± 112.6	50.7 ± 14.1	402.0 ± 98.4	50.3 ± 12.3
Phosphorus (mg)	612.4 ± 173.4	76.6 ± 21.7	575.8 ± 153.5	72.0 ± 19.2	602.6 ± 159.9	75.3 ± 20.0	604.1 ± 155.2	75.5 ± 19.4
Iron (mg)	9.9 ± 3.0	66.1 ± 20.2	9.2 ± 2.4	61.4 ± 15.9	12.2 ± 2.8	81.4 ± 18.6	12.3 ± 2.7	82.2 ± 17.8
Vitamin A (RE)	368.5 ± 320.6	46.1 ± 40.1	329.9 ± 155.6	41.2 ± 19.4	479.5 ± 153.9	59.9 ± 19.2	479.1 ± 147.6	59.9 ± 18.5
Thiamin (mg)	1.0 ± 0.4	67.4 ± 29.5	1.0 ± 0.4	66.3 ± 28.3	1.3 ± 0.3	88.9 ± 22.4	1.3 ± 0.4	87.8 ± 24.6
Vitamin C (mg)	65.1 ± 47.0	108.5 ± 78.4	73.6 ± 51.7	122.7 ± 86.2	88.7 ± 56.1	147.9 ± 93.4	82.4 ± 49.1	137.4 ± 81.8
Sodium (mg)	3004.1 ± 971.3	125.2 ± 40.5	2965.8 ± 944.3	123.6 ± 39.3	2609.4 ± 1054.1	108.7 ± 43.9	2635.6 ± 906.1	109.8 ± 37.8
Fiber (g)	7.6 ± 3.9	30.5 ± 15.6	7.7 ± 3.5	30.7 ± 13.9	8.0 ± 2.9	32.0 ± 11.7	7.7 ± 2.6	30.7 ± 10.4

Table 4.16 shows mean (±SD) of body composition and blood pressure parameters. At the first 4 weeks (week 4) of the dietary recommendation found that body weight, BMI, fat mass, and BMR were significantly lower than from baseline.

At the second 4 weeks (week 8), subjects received Gen-DM and, had the rest two meals of recommended regular diets found that body weight, BMI, body fat (%bw) and fat mass were significantly lower than baseline and week 4 but fat free mass, muscle mass, bone mass, BMR, metabolic age, and visceral fat were significantly lower than only baseline.

At the last period of study (week 12), subjects received Gen-DM, and had the rest two meals of recommended regular diets found that all body composition and blood pressure parameters were no significant differences from week 8 but body weight, BMI, fat mass, fat free mass, muscle mass, TBW (kg) and BMR were significantly lower than baseline and week 4, and body fat (%bw), bone mass, metabolic age and visceral fat were significantly lower than only baseline.

Follow-up of body weight and percentage body fat status of 50 TP employees during the study are showed in **Table 4.17**. The number of 2 underweight, and 2 obese class II subjects had not change during the study but their means of BMI were improved. Fifteen normal weight subjects can maintain their normal weight during the study. Twenty two overweight subjects at week 12, 27.3% of them had become normal weight, and the rest of them were still in overweight but their means of BMI was lower than baseline. Fifty percent of obese class I subjects were improved to be in overweight status at week 12, and 50.0% of obese class I subjects were still in obese class I but their means of BMI was lower than baseline.

One low body fat subject had become normal body fat during the study. Seven normal body fat subjects can maintain their normal body fat at week 12. Twenty nine over body fat subjects at week 12, 6.9% of them had become normal body fat, and the rest of them were still in over body fat but their means of percentage body fat was lower than baseline. Eight point three percent of excess body fat subjects were improved to be in over body fat status at week 12, and 91.7% of excess body fat subjects were still in excess body fat but their means of percentage body fat was lower than baseline.

Table 4.18 shows follow-up of visceral fat status (48) of 50 TP employees during the study. Forty two normal visceral fat subjects can maintain their normal visceral fat during the study. Eight over visceral fat subjects at week 12, 12.5% of them had become normal visceral fat, and the rest of them were still in over visceral fat but their means of visceral fat was lower than baseline.

Table 4.19 shows follow-up of SBP status of 50 TP employees during the study. Nineteen normal SBP subjects can maintain their normal SBP at week 12. Eighteen prehypertension subjects at week 12, 44.4% and 16.7% of them had become normal SBP and hypertension stage I, respectively, and the rest of them were still in prehypertension but their means of SBP was lower than baseline. Eighty five point seven percent of hypertension stage I subjects were improved to be in prehypertension at week 12, and 14.3% of hypertension stage I subjects were still in hypertension stage I which her SBP was higher than baseline.

Table 4.20 shows follow-up of DPB status of 50 TP employees during the study. Twenty nine normal DBP subjects can maintain their normal DBP at week 12. Eight prehypertension subjects at week 12, 37.5% and 25.0% of them had become normal DBP and hypertension stage I, respectively, and the rest of them were still in prehypertension but their means of DBP was lower than baseline. Fifty percent and 12.5% of hypertension stage I subjects were improved to be in normal DBP and prehypertension at week 12, respectively, and the rest of them were still in hypertension stage I but their means of DBP was lower than baseline.

Table 4.16 Mean (±SD) of body composition and blood pressure parameters of 50 TP employees during the study

Parameters	Week 0	Week 4	Week 8	Week 12
Weight (kg)	68.6 ± 13.7	68.1 ± 13.7[a3]	67.6 ± 13.7[a1b1]	67.4 ± 13.7[a1b1]
BMI (kg/m^2)	26.1 ± 4.1	25.9 ± 4.1[a3]	25.7 ± 4.1[a1b1]	25.7 ± 4.1[a1b2]
Body fat (%bw)	32.8 ± 7.6	32.6 ± 7.7	32.2 ± 7.8[a2b2]	32.3 ± 7.6[a3]
Fat mass (kg)	22.7 ± 7.7	22.4 ± 7.8[a3]	22.0 ± 7.8[a1b1]	22.0 ± 7.8[a1b2]
Fat free mass (kg)	45.9 ± 9.9	45.7 ± 9.8	45.6 ± 9.8[a2]	45.4 ± 9.7[a1b2]
Muscle mass (kg)	43.3 ± 9.5	43.1 ± 9.4	43.0 ± 9.4[a2]	42.8 ± 9.3[a1b2]
TBW (kg)	33.2 ± 7.2	33.1 ± 7.2	33.0 ± 7.3	32.8 ± 7.1[a2b2]
TBW (%bw)	49.0 ± 3.7	49.2 ± 3.7	49.2 ± 3.8	49.2 ± 3.5
Bone mass (kg)	2.59 ± 0.4	2.58 ± 0.5	2.57 ± 0.5[a2]	2.55 ± 0.4[a1]
BMR (kcal)	1355 ± 270	1348 ± 268[a3]	1343 ± 270[a1]	1339 ± 266[a1b2]
Metabolic age	47.6 ± 12.6	46.8 ± 12.7	46.3 ± 12.7[a1]	46.3 ± 12.5[a2]
Visceral fat	8.6 ± 3.6	8.5 ± 3.5	8.4 ± 3.5[a3]	8.3 ± 3.5[a2]
SBP (mmHg)	121 ± 15	118 ± 14	116 ± 16	118 ± 14
DBP (mmHg)	74 ± 12	74 ± 10	72 ± 12	73 ± 10
PR (bpm)	80 ± 10	78 ± 9	78 ± 10	77 ± 11

Significant difference from week 0 [a1]$p<0.001$, [a2]$p<0.01$, [a3]$p<0.05$

Significant difference from week 4 [b1]$p<0.01$, [b2]$p<0.05$

Table 4.17 Follow-up of body weight and percentage body fat status of 50 TP employees during the study

Nutritional status	Week 0	Week 4	Week 8	Week 12
	n(%[a])	n(%[b])	n(%[b])	n(%[b])
BMI				
Underweight	2 (4.0)			
Underweight		2 (100.0)	2 (100.0)	2 (100.0)
Normal weight	16 (32.0)			
Normal weight		16 (100.0)	16 (100.0)	15 (93.8)
Overweight		-	-	1 (6.3)
Overweight	22 (44.0)			
Normal weight		3 (13.6)	6 (27.3)	6 (27.3)
Overweight		19 (86.4)	16 (72.7)	16 (72.7)
Obese class I	8 (16.0)			
Overweight		2 (25.0)	4 (50.0)	4 (50.0)
Obese class I		6 (75.0)	4 (50.0)	4 (50.0)
Obese class II	2 (4.0)			
Obese class II		2 (100.0)	2 (100.0)	2 (100.0)
Body fat (%bw)				
Low body fat	1 (2.0)			
Normal body fat		1 (100.0)	1 (100.0)	1 (100.0)
Normal body fat	8 (16.0)			
Low body fat		-	1 (12.5)	-
Normal body fat		8 (100.0)	6 (75.0)	7 (87.5)
Over body fat		-	1 (12.5)	1 (12.5)
Over body fat	29 (58.0)			
Normal body fat		2 (6.9)	2 (6.9)	2 (6.9)
Over body fat		27 (93.1)	27 (93.1)	27 (93.1)
Excess body fat	12 (24.0)			
Over body fat		1 (8.3)	2 (16.7)	1 (8.3)
Excess body fat		11 (91.7)	10 (83.3)	11 (91.7)

[a] % of total subjects, [b] % of BMI and body fat (%bw) status at week 0

Table 4.18 Follow-up of visceral fat status of 50 TP employees during the study

Visceral fat status	Week 0	Week 4	Week 8	Week 12
	n(%[a])	n(%[b])	n(%[b])	n(%[b])
Normal visceral fat	42 (84.0)			
Normal visceral fat		42 (100.0)	42 (100.0)	42 (100.0)
Over visceral fat	8 (16.0)			
Normal visceral fat		-	1 (12.5)	1 (12.5)
Over visceral fat		8 (100.0)	7 (87.5)	7 (87.5)

[a] % of total subjects, [b] % of visceral fat status at week 0

Table 4.19 Follow-up of SBP status of 50 TP employees during the study

SBP status	Week 0	Week 4	Week 8	Week 12
	n(%[a])	n(%[b])	n(%[b])	n(%[b])
Normal	25 (50.0)			
Normal (≤120 mmHg)		21 (84.0)	21 (84.0)	19 (76.0)
Prehypertension (121-139 mmHg)		4 (16.0)	4 (16.0)	6 (24.0)
Prehypertension	18 (36.0)			
Normal (≤120 mmHg)		6 (33.3)	9 (50.0)	8 (44.4)
Prehypertension (121-139 mmHg)		11 (61.1)	6 (33.3)	7 (38.9)
Hypertension stage I (140-159 mmHg)		1 (5.6)	3 (16.7)	3 (16.7)
Hypertension stage I	7 (14.0)			
Normal (≤120 mmHg)		2 (28.6)	1 (14.3)	-
Prehypertension (121-139 mmHg)		3 (42.9)	3 (42.9)	6 (85.7)
Hypertension stage I (140-159 mmHg)		2 (28.6)	3 (42.9)	1 (14.3)

[a] % of total subjects, [b] % of SBP status at week 0

Table 4.20 Follow-up of DPB status of 50 TP employees during the study

DBP status	Week 0	Week 4	Week 8	Week 12
	n(%[a])	n(%[b])	n(%[b])	n(%[b])
Normal	34 (68.0)			
Normal (≤80 mmHg)		30 (88.2)	30 (88.2)	29 (85.3)
Prehypertension (81-89 mmHg)		3 (8.8)	4 (11.8)	5 (14.7)
Hypertension stage I (90-99 mmHg)		1 (2.9)	-	-
Prehypertension	8 (16.0)			
Normal (≤80 mmHg)		3 (37.5)	5 (62.5)	3 (37.5)
Prehypertension (81-89 mmHg)		5 (62.5)	2 (25.0)	3 (37.5)
Hypertension stage I (90-99 mmHg)		-	1 (12.5)	2 (25.0)
Hypertension stage I	8 (16.0)			
Normal (≤80 mmHg)		3 (37.5)	1 (12.5)	4 (50.0)
Prehypertension (81-89 mmHg)		2 (25.0)	3 (37.5)	1 (12.5)
Hypertension stage I (90-99 mmHg)		1 (12.5)	4 (50.0)	3 (37.5)
Hypertension stage II (100-110 mmHg)		2 (25.0)	-	-

[a] % of total subjects, [b] % of DBP status at week 0

Table 4.21 shows mean (±SD) of blood biochemistry parameters. At the first 4 weeks (week 4) of the dietary recommendation, subjects received dietary advice for lowering blood sugar and serum LDL-C found that all blood biochemistry parameters were no significant differences from baseline.

At the second 4 weeks (week 8), subjects received Gen-DM, and had the rest two meals of recommended regular diets found that all blood biochemistry parameters were no significant differences from week 4 but FPG, TC, and LDL-C were significantly lower than baseline.

At the last period of study (week 12), subjects received Gen-DM, and had the rest two meals of recommended regular diets found that all blood biochemistry parameters were no significant differences from week 8 except HDL-C was significantly higher than week 8. Fasting plasmas glucose and LDL-C were significantly lower than baseline and week 4, and TC was significantly lower than only baseline.

Hemoglobin (Hb), TG, uric acid, SGOT, SGPT, BUN, and creatinine were normal level during the study. Therefore, medical food (Gen-DM) that provided to subjects had safe and no adverse effects.

Table 4.22 shows follow-up of Hb, FPG, and uric acid status of TP employees during the study. Six anemia subjects had become normal Hb at week 12. Nineteen impaired fasting glucose subjects at week 12, 84.2% of them had become normal FPG, and the rest of them were still in impaired fasting glucose but their means of FPG was lower than baseline. Thirty three point three percent and 33.3% of diabetes were improved to be in normal FBS and impaired fasting glucose at week 12, respectively, and 33.3% of diabetes subjects were still in diabetes but his FPG was lower than baseline. Thirteen hyperuricemia subjects at week 12, 61.5% of them had become normal uric acid, and the rest of them were still in hyperuricemia but their means of uric acid was lower than baseline.

Table 4.23 shows follow-up of serum lipid profile status of TP employees during the study. All low HDL-C subjects had become normal HDL-C at week 12. Twenty borderline LDL-C subjects at week 12, 45.0% and 10.0% of them had become normal LDL-C and high LDL-C, respectively, and the rest of them were still in borderline LDL-C but their means of LDL-C were lower than baseline. Twenty high LDL-C subjects at week 12, 35.0%, 40.0%, and 10.0% of them had become normal, borderline, and very high LDL-C at week 12, respectively, and the rest of them were still in high LDL-C but their means of LDL-C was lower than baseline. Eleven point one percent, 11.1%, and 44.4% of very high LDL-C subjects were improved to be in normal, borderline, and high LDL-C at week 12 respectively, and 33.3% of high LDL-C subjects were still in very high LDL-C which their means of LDL-C was higher than baseline. Ten borderline TG subjects at week 12, 50.0% of them had become normal TG, and the rest of them were still in borderline TG but their means of TG was lower than baseline. Fifty percent of high TG subjects were improved to be in normal TG at week 12, and 50.0% of high TG subjects were still in high TG which their means of TG was higher than baseline.

Table 4.24-4.28 shows Pearson's correlation coefficient among various nutritional parameters.

Table 4.29 shows body composition and blood pressure status 50 TP employees during the study. At the end of this study we found 42.0% of subjects had normal weight, 20.0% of them had normal body fat, 86.0% of them had normal visceral fat, 54.0% of them had normal SBP, and 72.0% of them had normal DBP.

Table 4.30 shows blood biochemistry status 50 TP employees during the study. At the end of this study we found 98.0% of subjects had normal hemoglobin, 84.0% of them had normal FPG, 100.0% of them had normal HDL-C, 36.0% of them had normal LDL-C, 68.0% of them had normal TG, and 84.0% of them had normal uric acid.

Table 4.21 Mean (±SD) of blood biochemistry parameters of 50 TP employees during the study

Parameters	Week 0	Week 4	Week 8	Week 12
Hemoglobin (g/dL)	13.4 ± 1.4 (10.9-16.6)[a]	13.3 ± 1.4 (11.4-17.1)	13.5 ± 1.5 (11.0-16.8)	13.6 ± 1.2 (11.4-16.3)
FPG (mg/dL)	100.7 ± 16.1 (80-174)	97.3 ± 18.5 (79-203)	94.2 ± 14.1[a2] (76-166)	90.7 ± 11.0[a1b1] (70-129)
TC (mg/dL)	240.8 ± 31.1 (160-322)	233.7 ± 34.4 (176-340)	225.5 ± 37.4[a1] (160-309)	226.5 ± 41.0[a3] (135-333)
TG (mg/dL)	127.3 ± 49.1 (54-251)	122.1 ± 55.2 (54-347)	120.9 ± 57.1 (42-291)	126.2 ± 57.4 (37-300)
HDL-C (mg/dL)	56.1 ± 16.2 (20-107)	54.5 ± 12.8 (35-93)	55.3 ± 11.2 (38-82)	58.0 ± 11.9[c1] (40-91)
LDL-C (mg/dL)	166.3 ± 27.8 (77-256)	155.8 ± 28.7 (96-236)	146.3 ± 32.6[a1] (86-217)	143.8 ± 34.3[a1b1] (47-235)
Uric acid (mg/dL)	5.7 ± 1.7 (3.0-9.1)	5.5 ± 1.5 (3.0-8.8)	5.4 ± 1.6 (2.7-10.0)	5.4 ± 1.5 (2.9-8.6)
SGOT (U/L)	22.5 ± 6.6 (11-38)	23.8 ± 7.7 (13-50)	23.6 ± 8.0 (13-49)	24.0 ± 8.9 (12-61)
SGPT (U/L)	24.0 ± 12.8 (9-67)	24.1 ± 13.6 (11-71)	22.1 ± 10.9 (10-66)	22.7 ± 13.3 (11-74)
BUN (mg/dL)	13.8 ± 2.6 (9-20)	14.1 ± 2.5 (6-18)	14.6 ± 2.5 (10-20)	15.0 ± 2.6 (10-21)
Creatinine (mg/dL)	0.9 ± 0.2 (0.5-1.3)	0.9 ± 0.2 (0.5-1.3)	1.0 ± 0.2 (0.6-1.3)	1.0 ± 0.2 (0.7-1.4)

Significant difference from week 0 [a1]$p<0.001$, [a2]$p<0.01$, [a3]$p<0.05$

Significant difference from week 4 [b1]$p<0.05$

Significant difference from week 8 [c1]$p<0.05$

[a](min-max)

Table 4.22 Follow-up of hemoglobin, fasting plasma glucose, and uric acid status of TP employees during the study

Nutritional status	Week 0	Week 4	Week 8	Week 12
	n(%[a])	n(%[b])	n(%[b])	n(%[b])
Hb (g/dL)				
Anemia	6 (12.0)			
Anemia (<12 g/dL) (female) (<13 g/dL) (male)		2 (33.3)	3 (50.0)	-
Normal (≥12 g/dL) (female) (≥13 g/dL) (male)		4 (66.7)	3 (50.0)	6 (100.0)
FPG (mg/dL)				
IFG	19 (38.0)			
Normal (<100 mg/dL)		9 (47.4)	14 (73.7)	16 (84.2)
IFG (100-125 mg/dL)		10 (52.6)	5 (26.3)	3 (15.8)
Diabetes	3 (6.0)			
Normal (<100 mg/dL)		-	-	1 (33.3)
IFG (100-125 mg/dL)		1 (33.3)	2 (66.7)	1 (33.3)
Diabetes (≥126 mg/dL)		2 (66.7)	1 (33.3)	1 (33.3)
Uric acid (mg/dL)				
High uric acid	13 (26.0)			
Normal (≤7.0 mg/dL)		9 (69.2)	9 (69.2)	8 (61.5)
High (>7.0 mg/dL)		4 (30.8)	4 (30.8)	5 (38.5)

[a] % of total subjects, [b] % of Hb, FPG, and uric acid status at week 0

Table 4.23 Follow-up of serum lipid profile status of TP employees during the study

Nutritional status	Week 0	Week 4	Week 8	Week 12
	n(%[a])	n(%[b])	n(%[b])	n(%[b])
HDL-C (mg/dL)				
Low HDL-C	5 (10.0)			
Low (<40 mg/dL)		1 (20.0)	1 (20.0)	-
Normal (≥40 mg/dL)		4 (80.0)	4 (80.0)	5 (100.0)
LDL-C (mg/dL)				
Borderline LDL-C	20 (40.0)			
Normal (<130 mg/dL)		5 (25.0)	10 (50.0)	9 (45.0)
Borderline (130-159 mg/dL)		9 (45.0)	5 (25.0)	9 (45.0)
High (160-189 mg/dL)		6 (30.0)	5 (25.0)	2 (10.0)
High LDL-C	20 (40.0)			
Normal (<130 mg/dL)		3 (15.0)	6 (30.0)	7 (35.0)
Borderline (130-159 mg/dL)		8 (40.0)	7 (35.0)	8 (40.0)
High (160-189 mg/dL)		5 (25.0)	3 (15.0)	3 (15.0)
Very high (>189 mg/dL)		4 (20.0)	4 (20.0)	2 (10.0)
Very high LDL-C	9 (18.0)			
Normal (<130 mg/dL)		1 (11.1)	2 (22.2)	1 (11.1)
Borderline (130-159 mg/dL)		-	1 (11.1)	1 (11.1)
High (160-189 mg/dL)		5 (55.6)	4 (44.4)	4 (44.4)
Very high (>189 mg/dL)		3 (33.3)	2 (22.2)	3 (33.3)
TG (mg/dL)				
Borderline TG	10 (20.0)			
Normal (<150 mg/dL)		6 (60.0)	6 (60.0)	5 (50.0)
Borderline (150-199 mg/dL)		3 (30.0)	1 (10.0)	5 (50.0)
High (200-499 mg/dL)		1 (10.0)	3 (30.0)	-
High TG	4 (8.0)			
Normal (< 150 mg/dL)		3 (75.0)	2 (50.0)	2 (50.0)
Borderline (150-199 mg/dL)		1 (25.0)	1 (25.0)	-
High (200-499 mg/dL)		-	1 (25.0)	2 (50.0)

[a] % of total subjects, [b] % of serum lipid profile status at week 0

Table 4.24 Pearson's correlation coefficient between body weight status, percentage body fat, and fat mass with nutritional and nutrient parameters in 50 TP employees

Parameters	BMI		Body fat (%bw)		Fat mass	
	r	P-value	*r*	P-value	*r*	P-value
Weight (kg)	0.831	<0.001	0.234	<0.001	0.713	<0.001
BMI (kg/m^2)	-	-	0.699	<0.001	0.926	<0.001
Body fat (%bw)	0.669	<0.001	-	-	0.837	<0.001
Fat mass (kg)	0.926	<0.001	0.837	<0.001	-	-
Muscle (kg)	0.417	<0.001	-0.348	<0.001	0.192	<0.01
Bone mass (kg)	0.562	<0.001	-0.109	NS	0.422	<0.001
TBW (kg)	0.633	<0.001	-0.202	<0.01	0.399	<0.001
Visceral fat	0.709	<0.001	0.044	NS	0.477	<0.001
SBP (mmHg)	0.293	<0.001	0.002	NS	0.202	<0.001
DBP (mmHg)	0.102	NS	-0.244	<0.001	-0.038	NS
Hemoglobin (g/dL)	0.237	<0.001	-0.346	<0.001	0.041	NS
FPG (mg/dL)	0.508	<0.001	0.217	<0.01	0.438	<0.001
TG (mg/dL)	0.206	<0.01	0.031	NS	0.113	NS
LDL-C (mg/dL)	-0.235	<0.001	-0.121	NS	-0.162	<0.05
HDL-C (mg/dL)	-0.360	<0.001	-0.006	NS	-0.193	<0.01
Uric acid (mg/dL)	0.410	<0.001	-0.167	<0.05	0.217	<0.01
Energy intake (kcal)	0.201	<0.01	-0.066	NS	0.105	NS
Carbohydrate (g)	0.108	NS	-0.136	NS	0.005	NS
Sugar (g)	0.028	NS	0.070	NS	0.019	NS
Protein (g)	0.237	<0.001	-0.100	NS	0.118	NS
Fat (g)	0.267	<0.001	0.081	NS	0.220	<0.01
SFA (g)	0.252	<0.001	0.183	<0.01	0.249	<0.001
Cholesterol (mg)	0.290	<0.001	0.127	NS	0.240	<0.001
Sodium (mg)	0.174	<0.05	-0.108	NS	0.068	NS
Calcium (mg)	0.116	NS	0.000	NS	0.082	NS
Phosphorus (mg)	0.185	<0.01	-0.041	NS	0.105	NS
Iron (mg)	0.106	NS	-0.141	<0.05	0.005	NS

NS Not Significant

Table 4.25 Pearson's correlation coefficient between muscle mass, bone mass, and visceral fat with nutritional and nutrient parameters in 50 TP employees

Parameters	Muscle mass		Bone mass		Visceral fat	
	r	P-value	*r*	P-value	*r*	P-value
Weight (kg)	0.825	<0.001	0.916	<0.001	0.861	<0.001
BMI (kg/m^2)	0.417	<0.001	0.562	<0.001	0.709	<0.001
Body fat (%bw)	-0.348	<0.001	-0.109	NS	0.044	NS
Fat mass (kg)	0.192	<0.01	0.422	<0.001	0.477	<0.001
Muscle (kg)	-	-	0.940	<0.001	0.823	<0.001
Bone mass (kg)	0.940	<0.001	-	-	0.798	<0.001
TBW (kg)	0.975	<0.001	0.961	<0.001	0.886	<0.001
Visceral fat	0.823	<0.001	0.798	<0.001	-	-
SBP (mmHg)	0.412	<0.001	0.396	<0.001	0.492	<0.001
DBP (mmHg)	0.444	<0.001	0.355	<0.001	0.448	<0.001
Hemoglobin (g/dL)	0.742	<0.001	0.655	<0.001	0.661	<0.001
FPG (mg/dL)	0.395	<0.001	0.397	<0.001	0.520	<0.001
TG (mg/dL)	0.218	<0.01	0.164	<0.05	0.401	<0.001
LDL-C (mg/dL)	-0.038	NS	-0.029	NS	-0.077	NS
HDL-C (mg/dL)	-0.398	<0.001	-0.378	<0.001	-0.468	<0.001
Uric acid (mg/dL)	0.712	<0.001	0.636	<0.001	0.747	<0.001
Energy intake (kcal)	0.333	<0.001	0.301	<0.001	0.310	<0.001
Carbohydrate (g)	0.276	<0.001	0.227	<0.001	0.259	<0.001
Sugar (g)	-0.079	NS	-0.079	NS	0.008	NS
Protein (g)	0.438	<0.001	0.391	<0.001	0.374	<0.001
Fat (g)	0.264	<0.001	0.273	<0.001	0.264	<0.001
SFA (g)	0.098	NS	0.134	NS	0.181	<0.01
Cholesterol (mg)	0.231	<0.001	0.241	<0.001	0.236	<0.001
Sodium (mg)	0.351	<0.001	0.305	<0.001	0.320	<0.001
Calcium (mg)	0.093	NS	0.102	NS	0.109	NS
Phosphorus (mg)	0.280	<0.001	0.265	<0.001	0.245	<0.001
Iron (mg)	0.333	<0.001	0.281	<0.001	0.255	<0.001

NS Not Significant

Table 4.26 Pearson's correlation coefficient between SBP and DBP with nutritional and nutrient parameters in 50 TP employees

Parameters	SBP		DBP	
	r	**P-value**	***r***	**P-value**
Weight (kg)	0.410	<0.001	0.295	<0.001
BMI (kg/m^2)	0.293	<0.001	0.102	NS
Body fat (%bw)	0.002	NS	-0.244	<0.001
Fat mass (kg)	0.202	<0.01	-0.038	NS
Muscle (kg)	0.412	<0.001	0.444	<0.001
Bone mass (kg)	0.396	<0.001	0.355	<0.001
TBW (kg)	0.453	<0.001	0.438	<0.001
Visceral fat	0.492	<0.001	0.448	<0.001
SBP (mmHg)	-	-	0.685	<0.001
DBP (mmHg)	0.685	<0.001	-	-
Hemoglobin (g/dL)	0.391	<0.001	0.519	<0.001
FPG (mg/dL)	0.341	<0.001	0.193	<0.01
TG (mg/dL)	0.285	<0.001	0.310	<0.001
LDL-C (mg/dL)	0.030	NS	0.059	NS
HDL-C (mg/dL)	-0.174	<0.05	-0.202	<0.01
Uric acid (mg/dL)	0.422	<0.001	0.488	<0.001
Energy intake (kcal)	0.335	<0.001	0.238	<0.001
Carbohydrate (g)	0.318	<0.001	0.252	<0.01
Sugar (g)	0.242	<0.001	0.127	NS
Protein (g)	0.345	<0.001	0.271	<0.001
Fat (g)	0.267	<0.001	0.133	NS
SFA (g)	0.175	<0.05	0.083	NS
Cholesterol (mg)	0.231	<0.001	0.142	<0.05
Sodium (mg)	0.185	<0.01	0.172	<0.05
Calcium (mg)	0.070	NS	0.032	NS
Phosphorus (mg)	0.250	<0.001	0.182	<0.01
Iron (mg)	0.221	<0.01	0.177	<0.05

NS Not Significant

Table 4.27 Pearson's correlation coefficient between hemoglobin, FPG, and uric acid with nutritional parameters in 50 TP employees

Parameters	Hemoglobin		FPG		Uric acid	
	r	P-value	*r*	P-value	*r*	P-value
Weight (kg)	0.552	<0.001	0.533	<0.001	0.632	<0.001
BMI (kg/m^2)	0.237	<0.001	0.508	<0.001	0.410	<0.001
Body fat (%bw)	-0.346	<0.001	0.217	<0.01	-0.167	<0.01
Fat mass (kg)	0.041	NS	0.438	<0.001	0.217	<0.05
Muscle (kg)	0.742	<0.001	0.395	<0.001	0.712	<0.001
Bone mass (kg)	0.655	<0.001	0.397	<0.001	0.636	<0.001
TBW (kg)	0.688	<0.001	0.521	<0.001	0.720	<0.001
Visceral fat	0.661	<0.001	0.520	<0.001	0.747	<0.001
SBP (mmHg)	0.391	<0.001	0.341	<0.001	0.422	<0.001
DBP (mmHg)	0.519	<0.001	0.193	<0.01	0.488	<0.001
Hemoglobin (g/dL)	-	-	0.231	<0.001	0.657	<0.001
FPG (mg/dL)	0.231	<0.001	-	-	0.385	<0.001
TG (mg/dL)	0.271	<0.001	0.250	<0.001	0.304	<0.001
LDL-C (mg/dL)	0.033	NS	-0.053	NS	-0.005	NS
HDL-C (mg/dL)	-0.371	<0.001	-0.201	<0.01	-0.357	<0.001
Uric acid (mg/dL)	0.657	<0.001	0.385	<0.001	-	-
Energy intake (kcal)	0.283	<0.001	0.108	NS	0.281	<0.001
Carbohydrate (g)	0.292	<0.001	0.069	NS	0.227	<0.001
Sugar (g)	0.017	NS	0.069	NS	0.033	NS
Protein (g)	0.319	<0.001	0.168	<0.05	0.378	<0.001
Fat (g)	0.172	<0.05	0.098	NS	0.225	<0.001
SFA (g)	0.029	NS	0.129	NS	0.105	NS
Cholesterol (mg)	0.096	NS	0.188	<0.01	0.240	<0.001
Sodium (mg)	0.290	<0.001	0.077	NS	0.333	<0.001
Calcium (mg)	0.136	NS	-0.133	NS	0.062	NS
Phosphorus (mg)	0.275	<0.001	0.033	NS	-0.240	<0.001
Iron (mg)	0.320	<0.001	-0.040	NS	0.233	<0.001

NS Not Significant

Table 4.28 Pearson's correlation coefficient between serum lipid profile with nutritional parameters in 50 TP employees

Parameters	TG		HDL-C		LDL-C	
	r	P-value	*r*	P-value	*r*	P-value
Weight (kg)	0.219	<0.01	-0.395	<0.001	-0.119	NS
BMI (kg/m^2)	0.206	<0.01	-0.360	<0.001	-0.235	<0.001
Body fat (%bw)	0.031	NS	-0.006	NS	-0.121	NS
Fat mass (kg)	0.113	NS	-0.193	<0.01	-0.162	<0.05
Muscle (kg)	0.218	<0.01	-0.398	<0.001	-0.038	NS
Bone mass (kg)	0.164	<0.05	-0.378	<0.001	-0.029	NS
TBW (kg)	0.245	<0.001	-0.430	<0.001	-0.107	NS
Visceral fat	0.401	<0.001	-0.468	<0.001	-0.077	NS
SBP (mmHg)	0.285	<0.001	-0.174	<0.05	0.030	NS
DBP (mmHg)	0.310	<0.001	-0.202	<0.01	0.059	NS
Hemoglobin (g/dL)	0.271	<0.001	-0.371	<0.001	0.033	NS
FPG (mg/dL)	0.250	<0.001	-0.202	<0.01	-0.053	NS
TG (mg/dL)	-	-	-0.445	<0.001	0.018	NS
LDL-C (mg/dL)	0.018	NS	0.202	<0.01	-	-
HDL-C (mg/dL)	-0.445	<0.001	-	-	0.202	<0.01
Uric acid (mg/dL)	0.304	<0.001	-0.357	<0.001	-0.005	NS
Energy intake (kcal)	0.065	NS	-0.137	NS	-0.091	NS
Carbohydrate (g)	0.088	NS	-0.116	NS	-0.064	NS
Sugar (g)	0.037	NS	-0.055	NS	0.102	NS
Protein (g)	0.040	NS	-0.157	<0.05	-0.096	NS
Fat (g)	0.026	NS	-0.116	NS	-0.110	NS
SFA (g)	0.037	NS	0.000	NS	0.025	NS
Cholesterol (mg)	0.012	NS	-0.170	<0.05	-0.069	NS
Sodium (mg)	0.077	NS	-0.103	NS	-0.020	NS
Calcium (mg)	-0.117	NS	-0.085	NS	-0.091	NS
Phosphorus (mg)	-0.012	NS	-0.108	NS	-0.080	NS
Iron (mg)	0.043	NS	-0.088	NS	-0.145	<0.05

NS Not Significant

Table 4.29 Body composition and blood pressure status during the study

Parameters	Week 0	Week 12
	n(%[a])	n(%[a])
BMI status		
Underweight	2 (4.0)	2 (4.0)
Normal weight	16 (32.0)	21 (42.0)
Overweight	22 (44.0)	21 (42.0)
Obese class I	8 (16.0)	4 (8.0)
Obese class II	2 (4.0)	2 (4.0)
Percent body fat status		
Low body fat	1 (2.0)	-
Normal body fat	8 (16.0)	10 (20.0)
Over body fat	29 (58.0)	29 (58.0)
Excess body fat	12 (24.0)	11 (22.0)
Visceral fat status		
Normal visceral fat	42 (84.0)	43 (86.0)
Over visceral fat	8 (16.0)	7 (14.0)
SBP status		
Normal (<120 mmHg)	25 (50.0)	27 (54.0)
Prehypertension (120-139 mmHg)	18 (36.0)	19 (38.0)
Hypertension stage I (140-159 mmHg)	7 (14.0)	4 (8.0)
DBP status		
Normal (<80 mmHg)	34 (68.0)	36 (72.0)
Prehypertension (80-89 mmHg)	8 (16.0)	9 (18.0)
Hypertension stage I (90-99 mmHg)	8 (16.0)	5 (10.0)

[a] % of total subjects

Table 4.30 Blood biochemistry status during the study

Parameters	Week 0	Week 12
	n(%[a])	n(%[a])
Hemoglobin status		
Anemia (< 12 g/dL) (female) (< 13 g/dL) (male)	6 (12.0)	1 (2.0)
Normal (≥ 12 g/dL) (female) (≥ 13 g/dL) (male)	44 (88.0)	49 (98.0)
FPG status		
Normal (< 100 mg/dL)	28 (56.0)	42 (84.0)
IFG (100-125 mg/dL)	19 (38.0)	7 (14.0)
Diabetes (≥ 126 mg/dL)	3 (6.0)	1 (2.0)
HDL-C status		
Low (< 40 mg/dL)	5 (10.0)	-
Normal (≥ 40 mg/dL)	45 (90.0)	50 (100.0)
LDL-C status		
Normal (< 130 mg/dL)	1 (2.0)	18 (36.0)
Borderline (130-159 mg/dL)	20 (40.0)	18 (36.0)
High (160-189 mg/dL)	20 (40.0)	9 (18.0)
Very high (> 189 mg/dL)	9 (18.0)	5 (10.0)
TG status		
Normal (< 150 mg/dL)	36 (72.0)	34 (68.0)
Borderline (150-199 mg/dL)	10 (20.0)	12 (24.0)
High (200-499 mg/dL)	4 (8.0)	4 (8.0)
Uric acid status		
Normal (≤ 7.0 mg/dL)	37 (74.0)	42 (84.0)
High (> 7.0 mg/dL)	13 (26.0)	8 (16.0)

[a] % of total subjects

4.3 The suitability and expediency of medical food (Gen-DM®) (Questionnaire)

The suitability and expediency of medical food (Gen-DM®) were assessed by using questionnaire at weeks 5-12.

4.3.1 Satisfaction of medical food (Gen-DM®) intake

Evaluation of satisfaction was divided into five parameters consisting of flavors, texture, smell, dissolution, and portability. The score of each parameter was divided into six levels consisting of 5 (very good), 4 (good), 3 (medium), 2 (fair), 1 (poor), and 0 (very poor). At the end of this study, the results showed their average score that flavor, texture, smell, and dissolution are good, and portability is very good.

4.3.2 Adverse effect of medical food (Gen-DM®) intake

Adverse effects after taking Gen-DM was evaluated by questionnaire that the results showed 86.3% of subjects no adverse effects, 1.5% of them were nausea, 3.2% of them had a little stomach ache, 5.3% of them taste too sweet, 1.2% of them taste a less sweet, and 2.5% of them had other adverse effects such as diarrhea and headache. These symptoms occur only a first period and only a short time.

4.3.3 Satiety index of medical food (Gen-DM®) intake

Satiety index after taking Gen-DM was evaluated by questionnaire that the scores were divided six levels consisting of 5 (full), 4 (3 hours), 3 (2 hours), 2 (1 hour), 1 (30 minutes), and 0 (not full). At the end of this study, the results showed most of subjects were evaluated satiety index that after taking Gen-DM, they were full around 2-3 hours. When compare satiety index of taking Gen-DM with regular diet found that 68.0% of subjects were full less than regular diet, 25.5% of them were full more than regular diet, and 6.5% of them do not differences from regular diet.

4.3.4 The flavor of medical food (Gen-DM®)

During weeks 5-12, we ask their opinion about flavor of medical food (Gen-DM®) that subjects wanted to intake were evaluated by questionnaire that the results showed 43.0% of subjects choose original flavor, 19.5% of them choose chocolate flavor, 18.2% of them choose coffee flavor, 17.8% of them choose corn flavor, and 1.5% of them choose others flavor such as strawberry and green tea flavor.

4.3.5 The cost of medical food (Gen-DM®)

The cost of medical food (Gen-DM®) was evaluated by questionnaire that cost of 1 Gen-DM sachet (40g) was 30 baht, the results showed 72.8% of subjects choose buy Gen-DM because they thought it was reasonable price.

CHAPTER V
DISCUSSION

Diabetes is a chronic disease and is a leading cause of cardiovascular disease, blindness, kidney failure and lower-limb amputation. Cardiovascular disease is the most common cause of death and disability among people with diabetes (1). Obesity and overweight pose a major risk for chronic diseases, including type 2 diabetes, cardiovascular disease, hypertension, and stroke. The key causes are increased consumption of energy dense foods high in saturated fats and sugars, and reduced physical activity (3).

The Transport Co., Ltd is a public transportation and had 3,178 employees consisting of 1,585 driver employees and 1,593 office employees. In 2014 the TP Health Program by Leelahagul P found that some of the employees had diet-related chronic diseases such as obesity, diabetes, dyslipidemia, hyperuricemia, and hypertension. The Transport Co., Ltd had cost of healthcare each year more than thirty million bahts. Their chronic diseases occurred due to job responsibility that they can not choose the appropriate food for their health status, the uncertainty of mealtime, and limited of food sources. After nutritional therapy for six months in TP Health Program found that appropriate nutritional therapy can prevent and reduce the severity of diet-related chronic diseases in some TP employees. Therefore, we were interested in medical food sachet that used combined with the regular diet to treat those diet-related chronic diseases in TP employees.

This study aimed to assess the effect of Gen-DM sachet for TP employees could be taken when dining outside as one meal replacement, and had the rest two meals of recommended regular diets for improvement of their diet-related chronic diseases.

5.1 General information

Fifty TP employees (13 males and 37 females) who had high blood sugar (≥100 mg/dL) or high serum LDL-C (≥130 mg/dL) were included in this study, aged 24-60 years, consisting of 43 office employees and 7 driver employees.

5.1.1 Primary information

Most of 50 subjects were born in central and live in central region. Seven driver employees had highest education level at senior high school and most of 43 office employees had highest education level at bachelor's degree. We found that one in ten of subjects who had hyperuricemia, hypertension and high visceral fat were driver employees. Thus education levels of TP employees may be effect the behavior of dietary intake.

5.1.2 Socio-economic information

Their range income of driver employees had 10,000-30,000 Bahts/month whereas their range income of office employees had 10,000-100,000 Bahts/month. In our study found that office employees who had high socioeconomic status (SES) had higher average intake of energy, fat, saturated fatty acid, cholesterol, sugar, sodium, and fiber than driver employees who had lower SES.

Maye´n et al. (49) carried out a systematic review of cohort and cross-sectional studies in adults in low- and middle-income countries (LMICs) which published between 1996 and 2013. They assessed associations between markers of high-income countries, high socioeconomic status (SES) or urban and rural settings and dietary intake. The results showed that high SES or living in urban areas was associated with higher intakes of calories; protein; total fat; cholesterol; polyunsaturated, saturated, and monounsaturated fatty acids; iron; and vitamins A and C and with lower intakes of carbohydrates and fiber. High SES was also associated with higher fruit and/or vegetable consumption, diet quality, and diversity. Although very few studies were performed in low-income countries, similar patterns were generally observed in both LMICs except for fruit intake, which was lower in urban than in rural areas in low-income countries.

5.1.3 Health information

Twenty eight (56.0%) subjects reported they had no underlying diseases but we found 100.0% of them had underlying diseases: anemia (7.1%), hyperuricemia (17.6%), impaired fasting glucose and diabetes (42.9%), prehypertension and hypertension (46.4%), obesity (17.9%), and hypercholesterolemia (100.0%). This evidence showed that most of them did not know their underlying diseases or did not know the underlying diseases. Only 5 of them had received drug therapy for their underlying diseases. Six subjects did not know their family medical history. Thus, when TP employees had health checkups in organization, the physicians and health staff in organization should give them about the knowledge of their underlying diseases.

Our study found that most of 50 subjects reported exercise (72.0%), and we found female exercise (78.4%) more than male (58.3%) which shows that females had health awareness more than males. Thirty six subjects who reported exercise, most of them exercise <3 times/week (69.4%) and <30 minutes/time (66.6%), whereas WHO (50) recommended on physical activity for health that should be for adults aged 18-64 years should do at least 150 minutes of moderate-intensity aerobic physical activity throughout the week, or do at least 75 minutes of vigorous-intensity aerobic physical activity, and we found that most of them exercise by walking (52.7%). In this study found that most of 50 subjects had do housework by sweep or mop the home which it was housework that Thai people normally do, and most of them were seated work (44.0%).

Chau et al. (51) examined associations between occupational and leisure-time sitting, physical activity and obesity in working adults. They analyzed data from workers from the 2007–2008 Australian National Health Survey (n=10,785). Participants reported their activity at work (mostly sitting, standing, walking, or heavy labor), transport-related walking, leisure-time sitting and physical activity. Body mass index was objectively measured. Adjusted Cox proportional hazard regression models examined associations between occupational activity category, leisure-time sitting, physical activity and obesity risk. The results showed substantial proportions of men (42.0%) and women (47.0%) mostly sit at work. Workers with sitting jobs were significantly more likely to be sufficiently active during leisure-time than workers

with mostly standing, walking or heavy labor jobs (RR=0.88, 0.80, 0.86, respectively). Workers with mostly sitting jobs had significantly higher overweight/obesity risk than workers with mostly standing jobs (RR=0.88, 95% CI: 0.82–0.95) independent of physical activity and leisure-time sitting. Workers with leisure-time sitting of less than four hours per day had significantly lower obesity risk than workers with four or more hours per day of leisure-time sitting (RR=0.77, 95% CI: 0.69–0.87) independent of physical activity and occupational activity.

Uffelen et al. (52) were identified in March–April 2009 by literature searches in PubMed, PsycINFO, CENTRAL, CINAHL, EMBASE, and PEDro, with subsequent related-article searches in PubMed and citation searches in Web of Science. Identified studies were categorized by health outcome. Two independent reviewers assessed methodologic quality using a 15-item quality rating list (score range 0–15 points, higher score indicating better quality). Data on study design, study population, measures of occupational sitting, health risks, analyses, and results were extracted. The results showed 43 papers met the inclusion criteria (21.0% cross-sectional, 14% case–control, 65% prospective); they examined the associations between occupational sitting and BMI (n=12); cancer (n=17); cardiovascular disease (n=8); diabetes mellitus (n=4); and mortality (n=6). The median study-quality score was 12 points. Half the cross-sectional studies showed a positive association between occupational sitting and BMI, but prospective studies failed to confirm a causal relationship. There was some case–control evidence for a positive association between occupational sitting and cancer; however, this was generally not supported by prospective studies. The majority of prospective studies found that occupational sitting was associated with a higher risk of diabetes and mortality.

Most of 50 subjects had three meals/day (82.0%) but 14.0% of them had <3 meals/day that we found those subjects were driver employees. Forty three subjects who reported that ate snack, we found all of them had hypercholesterolemia, and 28 of them had overweight or obesity, 60.5% of hypercholesterolemia and 60.7% of overweight or obesity subjects drank coffee, tea, soft drink, and fruit juices. Seven driver employees, we found that all of them had hypercholesterolemia and 6 of them had overweight or obesity, 85.7% of hypercholesterolemia and 83.3% of overweight or obesity subjects drank coffee, tea, soft drink, and fruit juices.

Our study agree with the study by Bes-Rastrollo et al. (53), which studied longitudinal prospective Spanish dynamic cohort (10,162 university graduates; mean age:39 years) followed-up for an average of 4.6 years. Dietary habits were ascertained through a validated 136-item food-frequency questionnaire. Usual snackers were defined as those participants who answered affirmatively when asked in the baseline assessment if they usually eat between meals. Validated self-reported weight and BMI were collected at baseline and during follow-up. The results showed after adjusting for potential confounders, self-reported between-meal snacking was significantly associated with a higher risk of substantial weight gain (3 kg/year; $p<0.001$; 5 kg/year, $p<0.001$; 10.0% baseline weight, $p<0.001$). Among participants with a baseline BMI lower than 30 kg/m^2 (n: 9709) they observed 258 new cases of obesity. Usual snackers presented an adjusted 69.0% higher risk of becoming obese during follow-up (Hazard Ratio: 1.69; 95% confidence interval: 1.30–2.20).

Twenty three subjects who like cooking by frying and stirfrying, all of them had hypercholesterolemia, and 60.9% of them had overweight or obesity. The favorite seasoning that subjects add were sugar and fish sauce, we found most of 30 subjects who like to add sugar in food had impaired fasting glucose or diabetes (46.7%), and most of 33 subjects who like to add fish sauce in food had prehypertension or hypertension (63.3%). Twenty nine subjects who ate buffet, we found they had overweight or obesity (65.5%), and hypercholesterolemia (100.0%) which most of them ate meat buffet.

Vergnaud et al. (54) studied a total of 103,455 men and 270,348 women aged 25–70 years were recruited between 1992 and 2000 in 10 European countries. Diet was assessed at baseline with the use of country-specific validated questionnaires. A dietary calibration study was conducted in a representative subsample of the cohort. Weight and height were measured at baseline and self-reported at follow-up in most centers. Associations between energy from meat (kcal/day) and annual weight change (g/years) were assessed with the use of linear mixed models, controlled for age, sex, total energy intake, physical activity, dietary patterns, and other potential confounders. The results showed total meat consumption was positively associated with weight gain in men and women, in normal-weight and overweight subjects, and in smokers and nonsmokers. With adjustment for estimated energy intake, an increase in meat intake

of 250g/day (eg, one steak at 450 kcal) would lead to a 2-kg higher weight gain after 5 years (95% CI: 1.5, 2.7 kg). Positive associations were observed for red meat, poultry, and processed meat.

In our study we also found positive correlations between BMI and total energy intake (r=0.201, p=<0.01), total fat intake (r=0.267, p<0.001), saturated fatty acid intake (r=0.252, p<0.001), and cholesterol intake (r=0.290, p<0.001). Whereas we found the positive correlations of fat mass and total fat intake (r=0.220, p<0.01), saturated fatty acid intake (r=0.249, p<0.001), and cholesterol intake (r=0.240, p<0.001).

Beverage consumption, 100.0% of subjects who drank energy drink had overweight or obesity, whereas 72.7%, 65.8%, 61.3%, and 28.6% who drank alcohol, coffee, sweetened soft drink, and tea, respectively had overweight or obesity. Subjects who drank tea, alcohol, energy drink, and sweetened soft drink, 100.0% had hypercholesterolemia, whereas 97.4% of subjects who drank coffee had hypercholesterolemia. Subjects who drank sweetened soft drink, tea, coffee, energy drink, and alcohol, 38.7%, 35.7%, 28.9%, 20.0%, and 18.2%, respectively had hypertriglyceridemia which 54.5% of subjects who drank alcohol were males. Subjects who drank energy drink, alcohol, coffee, sweetened soft drink, and tea, 80.0%, 63.6%, 52.6%, 45.2%, and 7.1%, respectively had impaired fasting glucose or diabetes. All 5 subjects who drank energy drink were males consisting of 4 driver employees and 1 office employee.

Our study agree with the study by Malik et al. (55) they reported that consumption of sugar-sweetened beverages (SSBs), which include soft drinks, fruit drinks, iced tea, and energy and vitamin water drinks has risen across the globe. Regular consumption of SSBs has been associated with weight gain and risk of overweight and obesity, but the role of SSBs in the development of related chronic metabolic diseases, such as MS and type 2 diabetes, has not been quantitatively reviewed. They searched the MEDLINE database up to May 2010 for prospective cohort studies of SSBs intake and risk of MS and type 2 diabetes. They identified 11 studies (three for MS and eight for type 2 diabetes) for inclusion in a random-effects meta-analysis comparing SSBs intake in the highest to lowest quantiles in relation to risk of MS and type 2 diabetes. The results showed based on data from these studies,

including 310,819 participants and 15,043 cases of type 2 diabetes, individuals in the highest quantile of SSB intake (most often 1–2 servings/day) had a 26.0% greater risk of developing type 2 diabetes than those in the lowest quantile (none or <1 serving/month) (relative risk [RR] 1.26 [95% CI 1.12–1.41]). Among studies evaluating MS, including 19,431 participants and 5,803 cases, the pooled RR was 1.20 [1.02–1.42]. In conclusion, in addition to weight gain, higher consumption of SSBs is associated with development of MS and type 2 diabetes.

Water intake of 50 subjects, we found most of them drank water <7 glasses/day (~1.4-1.75 L/day) (64.0%) whereas USDA DRI (56) recommended water intake aged 19 and over years should be more than 3.7 L/day (male) and 2.7 L/day (female). However, we found 36 subjects did not drink enough water but only 6 subjects had low TBW.

Meat consumption, we found first order of meat that subjects always ate was pork (74.0%), 56.8% of subjects who ate pork had overweight or obesity. Subjects who ate fatty meats, skin meats, and organ meats, 65.9%, 64.5%, and 60.8%, respectively had overweight or obesity. Subjects who ate skin meats, fatty meats, and organ meats, 100.0%, 97.6%, and 97.4%, respectively had hypercholesterolemia. Subjects who ate organ meats, 31.6% and 26.3% had hypertriglyceridemia, and hyperuricemia, respectively. All subjects ate sea food, and we found 98.0% of them had hypercholesterolemia. All subjects ate eggs but we found only 44 subjects ate whole egg and they had hypercholesterolemia, whereas 6 subjects who ate only white egg that we found 5 of them had hypercholesterolemia.

Fat consumption, 39 subjects did not add non-dairy creamer into coffee or tea, we found 66.7% and 100.0% of them had overweight or obesity, and hypercholesterolemia, respectively, whereas 11 subjects add non-dairy creamer into coffee or tea, we found 54.5% and 90.9% of them had overweight or obesity, and hypercholesterolemia, respectively. Although, the prevalence of overweight or obesity and hypercholesterolemia in subjects who did not add-dairy creamer higher than subjects who add dairy creamer but when we investigated in others intake that we found subjects who did not add diary creamer had average energy, carbohydrate, fat, saturated fatty acid, and cholesterol intakes higher than subjects who add diary creamer. Most of 50 subjects used soybean oil (62.0%) for cooking which we found 6

of 7 driver employees used soybean oil and the rest of them used palm oil. Two of 50 subjects used lard for cooking and we found that they had hypercholesterolemia.

Schwingshackl et al. (57) carried out the systematic review and meta-analysis focused on randomized controlled trials assessing the long-term effects of low-fat diets compared with diets with high amounts of fat on blood lipid levels. Relevant randomized controlled trials were identified searching MEDLINE, EMBASE, and the Cochrane Trial Register until March 2013. Thirty-two studies were included in the meta-analysis. The result showed decreases in TC (weighted mean difference -4.55 mg/dL [-0.12 mmol/L], 95% CI -8.03 to -1.07; p=0.01) and LDL-C (weighted mean difference -3.11 mg/dL [-0.08 mmol/L], 95% CI -4.51 to -1.71 ; p<0.0001) were significantly more pronounced following low-fat diets, whereas rise in HDL-C (weighted mean difference 2.35 mg/dL [0.06 mmol/L], 95% CI 1.29 to 3.42; p<0.0001) and reduction in TG levels (weighted mean difference -8.38 mg/dL [-0.095 mmol/L], 95% CI -13.50 to -3.25; p=0.001) were more distinct in the high-fat diet groups. Including only hypocaloric diets, the effects of low-fat vs high-fat diets on TC and LDL-C levels were abolished. Meta-regression revealed that lower TC level was associated with lower intakes of saturated fat and higher intakes of polyunsaturated fat, and increases in HDL-C levels were related to higher amounts of total fat largely derived from monounsaturated fat (of either plant or animal origin) in high-fat diets (composition of which was ~17.0% of total energy content in the form of monounsaturated fatty acids, ~8.0% of total energy content in the form of polyunsaturated fatty acids), whereas increases in TG levels were associated with higher intakes of carbohydrates. In addition, lower LDL-C level was marginally associated with lower saturated fat intake.

Vegetable and fruit consumption, we found 50.0% of normal weight subjects and 46.9% of overweight or obesity subjects ate salad, 83.3% of normal weight subjects and 56.3% of overweight or obesity subjects ate stir-fried vegetable, and 61.1% of normal weight subjects and 62.5% of overweight or obesity subjects ate steamed vegetable. This our study showed normal weight subjects intake vegetable higher than overweight or obesity subjects. Ninety two percent of 50 subjects ate fresh fruits and we found that 12 subjects ate mango which 25.0% of them had impaired fasting glucose that all of them had overweight or obesity, and 9 subjects ate water

melon which 33.3% of them had impaired fasting glucose or diabetes that all of them had overweight or obesity. Glycemic index (GI) of mango and watermelon were 55 and 72, respectively (58) that it was medium and high GI. Thus, impaired fasting glucose subjects with overweight and obesity and fruit intake which high GI will increase risk of diabetes.

From this data, their consumption behavior found that they had high consumption of energy dense foods high in saturated fats and sugars that is a leading cause of diet-related chronic diseases (3).

5.2 Nutritional status

5.2.1 Dietary intake

Compliances of Gen-DM consumption averaged 98.2% which is in the acceptable level. Energy distributions, carbohydrate, protein, and fat did not change during the study. Mean dietary intake were derived from Gen-DM at weeks 5-12 was 28.2% of total energy, 30.0% of total carbohydrate, 23.7% of total protein, and 28.1% of total fat. Evaluation of satisfaction of taking Gen-DM found that their average score that flavor, texture, smell, and dissolution are good, and portability is very good. Hemoglobin (Hb), TG, uric acid, SGOT, SGPT, BUN, and creatinine were normal level throughout the study. Therefore, medical food (Gen-DM) that provided to subjects had safe and no adverse effects.

Animal protein intake at week 8 and 12 were significantly lower than baseline and week 4 because they received dietary advice about reducing fatty meats and skin meats intakes whereas vegetable protein intake was significantly increasing. However, we investigated average essential amino acid at weeks 5-12 from Gen-DM were isoleucine 0.7g, leucine 1.2g, lysine 1.0g, methionine 0.3g, phenylalanine 1.2g, threonine 0.5g, tryptophan 0.2g, and valine 0.7g (59, 60) that received 41.0-64.0% of WHO requirement/day (61).

Average essential fatty acid received from Gen-DM at weeks 5-12, we found linoleic acid and alpha-linolenic acid were 4.2% and 0.08% of total energy/day

(19), respectively, whereas WHO recommended (62) should be received linoleic acid and alpha-linolenic acid were 2.5-9.0% and 0.5-2.0% of total energy/day, respectively.

Thai RDI (47) recommended that the amount of sugar intake should be less than 10.0% of total energy intake/day. We found that at baseline and week 4, their mean of sugar intake was higher than Thai RDI, whereas at week 8 and 12, their mean of sugar intake was significantly lower than baseline and week 4 that specially week 12, their mean of sugar intake was lower than Thai RDI.

Office of the cane and sugar board (63) indicated the rate of consumption sugar Thailand's population that increased from 34.8g/person/day (~7 teaspoon/person/day) in 1983 to 92.6g/person/day (~19 teaspoon/person/day) in 2010. This data showed that sugar consumption has increased steadily in Thailand's population.

Gulati et al. (64) they review the data showing increasing sugar consumption in India, including traditional sources (jaggery and khandsari) and from sugar-sweetened beverages (SSBs). The results showed along with decreasing physical activity, this increasing trend of per capita sugar consumption assumes significance in view of the high tendency for Indians to develop insulin resistance, abdominal adiposity, and hepatic steatosis, and the increasing “epidemic” of type 2 diabetes and cardiovascular diseases. Importantly, there are preliminary data to show that incidence of obesity and type 2 diabetes could be decreased by increasing taxation on SSBs. Other prevention strategies, encompassing multiple stakeholders (government, industry, and consumers), should target on decreasing sugar consumption in the Indian population. In this context, dietary guidelines for Indians show that sugar consumption should be less than 10.0% of total daily energy intake, but it is suggested that this limit be decreased.

Saturated fatty acid intake should be less than 10.0% of total energy intake/day. We found that their mean of SFA intake was lower than Thai RDI during the study and their mean of SFA intake at week 8 and 12 were significantly lower than baseline and week 4.

Cholesterol intake should be less than 300 mg/day. We found that their mean of cholesterol intake was lower than Thai RDI during the study and their mean

of cholesterol intake at week 8 and 12 were significantly lower than baseline and week 4.

Sodium intake should be less than 2,400 mg/day. We found that their mean of sodium intake was higher than Thai RDI during the study but their mean of sodium intake at week 8 and 12 were significantly lower than baseline and week 4. Thus, subjects should be reduced sodium intake such as decreased fish sauce and salt intakes.

Fiber intake should be more than 25g/day. We found that their mean of fiber intake was lower than Thai RDI during the study and their mean of fiber intake at week 8 and 12 were higher than baseline and week 4. Thus, subjects should be increase fiber intake such as increased vegetable and fresh fruit intakes.

Therefore, addition Gen-DM as 30.0% of total energy can improved food quality which was evident from energy distribution; carbohydrate 51.6%, protein 17.9%, and fat 30.7% of total energy which is in the acceptable level, as well as sugar, SFA, cholesterol, and sodium intakes that were risk factors of diet-related chronic diseases were lower than baseline and suitable for lowering blood sugar and serum lipid profiles (24, 33, 39, 40).

5.2.2 Body composition and blood biochemistry

Body weight, percentage body fat, FPG, and LDL-C at first 4 weeks (week 4) of the dietary recommendation, they received dietary advice for lowering blood sugar and serum LDL-C, 70.0%, 62.0%, 72.0%, and 64.0% of subjects can reduce their body weight, percentage body fat, FPG, and LDL-C, respectively.

Body weight status classified by BMI. At baseline found that 44.0% and 20.0% of 50 subjects were overweight and obese, respectively. After receiving the dietary recommendation (week 4) found that 13.6% of overweight had improved to be in normal weight status, and 20.0% of obese subjects had improved to be in overweight status.

Obesity classified by percentage body fat. At baseline found that 58.0% and 24.0% of 50 subjects had over body fat and excess body fat, respectively. After receiving the dietary recommendation (week 4) found that 6.9% of over body fat

subjects had improved to be in normal body fat status, and 8.3% of excess body fat subjects had improved to be in over body fat status.

During the first 4 weeks (week4) of the dietary recommendation, reduction of mean energy that compare with energy requirement was 470 kcal/day, and reduction of mean fat, SFA, and cholesterol intake were 2.1g/day, 0.3g/day, and 12 mg/day, respectively from baseline. This data showed changed of body weight was higher than percentage body fat that may be due to because food quality. The change of percentage body fat during the first 4 weeks was less than the change of body weight may be due to reduction of energy intake and stable physical activities from baseline period.

This effect was also observed by Miller et al. (65) who carried out electronic databases were searched for randomised controlled trials (RCTs) comparing energy restriction plus exercise training to energy restriction alone. Studies published to May 2013 were included if they used multi-component methods for analysing body composition and assessed measures of fitness in obese adults. The result showed 14 RCTs met the inclusion criteria. Heterogeneity of study characteristics prevented meta-analysis. Energy restriction plus exercise training was more effective than energy restriction alone for improving cardiovascular fitness, muscle strength, and increasing fat mass loss and preserving lean body mass, depending on the type of exercise training.

Therefore, subjects had improvement of dietary consumption and body composition result in reduction of FPG and LDL-C levels. This evidence was supported by fasting plasma glucose status, at baseline found that 38.0% and 6.0% of 50 subjects had impaired fasting glucose and diabetes, respectively, after receiving the dietary recommendation (week 4) found that 47.4% of impaired fasting glucose subjects had improved to be in normal FPG status, and 33.3% of diabetes subjects had improved to be in impaired fasting glucose status. After receiving the dietary recommendation (week 4) found that 25.0%, 15.0%, and 11.1% of borderline, high, very high LDL-C subjects had improved to be in normal LDL-C status, respectively, 40.0% of high LDL-C subjects had improved to be in borderline LDL-C status, and 55.6% of very high LDL-C subjects had improved to be in high LDL-C status.

At the next 4 weeks (week 8), they received Gen-DM, and had the rest two meals of recommended regular diets, 70.0%, 68.0%, 62.0%, and 64.0% of subjects can reduce their body weight, percentage body fat, FPG, and LDL-C, respectively. We found 14.3% of overweight subjects had improved to be in normal weight status, and 25.0% of obese subjects had improved to be in overweight status, we also found 9.1% of excess body fat subjects had improved to be in over body fat status, whereas all over body fat subjects were still in over body fat status but their mean percentage body fat was lower than week 4. The figures of body composition improvement at week 8 were higher than at week 4 because of this period their sugar and SFA intakes which was risk factor of obesity were significantly lower than those at week 4.

After receiving Gen-DM, and had the rest two meals of recommended regular diets (week 8), we found 64.3% of impaired fasting glucose subjects had improved to be in normal FPG status, and one of diabetes subjects had improved to be in impaired fasting glucose status. Percent of subjects who reduce FPG was less than week 4 but FPG status had improved better than week 4 because of Gen-DM had fructose which enters the blood stream more slowly than glucose and its levels are much lower, but they persist longer in the circulation, and fructose stimulates only modest insulin secretion and does not require the presence of insulin to enter cells (14-16).

Gallagher et al. (29) studied the effects of sucrose, fructose, and sucralose on TG, glucose, and insulin in an acute study in healthy, overweight, and obese individuals. The results showed that fructose at a moderate dose did not significantly elevate TG compared with sucrose or sucralose and lowered the glucose iAUC. These results indicate that these sweeteners, at an equivalent sweetness, can be used in normal solid meals. Fructose showed a lower insulin response, which may be beneficial in the long term in individuals at risk of type 2 diabetes.

Moore et al. (30) studied in 5 adults with type 2 diabetes underwent an oral glucose tolerance test (OGTT) on two separate occasions, at least 1 week apart. Each OGTT consisted of 75g glucose with or without the addition of 7.5g fructose (F) (OGTT+F or OGTT–F), in random order. Arterialized blood samples were collected from a heated dorsal hand vein twice before ingestion of the carbohydrate and every 15 minutes for 3 hours afterward. The results showed that low-dose fructose improves

the glycemic response to an oral glucose load in adults with type 2 diabetes, and this effect is not a result of stimulation of insulin secretion.

Stanhope et al. (31) studied in a metabolic facility and gave the subjects consumed energy-balanced diets containing 55.0% of energy as complex carbohydrate for 2 weeks (GI=64). The subjects then consumed 25.o% of energy requirements as fructose- or glucose-sweetened beverages along with their usual ad libitum diets for 8 weeks at home and then as part of energy-balanced diets for 2 weeks at the metabolic facility (fructose GI=38, glucose GI=83). The 24-hours glucose and insulin profiles and fasting plasma glycated albumin and fructosamine concentrations were measured 0, 2, 8, and 10 weeks after beverage consumption. The results showed the results suggest that the specific effects of fructose, but not of glucose and insulin excursions, contribute to the adverse effects of consuming sugar-sweetened beverages on lipids and insulin sensitivity.

Samaisong et al. (23) studied 25 adults with type 2 diabetes. Providing Gen-DM 40g as a snack 2 meals/day. The results showed that subjects can control FPG and LDL-C as well, and can help reduce insulin resistance and improved function of insulin.

At week 8, we found 35.3%, 25.0%, and 14.3% of borderline, high, and very high LDL-C subjects had improved to be in normal LDL-C status, respectively, 25.0% and 46.2% of high and very high LDL-C subjects had improved to be in borderline LDL-C status, and 23.1% of very high LDL-C subjects had improved to be in high LDL-C status. Percent of subjects who reduce LDL-C was equal week 4 but LDL-C status had improved better than week 4 because of Gen-DM had soybean oil, soy protein isolate, and carnitine.

Soybean oil consisting of linoleic acid and alpha linolenic acid are essential fatty acid (EFA). Linoleic acid will be induced modified secretion of cholesteryl ester by liver and increased hepatic LDL-C receptor function (13, 19).

Chan et al (66) studied the effect of dietary oleic acid (OA), linoleic acid (LA), and linolenic acid (LNA) on plasma lipid metabolism was studied in eight normolipidemic men. A mixed-fat diet composed of conventional foods was fed during 6-day pre- and post-experimental periods. The same basic diet but with 75.0% of the fat (26.0% of total energy) provided by sunflower and olive; canola; soybean;

and sunflower, olive, and flax oils was fed during four 18-day experimental periods. The results showed mean plasma total cholesterol (-18.0%), low-density lipoprotein cholesterol, (-22.0%) and very low-density lipoprotein cholesterol (-41.0%) concentrations were significantly ($p<0.004$) lower after the experimental diets than after the mixed-fat diet. Mean serum apolipoprotein B (-19.0%) and apolipoprotein A-I (-9.0%) concentrations were also significantly ($p<0.0007$) lower after the experimental diets. The experimental diets were equally effective in lowering total and lipoprotein cholesterol and apolipoprotein concentrations in plasma, indicating that dietary OA, LA, and LNA were equally hypocholesterolemic.

Bjermo et al. (67) they randomly assigned 67 abdominally obese subjects (15.0% had type 2 diabetes) to a 10 weeks isocaloric diet high in vegetable n-6 polyunsaturated fatty acid (PUFA) (PUFA diet) or SFA mainly from butter (SFA diet), without altering the macronutrient intake. Liver fat was assessed by MRI and magnetic resonance proton (1H) spectroscopy (MRS). Proprotein convertase subtilisin/kexin type-9 (PCSK9, a hepatic LDL-receptor regulator), inflammation, and adipose tissue expression of inflammatory and lipogenic genes were determined. The results showed compared with SFA intake, n-6 PUFAs reduce liver fat and modestly improve metabolic status, without weight loss. A high n-6 PUFA intake does not cause any signs of inflammation or oxidative stress. Downregulation of PCSK9 could be a novel mechanism behind the cholesterol-lowering effects of PUFAs.

Carnitine is an important metabolite which function is indispensable for intermediary metabolism in eukaryotic cells. Its prime function is to act as a carrier for the transport of activated long-chain fatty acids from the cytosol into the mitochondrial matrix where beta-oxidation takes place, and It is involved in the metabolism branched chain amino acid (BCAA) and glucose (21, 22).

Malaguarnera et al. (68) they evaluated the efficacy of L-carnitine on the size of LDL particles in type 2 diabetes mellitus patients treated with simvastatin. Eighty diabetic patients were randomly assigned to 1 of 2 treatment groups for 3 months. The 2 groups received either simvastatin monotherapy 20mg (n=40) or L-carnitine 2g/day and simvastatin 20mg (n=40). The following variables were assessed at baseline; after washout; and at 1, 2, and 3 months of treatment: BMI, FPG, glycosylated hemoglobin, TC, LDL-C, LDL subclasses, LDL size, HDL-C, TG,

apolipoprotein A-1, and apolipoprotein B-100. The result showed after 12 weeks, comparing the 2 groups, we observed a decrease in FPG (1.45 vs 0.61 mmol/L, $p<0.001$) and an increase in glycosylated hemoglobin (0.2% vs 0.4%, $p<0.05$). Moreover, there was a decrease in TC (2.07 vs 1.45 mmol/L, $p<0.001$), LDL-C (1.65 vs 1.29 mmol/L, $p<0.001$), TG (1.36 vs 0.41 mmol/L, $p<0.001$), apo B-100 (49 vs 9 g/L, $p<0.001$), and small-sized LDL proportion (10.8% vs 4.9%, $p<0.001$), whereas LDL particle size increased (6 vs 3 Å, $p<0.001$) and HDL-C increased (0.2 vs 0.11 mmol/L, $p<0.001$).

Soy protein isolate is a protein good quality. The form of protein used in enteral solutions include intact proteins, hydrolyzed protein, and crystalline amino acids. Intact proteins are in their original natural form. Some examples are eggs, milk, and meat proteins. Intact proteins separated from the original food are termed “isolates.” Some examples are soy protein isolate, lactalbumin, casein or whey from milk, and albumin from egg white. Because of their size, they do not have a significant impact on the formula's osmolality, but they do require normal levels of pancreatic enzymes for complete digestion. The form of protein becomes important when a patient’s digestive or absorptive capacity is compromised (20).

Jenkins et al. (69) attempted to estimate the intrinsic and extrinsic (displacement) potential of soy in reducing LDL-C to determine whether the heart health claim for soy continues to be justified. The intrinsic effect of soy was derived from a meta-analysis using soy studies (20–133 g/day soy protein) included in the recent American Heart Association (AHA) Soy Advisory. The extrinsic effect of soy in displacing foods higher in saturated fat and cholesterol was estimated using predictive equations for LDL-C and NHANES III population survey data with the substitution of 13–58 g/day soy protein for animal protein foods. The meta-analysis of the AHA Soy Advisory data gave a mean LDL-C reduction of 0.17 mmol/L ($n=22$; $p<0.0001$) or 4.3% for soy, which was confirmed in 11 studies reporting balanced macronutrient profiles. The estimated displacement value of soy (13–58g/day) using NHANES III population survey data was a 3.6–6.0% reduction in LDL-C due to displacement of saturated fats and cholesterol from animal foods. The LDL-C reduction attributable to the combined intrinsic and extrinsic effects of soy protein

foods ranged from 7.9 to 10.3%. Thus, soy remains one of a few food components that reduces serum cholesterol (>4.0%) when added to the diet.

After consuming Gen-DM for 8 weeks (week 12), we found body weight, percentage body fat, FPG, and LDL-C did not difference from week 8. However, body composition and blood biochemistry were still improved that 54.0%, 50.0%, 66.0%, and 44.0% of subjects can reduce their body weight, percentage body fat, FPG, and LDL-C, respectively. Energy and sugar intakes of subjects who can reduce their body weight and FPG were lower than week 8, whereas subjects who can reduce their percentage body fat and LDL-C had energy, sugar, SFA, and cholesterol intakes were lower than week 8 despite of mean dietary intake did not difference. When we investigated body composition and blood biochemistry status found that 5.0% of overweight subjects had improved to be in normal weight status, and all obese subjects were still in obese status and their mean of BMI was unchanged from week 8, and 96.7% of over body fat subjects were still in over body fat status and their mean of percentage body fat was unchanged from week 8, whereas all excess body fat subjects were still in excess body fat status and their mean of percentage body fat was unchanged from week 8.

We found FPG and LDL-C at week 12 had still improved better than week 8 but was no significant difference which FPG and LDL-C had still improved because composition of Gen-DM such as fructose, soybean oil, soy protein isolate, and carnitine etc. However, FPG and LDL-C at week 12 were compared with baseline that subjects can reduce FPG and LDL-C were 76.0% and 74.0%, respectively, and were significantly lower than baseline and week 4.

Hemoglobin, HDL-C, TG, uric acid, SGOT, SGPT, BUN and, creatinine levels were normal during the study. At the end of our study, we found 70.0%, 52.0% of subjects had increased Hb and HDL-C, respectively whereas 48.0% and 58.0% of subjects had decreased TG and uric acid, respectively.

HDL-C at week 12 was significantly higher than week 8. We also found significant negative correlation of BMI with HDL-C ($r= -0.360$, $p<0.001$). Rena et al. (70) They conducted an observational analysis of participants in the Look AHEAD (Action For Health in Diabetes) study (n=5,145, 40.5% male, 37% from ethnic/racial minorities) and examined the association between the magnitude of weight loss and

changes in CVD risk factors at 1 year and the odds of meeting predefined criteria for clinically significant improvements in risk factors in individuals with type 2 diabetes. The results showed the magnitude of weight loss at 1 year was strongly ($p<0.0001$) associated with improvements in glycemia, BP, TG, and HDL-C but not with LDL-C ($p=0.79$). Compared with weight-stable participants, those who lost 5.0 to <10.0% ([means±SD] 7.25±2.1 kg) of their body weight had increased odds of achieving a 0.5% point reduction in HbA1c (odds ratio 3.52 [95% CI 2.81–4.40]), a 5 mmHg decrease in DBP (1.48 [1.20–1.82]), a 5 mmHg decrease in SBP (1.56 [1.27–1.91]), a 5 mg/dL increase in HDL-C (1.69 [1.37–2.07]), and a 40 mg/dL decrease in TG (2.20 [1.71–2.83]). The odds of clinically significant improvements in most risk factors were even greater in those who lost 10.0–15.0% of their body weight.

5.2.3 Blood pressure

Blood pressure level were normal during the study. At the end of our study we found 52.0% and 56.0% of 50 subjects can reduce their SBP and DBP which maximum reductions were 31 mmHg and 28 mmHg, respectively. We also found significant correlation of SBP ($r=0.185$, $p<0.01$) and DBP ($r=0.172$, $p<0.05$) with sodium intake.

Aburto et al. (71) studied randomised controlled trials and prospective cohort studies in non-acutely ill adults and children assessing the relations between sodium intake and blood pressure, renal function, blood lipids, and catecholamine levels, and in non-acutely ill adults all cause mortality, cardiovascular disease, stroke, and coronary heart disease. The results showed in adults a reduction in sodium intake significantly reduced resting SBP by 3.39 mmHg (95% confidence interval 2.46 to 4.31) and resting DBP by 1.54 mmHg (0.98 to 2.11). When sodium intake was <2g/day vs ≥2 g/day, SBP was reduced by 3.47 mmHg (0.76 to 6.18) and DBP by 1.81 mmHg (0.54 to 3.08). Increased sodium intake was associated with an increased risk of stroke (risk ratio 1.24, 95% confidence interval 1.08 to 1.43), stroke mortality (1.63, 1.27 to 2.10), and coronary heart disease mortality (1.32, 1.13 to 1.53).

CHAPTER VI
CONCLUSION

This study was conducted to study the effect of Gen-DM sachet for TP employees could be taken when dining outside as one meal replacement, and had the rest two meals of recommended regular diets for improvement of their diet-related chronic diseases. We studied a 12-week repeated measures designs in 50 TP employees aged 24-60 years who had high blood sugar (≥100 mg/dL) or high serum LDL-C (≥130 mg/dL), consisting of 13 males and 37 females. Providing nutritional therapy as the following, first 4 weeks (weeks 1-4) subjects received dietary advice for lowering blood sugar and serum LDL-C, and weeks 5-12 subjects received two meals of dietary advice for weeks 1-4 and replaced the rest of the meal with medical food, Gen-DM, 1-2 sachets (based on their total energy intake at baseline).

6.1 Nutritional status

Nutritional status at the beginning of study in 50 TP employees based on BMI, 64.0% were overweight, whereas based on percentage body fat, 82.0% had over body fat. Diet-related chronic diseases, we found 12.0%, 44.0%, 10.0%, 98.0%, 28.0%, and 26.0% of subjects were anemia, hyperglycemia, low HDL-C level, hypercholesterolemia, hypertriglyceridemia, and hyperuricemia, respectively.

6.2 Nutritional therapy

After first 4 weeks, subjects received only dietary advice for lowering blood sugar and serum LDL-C for 4 weeks, we found the percentage of overweight, over body fat, hyperglycemia, and hypercholesterolemia subjects were less than those at baseline, 58.0%, 80.0%, 32.0%, and 80.0%, respectively.

For the next 8 weeks, subjects received Gen-DM replaced one meal and the rest two meals of recommended regular diets and try to maintain their energy intake and physical activity as in the baseline period. After receiving this medical food 1 meal and 2 meals of recommended regular diets for 8 weeks (weeks 5-12), at the first 4 weeks (weeks 5-8), there were lower percentage of hyperglycemia and hypercholesterolemia subjects, 20.0% and 62.0%, respectively. At the end of study the next 4 weeks of receiving those diets (weeks 9-12) there were lowest percentage of hyperglycemia subjects, and percentage of hypercholesterolemia subjects was comparable to week 8.

From previous study, the TP Health Program by Leelahagul P. in 2014 studied 32 TP employees who participated in six months of nutritional therapy we found at the end of study, 65.6%, 56.3%, 50.0%, 52.0%, 68.2%, and 47.1% of them can reduce their body weight, percentage body fat, FPG, LDL-C, TG, uric acid levels. In our study we found, 72.0%,70.0%,76.0%, 74.0%, 48.0%, and 58.0% of 50 subjects can reduce their body weight, percentage body fat, FPG, LDL-C, TG, uric acid levels.

Therefore, our study, subjects receiving 1-2 sachet Gen-DM replaced one meal together with two meals of recommended regular diets, show their body weight, percentage body fat, FPG, LDL-C, and uric acid can reduce more effective than previous study which subjects receiving nutritional therapy by only nutritional advice for improving their nutritional status.

Cost of Gen-DM (30 baht/sachet) was lower than or similar cost of medicines but Gen-DM also provided other high quality nutrients and no adverse effect to their body, and Gen-DM also appropriate for persons that can not control their intake and/or can not choose the appropriate food for their health status such as officer and driver employees.

6.3 Recommendation

This study showed that providing appropriate nutritional therapy can help subjects improved their nutritional status for example to lowering blood sugar and serum LDL-C, they should avoid intake of fatty meats, skin meats, organ meats, egg

yolk, seafood such as shrimp and crab, high saturated fatty acid foods, and high sugar foods, as well as encourage them to have more exercise and physical activities.

However, specific formula medical food combined with recommended regular diets could improve nutritional status and reduce the severity of diet-related chronic diseases in some persons who can not practice as recommendation.

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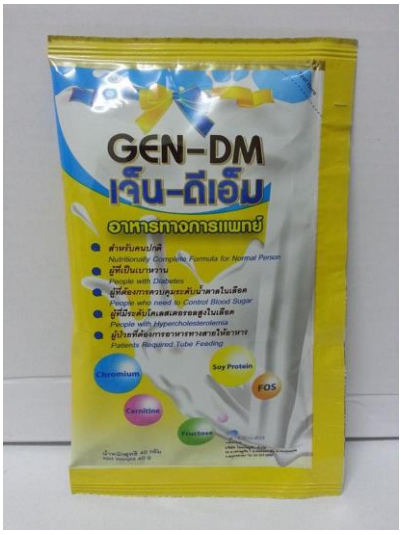
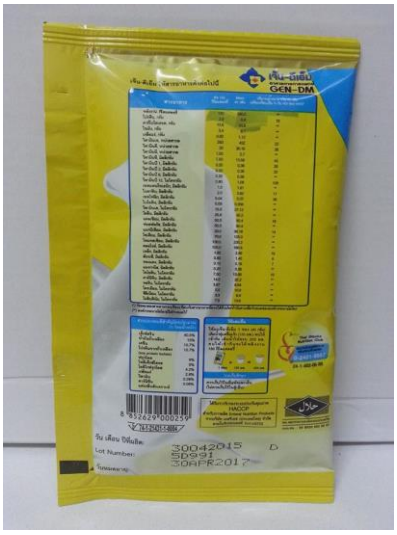
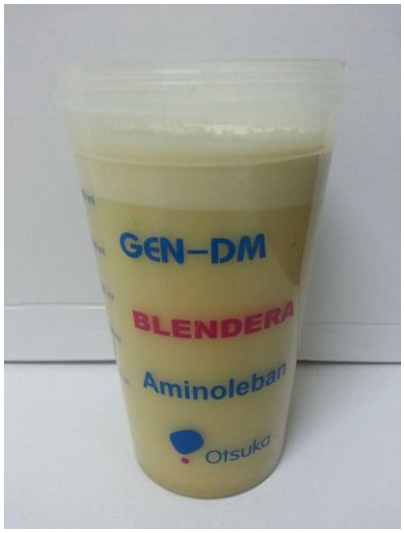
APPENDICES

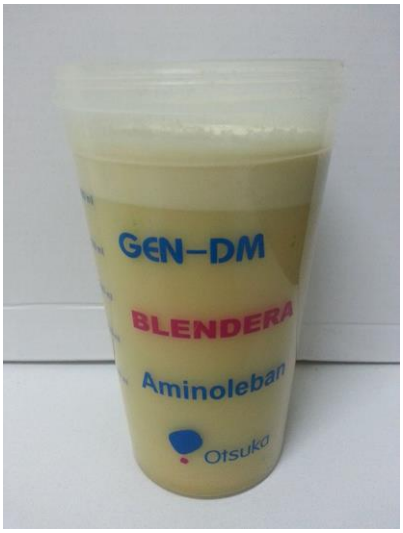
APPENDIX A
DIET FOR STUDY





1 sachet (40g) of Gen-DM





1 glass of 1 sachet dissolved in 200 ml water

APPENDIX B
NUTRITION EDUCATION

โครงการวิจัย "ประสิทธิผลของการดื่มอาหารทางการแพทย์ (Gen-DM®) ขนาดพกพา 40 กรัม ต่อการควบคุมระดับน้ำตาลในเลือดและไขมันในเลือดของพนักงานบริษัท ขนส่ง จำกัด"

การปฏิบัติตัวในช่วงการควบคุมรับประทานอาหารระยะเวลา 1 เดือน

โดย รศ.ดร. ปรียา ลีพหกุล โทร 081-8699839

นศ. ธีรภาพ ปานคล้าย โทร 084-6270901

1. ตลอดระยะเวลา 1 เดือนในการควบคุมการรับประทานอาหาร ผู้ใดเคยมีกิจกรรมอย่างไรให้ทำตามเดิมตลอดไป
2. การควบคุมการรับประทานอาหารในช่วง 1 เดือน ควรปฏิบัติตัว ดังนี้
   - หลีกเลี่ยงอาหารพวกเนื้อสัตว์ที่ติดมัน เครื่องในสัตว์ ไข่แดง หนังสัตว์ เช่น หนังหมู หนังไก่
   - หลีกเลี่ยงอาหารทะเลบางชนิด เช่น กุ้งชนิดต่าง ๆ หอยนางรม ปลาหมึกสด ปลาหมึกแห้ง
   - หลีกเลี่ยงผลิตภัณฑ์จากนม เช่น เนย ครีม เนยแข็ง
   - หลีกเลี่ยงขนมหวานที่มีส่วนประกอบของน้ำตาล และกะทิหรือมะพร้าว ขนมที่มีไขมันแฝงอยู่ เช่น ขนมขบเคี้ยว ขนมกินเล่น ขนมเบเกอรี่ เช่น โดนัท ขนมปังไส้ต่าง ๆ
   - หลีกเลี่ยงอาหารที่ปรุงด้วยน้ำมัน อาหารทอด เช่น ไก่ชุบแป้งทอด กล้วยทอด อาหารที่มีส่วนผสมของกะทิ เช่น แกงเขียวหวาน และพยายามปรุงอาหารโดยใช้วิธีต้ม นึ่ง ย่าง อบแทน
   - หลีกเลี่ยงน้ำมันที่มีกรดไขมันอิ่มตัวสูง เช่น น้ำมันปาล์ม น้ำมันมะพร้าว และไขมันที่ได้จากสัตว์ เช่น เนย มันหมู มันวัว มันไก่
   - พยายามใช้ไขมันจากพืชในการประกอบอาหาร เช่น น้ำมันถั่วเหลือง น้ำมันรำข้าว
   - เลือกดื่มนมพร่องมันเนย นมขาดมันเนยหรือนมไขมัน 0%
   - ควรหลีกเลี่ยงผลไม้ที่มีรสหวานจัด เช่น ทุเรียน มะม่วงสุก น้อยหน่า
   - ควรหลีกเลี่ยงการเติมเครื่องปรุงต่าง ๆ เพิ่มลงในอาหาร เช่น น้ำปลา น้ำตาล น้ำปลาพริก
3. อย่าลืมจดบันทึกอาหารที่รับประทานทุกอย่างทุกวัน

ขอบคุณมากนะคะ

รศ.ดร. ปรียา ลีพหกุล

โครงการวิจัย "ประสิทธิผลของการดื่มอาหารทางการแพทย์ (Gen-DM®) ขนาดพกพา (40 กรัม) ต่อการควบคุมระดับน้ำตาลในเลือดและไขมันในเลือดของพนักงานบริษัท ขนส่ง จำกัด"

ขั้นตอนวิธีการรับประทาน Medical Food (Gen-DM®)

โดย รศ.ดร. ปรียา ลีพหกุล โทร 081-8699839

นศ. ธีรภาพ ปานคล้าย โทร 084-6270901

1. ตลอดระยะเวลา 1 เดือนควบคุมอาหารเหมือนเดิมทุกประการ
2. ตลอดระยะเวลา 1 เดือนในการรับประทาน Gen-DM ผู้ใดเคยมีกิจกรรมอย่างไรให้ทำตามเดิมตลอดไป
3. มื้ออาหารที่จะรับประทาน Gen-DM ทดแทนอาหารอื่นแล้วแต่สะดวก จะเป็นมื้อหลักมื้อใดมื้อหนึ่งก็ได้
4. ในมื้อที่รับประทาน Gen-DM ให้รับประทานมื้อละ 1-2 ซอง โดยชงดังนี้

วิธีการชง Gen-DM (1 ซอง 40 กรัม)

1. **ฉีกซองเทใส่แก้ว 1 ซอง ผสมด้วยน้ำเปล่าประมาณ 200 มล. จะเป็นน้ำอุ่น เย็น หรืออุณหภูมิห้อง เลือกได้ตามใจชอบ คนหรือเขย่าให้เข้ากัน แล้วดื่ม**
2. **ถ้าบางคนรู้สึกหิวอีกภายใน 30 นาที ให้รับประทานเพิ่มได้อีก 1 ซอง**
3. **หรืออาจรับประทาน 1 ซอง ควบคู่กับผลไม้อีกเล็กน้อยประมาณ 1 จานรองถ้วยกาแฟ เช่น ฝรั่ง หรือ ส้ม หรือ แอปเปิล 1 ผลเล็ก**

5. อาหารมื้ออื่นรับประทานตามปกติในปริมาณที่แนะนำสำหรับแต่ละคน จดบันทึกอาหารโดยละเอียดเหมือนเดิมทุกวัน
6. แต่ละครั้ง (สัปดาห์) จะได้รับ Gen-DM จำนวน 14 ซอง

**น้ำเปล่าสามารถดื่มได้ตลอดทั้งวัน

ขอบคุณมากนะคะ

รศ.ดร. ปรียา ลีพหกุล

APPENDIX C
QUESTIONAIRE FORM

แบบสอบถามโครงการ "บขส.สดใส ใส่ใจสุขภาพ"
สำหรับผู้เข้าร่วมโครงการวิจัย "ประสิทธิผลของการดื่มอาหารทางการแพทย์ (Gen-DM®) ขนาดพกพา 40 กรัม ต่อการควบคุมระดับน้ำตาลและไขมันในเลือดของพนักงานบริษัท ขนส่ง จำกัด"

โดย รศ.ดร.ปรียา ลีพหกุล และนักศึกษาปริญญาโท
หลักสูตรโภชนศาสตร์ คณะแพทยศาสตร์โรงพยาบาลรามาธิบดี มหาวิทยาลัยมหิดล

คำชี้แจง

1. ข้อมูลที่ได้จากการตอบแบบสอบถามจะเก็บเป็นความลับและจะนำไปใช้ในโครงการวิจัยเพียงอย่างเดียว
2. ขอความร่วมมือผู้เข้าร่วมโครงการทุกท่าน อ่านคำชี้แจงก่อนลงมือทำแบบสอบถาม และตอบให้ตรงตามความเป็นจริงมากที่สุด
3. แบบสอบถาม แบ่งออกเป็น 4 ตอน มีทั้งหมด 6 หน้า

ตอนที่ 1 ข้อมูลทั่วไป	(8 ข้อ)
ตอนที่ 2 ข้อมูลสถานภาพทางเศรษฐกิจและสังคม	(3 ข้อ)
ตอนที่ 3 ข้อมูลด้านสุขภาพ	(12 ข้อ)
ตอนที่ 4 ข้อมูลด้านอาหารและเครื่องดื่ม	(28 ข้อ)

ชื่อ-สกุล.....รหัสพนักงาน.....

ท่านทำงานที่บริษัท ขนส่ง จำกัด มาตั้งแต่ ปี พ.ศ.....

<u>โปรดเขียนเครื่องหมาย✓ลงใน☐หน้าข้อความและเติมคำในช่องว่างที่ตรงกับความเป็นจริงของท่านมากที่สุด</u>

ตอนที่ 1 ข้อมูลทั่วไป

1.1 วันเดือนปีเกิด วันที่…….....…เดือน…….....พ.ศ…….....

1.2 ศาสนา ☐ 1.พุทธ ☐ 2.คริสต์ ☐ 3.อิสลาม ☐ 4.อื่นๆโปรดระบุ……...

1.3 ท่านมีพี่น้องร่วมบิดามารดาเดียวกันทั้งหมด.....คน (ไม่รวมตัวท่านเอง)

พี่ชาย.....คน น้องชาย.....คน พี่สาว.....คน น้องสาว.....คน

1.4 ภูมิลำเนาที่เกิด อำเภอ..... จังหวัด.....

1.5 ที่อยู่ปัจจุบัน บ้านเลขที่.....หมู่ที่.....ซอย.....ถนน.....

ตำบล/แขวง.....อำเภอ/เขต.....

จังหวัด.....

ท่านพักอาศัยในที่อยู่ปัจจุบันมานาน.....ปี

1.6 สถานภาพสมรส

☐ 1. โสด ☐ 2.แต่งงาน ☐ 3.อื่นๆ

1.7 ระดับการศึกษาสูงสุดของท่าน

☐ 1. ต่ำกว่าประถมศึกษา ☐ 2. ประถมศึกษา ☐ 3. มัธยมศึกษาตอนต้น

☐ 4. มัธยมศึกษาตอนปลาย ☐ 5. ประกาศนียบัตรวิชาชีพ (ปวช.)

☐ 6. ประกาศนียบัตรวิชาชีพชั้นสูง (ปวส.) ☐ 7. ปริญญาตรีสาขา.....

☐ 8. ปริญญาโทสาขา..... ☐ 9. ปริญญาเอกสาขา.....

1.8 ท่านมีบุตร

☐ เพศชาย.....คน ☐ เพศหญิง.....คน ☐ ไม่มี

ตอนที่ 2 ข้อมูลสถานภาพทางเศรษฐกิจและสังคม

2.1 ปัจจุบันที่พักอาศัยของท่านอยู่รวมกันทั้งหมด.....คน

ได้แก่.....

2.2 รายได้เฉลี่ยของท่าน

☐ 1. < 10,000 บาท/เดือน ☐ 2. 10,000-30,000 บาท/เดือน ☐ 3. 30,001 - 50,000 บาท/เดือน

☐ 4. 50,001-70,000 บาท/เดือน ☐ 5. 70,001 - 100,000 บาท/เดือน ☐ 6. >100,000 บาท/เดือน

2.3 รายได้เฉลี่ยของครอบครัว

☐ 1. < 10,000 บาท/เดือน ☐ 2. 10,000-30,000 บาท/เดือน ☐ 3. 30,001 - 50,000 บาท/เดือน

☐ 4. 50,001-70,000 บาท/เดือน ☐ 5. 70,001 - 100,000 บาท/เดือน ☐ 6. >100,000 บาท/เดือน

ตอนที่ 3 ข้อมูลทางด้านสุขภาพของผู้ตอบแบบสอบถาม

3.1 ท่านมีโรคประจำตัวหรือไม่

☐ 1.ไม่มี ☐ 2.มี

3.2 โรคประจำตัวของท่านคือ

☐ 1.โรคเบาหวาน ☐ 2.ความดันโลหิตสูง ☐ 3.โคเลสเตอรอลในเลือดสูง

☐ 4.ไตรกลีเซอไรด์ในเลือดสูง ☐ 5.โรคหัวใจ ☐ 6.กรดยูริกในเลือดสูง

☐ 7.โรคกระเพาะ ☐ 8.โรคภูมิแพ้ ☐ 9.โรคไมเกรน ☐ 10.อื่นๆโปรดระบุ…….

3.3 ท่านคิดว่าโรคประจำตัวของท่านในข้อ 3.2 สาเหตุมาจากกรรมพันธุ์หรือไม่

☐ 1.ใช่ เพราะ.....

☐ 2.ไม่ใช่

3.4 ยาที่ท่านรับประทานประจำอยู่คือ

ชื่อยา.....ขนาด.....วิธีรับประทาน.....

ชื่อยา.....ขนาด.....วิธีรับประทาน.....

ชื่อยา.....ขนาด.....วิธีรับประทาน.....

ชื่อยา.....ขนาด.....วิธีรับประทาน.....

ชื่อยา.....ขนาด.....วิธีรับประทาน.....

3.5 โรคใดต่อไปนี้ที่พบในสมาชิกครอบครัวของท่าน (ระบุ เช่น พี่ น้อง พ่อ แม่ ปู่ ย่า ตา ยาย)

☐ 1.อ้วน ระบุ..... ☐ 2.เบาหวาน ระบุ.....

☐ 3.ความดันโลหิตสูง ระบุ..... ☐ 4.โคเลสเตอรอลสูง ระบุ.....

☐ 5.ไตรกลีเซอไรด์สูง ระบุ..... ☐ 6.กรดยูริกสูง ระบุ.....

☐ 7.โรคกระเพาะ ระบุ..... ☐ 8.โรคภูมิแพ้ ระบุ.....

☐ 9.โรคไมเกรน ระบุ..... ☐ 10.โรคหัวใจ ระบุ.....

☐ 11.ไม่ทราบ ☐ 12.โรคอื่นๆระบุ.....

3.6 ท่านออกกำลังกายหรือไม่

☐ 1.ไม่ออก ☐ 2.ออก

3.7 ท่านออกกำลังกายอย่างน้อยกี่ครั้งต่อสัปดาห์

☐ 1. < 3 ครั้ง/สัปดาห์ ☐ 2. 3-5 ครั้ง/สัปดาห์ ☐ 3. > 5 ครั้ง/สัปดาห์

3.8 ระยะเวลาในการออกกำลังกายแต่ละครั้ง

☐ 1. < 30 นาที ☐ 2. 30-60 นาที ☐ 3. > 60 นาที

3.9 ท่านออกกำลังกายด้วยวิธีใดบ้าง (เลือกตอบได้มากกว่า 1 ข้อ)

1.เล่นกีฬา

☐ ฟุตบอล ☐ แบตมินตัน ☐ เทนนิส ☐ ว่ายน้ำ ☐ ปิงปอง

☐ บาสเกตบอล ☐ อื่นๆ……...

2.กายบริหาร

☐ ใช้อุปกรณ์ในห้องยิม เช่น ยกน้ำหนัก ☐ เต้นแอโรบิก ☐ โยคะ ☐ เต้นรำ

☐ อื่นๆ.....

3. ☐ วิ่ง 4. ☐ เดิน 5. ☐ อื่นๆโปรดระบุ.....

3.10 งานบ้านที่ใช้พลังงานมากซึ่งท่านทำเป็นประจำ

☐ 1.กวาดบ้านถูบ้าน ☐ 2.ล้างรถ ☐ 3.ทำสวนปลูกต้นไม้ ☐ 4.อื่นๆ โปรดระบุ.....

3.11 ลักษณะงานประจำของท่าน

☐ 1.นั่งโต๊ะตลอดเวลาทำงาน

☐ 2.นั่งโต๊ะสลับกับการเดินทำงาน เฉลี่ยนั่ง.....ชั่วโมง/วัน เดิน.....ชั่วโมง/วัน

☐ 3.ขับรถตลอดเวลาทำงาน เฉลี่ย.....ชั่วโมง/วัน

3.12 ช่วงเวลาและระยะเวลาการนอนของท่านโดยเฉลี่ย

☐ 1.ช่วงเวลาปกติของคนทั่วไป นาน.....ชั่วโมง/วัน

☐ 2.ช่วงเวลาที่ท่านนอนประจำเวลา.....นาน.....ชั่วโมง/วัน

ตอนที่ 4 ข้อมูลด้านอาหารและเครื่องดื่มของผู้ตอบแบบสอบถาม

4.1 มื้ออาหารที่รับประทานต่อวัน

☐ 1. < 3 มื้อ/วัน ☐ 2. 3 มื้อ/วัน ☐ 3. > 3 มื้อ/วัน

4.2 โปรดระบุที่ท่านรับประทานต่อวัน

☐ 1.เช้า เวลา..... ☐ 2.สาย เวลา..... ☐ 3.กลางวัน เวลา.....

☐ 4.บ่าย เวลา..... ☐ 5.เย็น เวลา..... ☐ 6.ดึก เวลา.....

☐ 7.อื่นๆ โปรดระบุ.....

4.3 ท่านรับประทานอาหารระหว่างมื้อหรือไม่

☐ 1.รับประทาน ☐ 2.ไม่รับประทาน

4.4 ส่วนใหญ่ของอาหารระหว่างมื้อของท่านเป็น

☐ 1.ขนมกรุบกรอบ เช่น มันฝรั่งทอด ข้าวเกรียบ ขนมปังกรอบต่างๆ

☐ 2.ขนมหวาน เช่น บัวลอย ลอดช่อง กล้วยบวชชี

☐ 3.ขนมปังต่างๆ เช่น เค้ก ขนมปังไส้ต่างๆ คุ๊กกี้

☐ 4.เครื่องดื่มต่างๆ เช่น ชา กาแฟ ไมโลโอวัลติน น้ำผลไม้

☐ 5.เครื่องดื่มชูกำลัง เช่น ลิโพ เอ็ม150

☐ 6.ผลไม้สด

☐ 7.อื่นๆ ระบุ.....

4.5 ดื่มชาหรือไม่

☐ 1.ไม่ดื่ม ☐ 2.ดื่ม ระบุชนิด.....

ปริมาณต่อวันหรือต่อสัปดาห์.....

4.6 ดื่มกาแฟหรือไม่

☐ 1.ไม่ดื่ม ☐ 2.ดื่ม ระบุชนิด.....

ปริมาณต่อวันหรือต่อสัปดาห์.....

4.7 ดื่มแอลกอฮอล์หรือไม่

☐ 1.ไม่ดื่ม ☐ 2.ดื่ม ระบุชนิด.....

ปริมาณต่อวันหรือสัปดาห์.....

4.8 ดื่มเครื่องดื่มชูกำลังหรือไม่

☐ 1.ไม่ดื่ม ☐ 2.ดื่ม ระบุชนิด.....

ปริมาณต่อวันหรือต่อสัปดาห์.....

4.9 ดื่มเครื่องดื่มประเภทน้ำหวาน (น้ำอัดลม น้ำแดง นมเย็น เป็นต้น) หรือไม่

☐ 1.ไม่ดื่ม ☐ 2.ดื่ม ระบุชนิด.....

ปริมาณต่อวันหรือสัปดาห์.....

4.10 เนื้อสัตว์ที่ท่านรับประทานบ่อยมากที่สุดเรียงตามลำดับ (มากที่สุด = 1 รองลงมา = 2……..)

……หมู ……วัว ……ไก่ เป็ด

……ปลา ……อาหารทะเล เช่น กุ้ง ปู ……ไม่ทานเนื้อสัตว์

4.11 ท่านรับประทานเนื้อสัตว์ติดมัน

ทุกครั้งที่พบในอาหาร ☐ 1.รับประทานหมด ☐ 2.รับประทานบางส่วน

☐ 3.ไม่รับประทานเลย

4.12 ท่านรับประทานหนังสัตว์

ทุกครั้งที่พบในอาหาร ☐ 1.รับประทานหมด ☐ 2.รับประทานบางส่วน

☐ 3.ไม่รับประทานเลย

4.13 ท่านรับประทานเครื่องในสัตว์

ทุกครั้งที่พบในอาหาร ☐ 1.รับประทานหมด ☐ 2.รับประทานบางส่วน

☐ 3.ไม่รับประทานเลย

4.14 ท่านรับประทานกุ้งและปลาหมึกบ่อยหรือไม่.....ครั้ง/สัปดาห์

4.15 ท่านรับประทานไข่อย่างไร (ตอบทุกข้อ)

☐ 1.รับประทานทุกวันเฉลี่ยจำนวน.....ฟอง/วัน หรือ.....ฟอง/สัปดาห์

☐ 2.ท่านรับประทานเฉพาะไข่ขาว

☐ 3.ท่านรับประทานเฉพาะไข่แดง

☐ 4.ท่านรับประทานทั้งไข่ขาวและไข่แดง

4.16 ท่านชอบรับประทานแกงชนิดไหนมากที่สุดเรียงตามลำดับ (มากที่สุด = 1 รองลงมา = 2……..)

…...แกงกะทิ …...แกงป่า …...แกงส้มหรือแกงเหลือง …...แกงเลียง

4.17 ท่านเติมครีมเทียมลงในเครื่องดื่มทุกครั้งหรือไม่

☐ 1.ไม่เติม ☐ 2.เติม.....ช้อนชา

4.18 ท่านดื่มนมเป็นประจำหรือไม่

☐ 1.ไม่ดื่ม ☐ 2.ดื่ม ชนิด.....ปริมาณ.....ต่อวัน

4.19 ท่านรับประทานน้ำเต้าหู้หรือไม่

☐ 1.ไม่รับประทาน ☐ 2.รับประทาน.....ครั้งต่อสัปดาห์

ปริมาณต่อครั้ง.....

4.20 ท่านรับประทานเต้าหู้ (อ่อนหรือแข็ง) เป็นประจำหรือไม่

☐ 1.ไม่รับประทาน ☐ 2.รับประทานทุกวัน ☐ 3.รับประทาน 3 ครั้งต่อสัปดาห์

4.21 เรียงลำดับวิธีการปรุงอาหารที่ท่านชอบ (มากที่สุด = 1 รองลงมา = 2……..)

…….ทอด .....ผัด .....นึ่ง/ตุ๋น/ต้ม .....ปิ้ง/ย่าง/อบ

4.22 ท่านเติมเครื่องปรุงต่อไปนี้ในอาหารที่กำลังจะรับประทานอย่างไร

น้ำตาลทราย	☐ 1.ไม่เติม	☐ 2.เติม.....ช้อนชา/ก๋วยเตี๋ยว 1 ชาม
น้ำปลา	☐ 1.ไม่เติม	☐ 2.เติม.....ช้อนชา/ก๋วยเตี๋ยว 1 ชาม
น้ำปลาพริก	☐ 1.ไม่เติม	☐ 2.เติม.....ช้อนชา/ข้าวราดแกง 1 จาน
น้ำส้มสายชู	☐ 1.ไม่เติม	☐ 2.เติม.....ช้อนชา/ก๋วยเตี๋ยว 1 ชาม
พริกป่น	☐ 1.ไม่เติม	☐ 2.เติม.....ช้อนชา/ก๋วยเตี๋ยว 1 ชาม

4.23 ท่านรับประทานอาหารประเภทผัก ผลไม้ อย่างไรบ้าง

☐ 1.ผักสลัด.....ครั้ง/สัปดาห์ ปริมาณ/ครั้ง.....น้ำสลัดที่ท่านนิยมมากที่สุด.....

☐ 2.ผัดผัก.....ครั้ง/สัปดาห์ ปริมาณ/ครั้ง.....

☐ 3.ผักลวก/ผักต้ม.....ครั้ง/สัปดาห์ ปริมาณ/ครั้ง.....

☐ 4.ผลไม้สด.....ครั้ง/สัปดาห์ ปริมาณ/ครั้ง.....

ชนิดของผลไม้ที่ท่านชอบมากที่สุด 3 อันดับแรก.....

4.24 น้ำมันที่ท่านใช้ปรุงอาหารเป็นประจำที่บ้าน.....

4.25 อาหารที่ท่านรับประทานประจำทุกวันส่วนใหญ่ได้มาจาก

มื้อเช้า	☐ 1.ปรุงเอง	☐ 2.ซื้อจากร้านอาหาร
มื้อกลางวัน	☐ 1.ปรุงเอง	☐ 2.ซื้อจากร้านอาหาร
มื้อเย็น	☐ 1.ปรุงเอง	☐ 2.ซื้อจากร้านอาหาร

4.26 ท่านไปรับประทานอาหารแบบบุฟเฟต์โดยเฉลี่ย.....ครั้ง

4.27 ชนิดของบุฟเฟต์ที่ท่านรับประทาน.....

4.28 ปริมาณน้ำเปล่าที่ท่านดื่ม.....แก้ว/วัน

APPENDIX D
DIETARY RECORDS

ใบบันทึกอาหารทุกวัน และนำมาส่งในวันที่มาประเมินสัดส่วนร่างกายด้วยทุกครั้ง

รศ.ดร.ปรียา ลีพหกุล

กลุ่มสาขาวิชาโภชนศาสตร์

อาคารวิจัยชั้น 2 คณะแพทยศาสตร์โรงพยาบาลรามาธิบดี โทร 02-2012625

ชื่อ.....นามสกุล.....โทร.....

วันที่	รายการอาหาร	ส่วนประกอบและปริมาณ

APPENDIX E
EVALUATION FORM

แบบประเมินการรับประทานอาหารทางการแพทย์เจ็น-ดีเอ็ม (Gen-DM®)

โดย รศ.ดร.ปรียา ลีพหกุล

อาคารวิจัยชั้น 2 คณะแพทยศาสตร์โรงพยาบาลรามาธิบดี โทร 02-201-2625

ชื่อ-สกุล.....สัปดาห์ที่.....

<u>กรุณาให้คะแนนการรับประทานอาหารทางการแพทย์เจ็น-ดีเอ็ม (Gen-DM®) โดยใส่เครื่องหมาย X ช่องคะแนนความคิดเห็นของท่าน</u>

ตอนที่ 1 อาหารทางการแพทย์เจ็น-ดีเอ็ม (Gen-DM®)

ระดับคะแนน 5 = มากที่สุด 4 = มาก 3 = ปานกลาง 2 = น้อย 1 = น้อยที่สุด 0 = ไม่มี

รายการ	คะแนนความคิดเห็น					
	5	4	3	2	1	0
1.รสชาติของเจ็น-ดีเอ็ม (Gen-DM®)						
2.ลักษณะของเจ็น-ดีเอ็ม (Gen-DM®)						
3.กลิ่นของเจ็น-ดีเอ็ม (Gen-DM®)						
4.พกพาไปรับประทานสะดวก						
5.ชงรับประทานง่ายสะดวก						

ตอนที่ 2 หลังจากรับประทานอาหารทางการแพทย์เจ็น-ดีเอ็ม (Gen-DM®)

ระดับคะแนน 5 = อิ่มนานจนถึงมื้อต่อไป 4 = อิ่มนาน 3 ชม. 3 = อิ่มนาน 2 ชม.
2 = อิ่มนาน 1 ชม. 1 = อิ่มนาน 30 นาที 0 = ไม่รู้สึกอิ่ม

1.ท่านรับประทานเจ็น-ดีเอ็ม (Gen-DM®) .....ซอง/มื้อ

รายการ	คะแนนความคิดเห็น					
	5	4	3	2	1	0
2.หลังรับประทานเจ็น-ดีเอ็ม (Gen-DM®) ซองที่ 1						
3.หลังรับประทานเจ็น-ดีเอ็ม (Gen-DM®) ซองที่ 2						

4.ความรู้สึกหลังรับประทานเจ็น-ดีเอ็ม (Gen-DM®)

☐ 1.อิ่มน้อยกว่าอาหารปกติ ☐ 2.อิ่มมากกว่าอาหารปกติ

เพิ่มเติม.....

5.ความรู้สึกหลังรับประทานเจ็น-ดีเอ็ม (Gen-DM®)

☐ 1.ไม่มี ☐ 2.มีอาการคลื่นไส้ ☐ 3.มีอาการปวดท้องเล็กน้อย

☐ 4.รู้สึกหวานมากเกินไป ☐ 5.รู้สึกจืดมากเกินไป ☐ 6.อื่นๆ.....

6.ท่านอยากรับประทานเจ็น-ดีเอ็ม (Gen-DM®) รสชาติใดมากที่สุด

☐ 1.รสข้าวโพด ☐ 2.รสช็อคโกแลต ☐ 3.รสกาแฟ

☐ 4.รสดั้งเดิม ☐ 5.อื่นๆ.....

7.ถ้าเจ็น-ดีเอ็ม (Gen-DM®) ขนาดพกพา 40 กรัม 1 ซอง ราคา 30 บาท ท่านจะซื้อมารับประทานหรือไม่

☐ 1. ซื้อ ☐ 2.ไม่ซื้อ

ข้อคิดเห็นเพิ่มเติม

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APPENDIX F
PHYSICAL ACTIVITY RECORD FORM

บันทึกการออกกำลังกายหรือกิจกรรมทางกาย

โดย รศ.ดร. ปรียา ลีพหกุล

อาคารวิจัยชั้น 2 คณะแพทยศาสตร์โรงพยาบาลรามาธบดี โทร. 02-201-2652

ชื่อ.....หน่วยงาน.....เบอร์โทรศัพท์.....

ครั้งที่นัดพบ	ประเภทของการออกกำลังกายหรือกิจกรรมทางกาย	ระยะเวลา (นาที)	ความถี่ (ครั้ง/สัปดาห์)

APPENDIX G
CRITERIA FOR NUTRITIONAL STATUS

Nutritional status	Criteria	
Body mass index (kg/m^2)		
Underweight	<18.5	
Normal weight	18.5-24.9	
Overweight	25.0-29.9	
Obese class I	30.0-34.9	
Obese class II	35.0-39.9	
Obese class III	≥40.0	
Percentage body fat	**Male**	**Female**
Low body fat	<10%	<20%
Normal body fat	10-20%	20-30%
Over body fat	30-40%	40-50%
Excess body fat	>40%	>50%
Fasting plasma glucose	**FPG**	
Impaired fasting glucose	100-125 mg/dL	
Diabetes	≥126 mg/dL	
Dyslipidemia		
Low HDL-C	<40 mg/dL	
High LDL-C	≥130 mg/dL	
High TG	≥150 mg/dL	
Anemia	**Male**	**Female**
Hemoglobin	<12 g/dL	<13 g/dL
Hyperuricemia		
Uric acid	>7.0 mg/dL	
Blood pressure	**SBP**	**DBP**
Prehypertension	120-139 mmHg	80-90 mmHg
Hypertension	≥140 mmHg	≥90 mmHg

APPENDIX H
INFORMED CONSENT FORM

หนังสือยินยอมโดยได้รับการบอกกล่าวและเต็มใจ

(Informed Consent Form)

ชื่อโครงการ ประสิทธิผลของการดื่มอาหารทางการแพทย์ (Gen-DM®) ขนาดพกพา 40 กรัม ต่อการควบคุมระดับน้ำตาลและไขมันในเลือดของพนักงานบริษัท ขนส่ง จำกัด

ผู้ทำการวิจัย รศ.ดร. ปรียา ลีฬหกุล

หลักสูตรโภชนศาสตร์ คณะแพทยศาสตร์ โรงพยาบาลรามาธิบดี มหาวิทยาลัยมหิดล

***ชื่อผู้เข้าร่วมการวิจัย**.....**อายุ**.....

คำยินยอมของผู้เข้าร่วมการวิจัย

ข้าพเจ้านาย/นาง/นางสาว..... ได้ทราบรายละเอียดของโครงการวิจัย ตลอดจนประโยชน์ และข้อเสี่ยงที่จะเกิดขึ้นต่อข้าพเจ้าจากผู้วิจัยแล้วอย่างชัดเจน ไม่มีสิ่งใดปิดบังซ่อนเร้นและยินยอมให้ทำการวิจัยในโครงการที่มีชื่อข้างต้น และข้าพเจ้ารู้ว่าถ้ามีปัญหาหรือข้อสงสัยเกิดขึ้นข้าพเจ้าสามารถสอบถามผู้วิจัยได้ และข้าพเจ้าสามารถไม่เข้าร่วมโครงการวิจัยนี้เมื่อใดก็ได้ โดยไม่มีผลกระทบต่อการรักษาที่ข้าพเจ้าพึงได้รับ นอกจากนี้ผู้วิจัยจะเก็บข้อมูลเฉพาะเกี่ยวกับตัวข้าพเจ้าเป็นความลับและจะเปิดเผยได้เฉพาะในรูปที่เป็นสรุปผลการวิจัย การเปิดเผยข้อมูลเกี่ยวกับตัวข้าพเจ้าต่อหน่วยงานต่างๆที่เกี่ยวข้อง กระทำได้เฉพาะกรณีจำเป็นด้วยเหตุผลทางวิชาการเท่านั้น

ลงชื่อ……(ผู้เข้าร่วมการวิจัย)

……..(พยาน)

……(พยาน)

วันที่ ……..

คำอธิบายของผู้วิจัย

ข้าพเจ้าได้อธิบายรายละเอียดของโครงการ ตลอดจนประโยชน์ของการวิจัย รวมทั้งข้อเสี่ยงที่อาจจะเกิดขึ้นแก่ผู้เข้าร่วมการวิจัยทราบแล้วอย่างชัดเจนโดยไม่มีสิ่งใดปิดบังซ่อนเร้น

ลงชื่อ……(ผู้วิจัย)

วันที่……

หมายเหตุ : กรณีผู้เข้าร่วมการวิจัยไม่สามารถอ่านหนังสือได้ ให้ผู้วิจัยอ่านข้อความในหนังสือยินยอมฯ นี้ให้แก่ผู้เข้าร่วมการวิจัยฟังจนเข้าใจดีแล้ว และให้ผู้เข้าร่วมการวิจัยลงนามหรือพิมพ์ลายนิ้วหัวแม่มือรับทราบในการให้ความยินยอมดังกล่าวข้างต้นไว้ด้วย

*ผู้เข้าร่วมการวิจัย หมายถึง ผู้ยินยอมตนให้ทำวิจัย

BIOGRAPHY

NAME	Mr. Teerapap Panklai
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