MINISTRY OF EDUCATION MINISTRY OF HEALTH

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**LE THI HUONG GIANG**

**THE SITUATION OF OVERWEIGHT, OBESITY**

**AND THE EFFECTIVENESS OF INTERVENTION OF CALORIE LIMIT SUPPLEMENTS ON OVERWEIGHT**

**AND OBESE WOMEN 40-65 YEARS OLD IN SOME DISTRICTS OF HANOI CITY (2016 - 2021)**

**Specialization: Nutrition**

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**Reviewer 1:**

**Reviewer 2:**

**Reviewer 3:**

**The thesis will be defended at the Institute-level doctoral thesis grading committee at the National Institute of Nutrition**

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**The thesis can be found at:**

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**LIST OF WORKS**

**RELATED TO THE PUBLISHED THESIS**

1. Yoshiki Shimizu, Linh Anh Vu, Yuuri Takeshita, Sayuri Matsuoka, Bui Thi Nhung, Le Danh Tuyen, **Le Thi Huong Giang**, Nguyen Đo Van Anh, Vu Thi Minh Thuc (2019). Effect of a Dietary Supplement Containing Gymnema sylvestre Extract, Mulberry Leaf Extract, Green Tea Extract, Chitosan, Kidney Bean Extract, and Kaempferia parviflora Extract on Abdominal Fat of Vietnamese Adult Women. *Jpn Pharmacol Ther*（薬理と治療）vol. 47 no. 11 2019

2. **Le Thi Huong Giang,** Le Danh Tuyen, Bui Van Tuoc, Nguyen Thi Huyen Trang, Pham Minh Phuc, Bui Thi Nhung (2022). *"Characteristics of some anthropometric indicators and nutritional status of women aged 40-65 years in Hanoi in 2016*, Journal of Nutrition & Food. 2022;18(3+4):79-87. DOI:10.56283/1859-0381/378.

3. **Le Thi Huong Giang,** Le Danh Tuyen, Nguyen Huu Chinh, Nguyen Do Van Anh, Pham Minh Phuc, Bui Thi Nhung (2022) *"Metabolic syndrome in women 40-65 years old with BMI ≥ 23kg/m2* in *some communes in Hanoi, 2016*". Journal of Nutrition & Food. 18(5+6).DOI:10.56283/1859-0381/038.

**INTRODUCTION**

Overweight and obesity (TCBP) is increasing in all countries. TCBP increasesthe risk of insulin resistance, causes lipid metabolism disorders, and increases the risk of diseases such as hypertension, diabetes, cancer, cardiovascular events, and death. In 2016, the world had 1.9 billion adults with TCBP, of which 650 million were obese (BP). In countries such as South and Southeast Asia, it accounted for 29.9 % (2016), while the United States accounted for 42.4%, the highest rate in the 40-59 age group.

Obesity is known to result from an imbalance between energy intake and energy expenditure. To improve TCBP status, solutions to reduce body weight have been applied such as adjusting nutrition, increasing physical activity, surgery, taking drugs and products to support weight loss... However, the solutions all have advantages and disadvantages that require users to adhere strictly and strictly.

Calorie limit supplements with gymnema sylvestre natural essences, catechins in green tea leaves, imino sugar from mulberry leaves, chitosan from crabs, phaseolamin in kidney beans and kaempferia parviflora (black ginger) are believed by scientists to bea food Supplementation with normal diet works to reduce body fat. This product has been studied and confirmed to inhibit serum glucose and triglyceride levels after meals, increase fatty acid oxidation andbe observed when supplemented with normal diet. Calorielimit supplements are thought to reduce body fat.

Domestic research on supplements of natural origin improving weight status and reducing body fat in TCBP people has been rarely mentioned, especially among middle-aged women.

So, the study was conducted with the following two objectives in mind:

*1.*  *Describe* overweight, obesity and some *factors related to overweight and obesity in women 40-65 years old* in *Ha Dong district and Chuong My district, Hanoi in 2016.*

*2.*  *Evaluate the effectiveness of improving overweight, obesity* and *changing some biochemical indicators* in *women 40-65 years old with Calorie Limit supplements in Ha Dong district and Chuong My district, Hanoi.*

**New contributions of the thesis**

The research has provided valuable scientific information on the status of TCBP in women aged 40-65 years and revealed factors related to TCBP such as age, central fat, visceral fat, diet... The prevalence of overweight and obesity in women aged 40-65 years at the study site was (36.41%), the prevalence of abdominal obesity (78%), the prevalence of abdominal obesity in the group with a BMI of < 23 (kg/m2) accounted for 55.9%; and the BMI group ≥ 23(kg/m2) (92.8%).

The topic has proven the effectiveness of *Calorie Limit* supplements on overweight and obese women 40-65 years old, after 12 weeks of intervention, in the intervention group reduced body weight, reduced visceral fat, reduced subcutaneous fat in the abdomen, reduced the incidence of metabolic syndrome, and some biochemical indicators of the object of study. With the average weight reduced by 1.4 ± 0.95 kg, the average waist reduced by 4.41±2.14 cm, the average visceral fat decreased by 5.8 cm2 and the average abdominal subcutaneous fat decreased by 3.9 cm2. The results also showed that the effectiveness of treatment reduced the incidence of HCCH when only treating 2 people reduced 1 case

**The layout of the thesis**

The thesis consists of 120 pages, the layout is as follows: Setting problems and research objectives: 3 pages; Overview: 34 pages; Subjects and methods of study: 25 pages; Research results: 26 pages; Discussion: 27 pages; Conclusions and recommendations: 3 pages. The thesis has 34 tables, 18 figures, 210 references

Chapter 1. OVERVIEW

# 1.1. Overweight and obesity of women 40-65 years old.

Overweight and obesity and has called it a pandemic. According to WHO, "There is now ample evidence that Overweight and obesity rates are increasing worldwide at an alarming rate, increasing rapidly in children and adults. In 2016, the prevalence of Overweight and obesity tripled compared to 1975, about 13% of the adult population in the world (39% of men and 40% of women) was overweight; (11% of men and 15% of women) are obese and with 39 million children under 5 and 340 million adolescents are overweight or obese.

In Vietnam, in 2011, comparing the results of two national surveys showed that in just 5 years (2000 - 2005), the rate of overweight and obesity in Vietnam has doubled (3.7% in 2000 to 7% in 2005. The study, in Ho Chi Minh City, found that 33.6% of women and 31.6% of men had TCBP. This study also concluded that the TCBP rate increases with increasing age, In Hanoi, in 2007 the TCBP rate in women was 26.2%; BMI=22.9±2.8kg/m2; Families with people with TCBP are 3.1 times more likely to have TCBP. The 2009-2010 National Nutrition Census once again showed that the prevalence of TCBP among adults was increasing rapidly nationwide at 13.1% and 1.1%, respectively, and 6% and 0.4% in rural areas. Thus, the TCBP rate of adults in rural areas is similar to the national TCBP rate in 2005, this rate in urban areas is 2 times higher than this figure.

## 1.2. The composition of active ingredients extracted from nature in Calorie limit products has been studied.

### *Active ingredient cextracted from* *gymnema sylvestre leaves*.

Gymnema sylvestre v, with its active ingredient, gymnemic acid, has long been used as an herbal medicine for diabetes. Studies in rats with diabetes have also shown that gymnemic acid, with its insulin-releasing effect, may be an anti-obesity and hypoglycemic precursor. The active ingredientmay have anti-inflammatory effects, support weight loss and reduce levels of "bad" LDL cholesterol and triglycerides. When gymnemic acid was studied in moderately obese people, it resulted in a reduction in body weight of 5-6%, a decrease in triglyceride and LDL-C levels of 20.2%, respectively; 19% simultaneously increased HDL cholesterol levels by 22%.

### *Active ingredients areextracted from mulberry leaves.*

The extract of white mulberry blocks alpha-glucosidase, then hydrolyzes polysaccharides in the intestine, reducing the glycemic index of carbohydrates, the result showed a reduction of up to 10% of body weight in 3 months. In addition, mulberry essence significantly reduces blood glucose and insulin in people who use the product. The Eva M study found that mulberry leaves are rich in caffeoylquinic acid (6.8–8.5 mg/gdw) and flavonols (3.7–9.8 mg/gdw)

### *Active ingredients areextracted from green tea leaves (Green Tea Exact).*

Green tea leaves usually contain 10% to 20% catechins, mainly EGCG. In research, supplementing every day with 1 capsule containing 379 mg of green tea essence for 3 months has proven to have blood pressure-lowering, anti-inflammatory and antioxidant effects, lowering blood lipids. A meta-analysis of 154 studies found that green tea essence had an impact on reducing body fat mass percentage by -0.76 (95% CI): -1.44 to -0.09; P = 0.03; I2 = 0%; n = 260). Drinking green tea resulted in significant improvements in weight ([SMD]: -0.75 [-1.18, -0.319]), body mass index ([SMD]: -1.2 [-1.82, -0.57]), waist circumference ([SMD]: -1.71 [-2.66, -0.77]), hip circumference ([SMD]: -0.42 [-1.02, -0.19]), and total cholesterol, ([SMD]: -0.43[-0.77, -0.09]).

### *Chitosan from crab* *shells.*

The study found that combining a reduced-calorie diet with a daily supplement of 750 mg of chitosan for 6 months, reduced body weight (15.9 kg) compared to the placebo group (10.9 kg). In addition, systolic and diastolic blood pressure also decreased more in the chitosan group, the study concluded. Chitosan highlights the reduction in blood pressure associated with weight loss. Glucose levels of diabetics with reduced weight or obesity (SMD: - 0.39 mmol/L, 95% CI: - 0.62 to - 0.16) and hemoglobin A1c (HbA1c) levels (SMD: -1.10; 95% CI: - 2.15 to - 0.06) when chitosan is supplemented for at least 13 weeks at a dose of 1.6–3 g daily but does not affect insulin levels (SMD: - 0.20 pmol/L, 95% CI: - 0.64 to 0.24).

### *Active ingredient ccomes from kidney beans.*

Kidney Bean, also known as Kidney Bean, is an excellent source of plant protein. Extract of chickpeas has been shown to inhibit the digestive enzyme Alpha-Amylase. Udani et al. demonstrated the weight loss power of chickpea extract. The intervention group using the product lost 4% of their body weight compared to a reduction of only 0.47% in the control group.

### *Active ingredient cextracted from Black Ginger.*

Black ginger has the scientific name Kaempferia parviflora (KP). Author Masaya Miyazaki and colleagues demonstrated KP's ability to reduce belly fat. Research by Yoshino S and CS also showed that 12 mg of polymethoxyflavones purified from black ginger had an effect on reducing visceral fat in overweight adults.

Chapter 2. RESEARCH SUBJECTS AND METHODS

2.1. Subjects of study.

Women aged 40-65 years, living in the study area,

***Phase 1*** *selection:* Women aged 40 – 65 years. Consent to participate in the study.  *Exclusion criteria*: There are hunchback malformations, scoliosis, birth defects; mute, deaf. Are pregnant and breastfeeding. Had an acute illness at the time of the investigation.

***Phase 2*** *selection:* Women were investigated at the pre-intervention stage. BMI of 23-30 kg/m² and waist circumference of 80 cm or more. Agree and sign the study application. *Exclusion criteria:* Frequent use of other weight loss drugs and products. Are being treated for acute diseases at the time of the study or have a history of diabetes, liver, kidney, cardiovascular diseases, etc. Have intended to become pregnant immediately after consenting to the study or are pregnant or breastfeeding. Have participated in another clinical study within one month prior to the current study. Are dieting, exercising strength to lose weight.

2.2. Study period.

***Phase 1***: Cross-sectional investigation was carried out from March to April 2016. ***Phase 2*:** intervention study (from 9/2016 to 12/2016). Data analysis, dissertation completion between june 2017 and August 2022.

2.3. Study design.

The study design consists of 2 phases:

***Phase 1:*** Cross-sectional investigation: Assessing the status of TCBP of women aged 40-65 years.  ***Phase 2:*** Study of intervention trials, randomized, double-blind, controlled, food supplements containing natural active ingredients and evaluation of post-intervention efficacy.

**2.4. Sample size and sample selection method**.

Sample size: *Objective 1:* Cross-sectional descriptive study, The calculated sample size is 590 subjects. An additional 15% provision for insufficient data collection or subjects and rounded to 700 subjects, actually studied 673 subjects. *Objective 2:* Community intervention study, double-blind, controlled, the required sample size is 55 subjects per group, and the sample size of the two groups is 110. In fact, 112 objects were selected.

Sampling method: *Objective 1:* single random sample selection method. Purposefully select 04 communes, wards and townships in Chuong My district and Ha Dong district. Make a list of all 40-65 year old women in the study area. Randomly select 700 objects. *Objective 2: Select* the target of intervention, target 2 locations Chuc Son town, Chuong My district and Duong Noi ward, Ha Dong district. Participants in the phase 1 study who are eligible to participate in the study with BMI in the range of 23-30 kg/m2, waist circumference of 80cm or more were selected to participate in the study in phase 2 divided into 2 intervention groups and control groups.

# 2.5. Researchvariables.

**Variables**:  *Variablesindicate the general characteristics of the subject:* Age; Residence; Take medications, weight loss products.  *Index variables of nutritional status and activities****:*** Weight; Height; BMI; waist circumference; hip circumference; Last 24-hour rations; Physical activity. *Group of variables on* the results of the intervention***:*** Changes in weight, waist circumference hip circumference; visceral fat area, subcutaneous fat area, total body fat area, blood biochemical indicators.

2.6. **Method of supplementation of intervention products***:*

Subjects of the intervention group were given supplementary food tablets at a dose of 12 tablets / day in 3 divided doses, each time 04 tablets, the control group was given placebo tablets with a dose of 12 tablets / day in 3 divided doses, each time 04 tablets.  *How to use the product:* Drink it just before meals along with a glass of water.

**Stage 1:**

Cross-sectional research

DTNC gets:

- Name and age,

Measure height, weight, waistline,

**Subjects eligible for screening (n=673)**

Excluded from NC (n=561)

-Does not meet NC entry criteria (n=355)

- There is an exclusion criterion (n=101)

-Disagree to participate (n=105)

**Stage 2:**

Intervention, monitoring, analysis

DTNC gets:

- Measure CC, CN, VE, V, BMI, E/M ratio

-Survey rations last 24 hours for 3 consecutive days;

-Wear a pedometer;

- Blood pressure measurement;

- Blood, urine

*(at time T0, T4, T8, T12)*

-CT scan *(at time T0, T8, T12);*

**Randomly selected (n=112)**

**Control group (n= 56)**

-Agree to participate (n=48)

-Opt-out (n=8)

Use 12 calorie limit capsules daily for 12 weeks

**Intervention group ( n= 56)**

- Agree to participate (n=50)

-Opt-out (n=6)

Use 12 placebo capsules daily for 12 weeks



**Withdrew** (n =5)

- Allergy (n=3)

- Treatment (n=2)

**Withdrew** (n= 2)

(Personal reasons)

**End of intervention (n=44)**

(Excluded from analysis (n=1)

**End of intervention**

**(n = 46)**

**Form. RESEARCH DIAGRAM**.

**2.7.**  **Error control measures**: Follow the techniques in sample selection. Develop detailed and clear criteria for selecting intervention and control groups. Using fixed instruments, using standard instruments of the same type and using precision techniques, at the same time measuring and unifying the investigation method in all DTVs, to avoid errors caused by people and instruments. Biochemical tests comply with the process of sampling, sample storage, measurements are analyzed by updated standard methods, with exceptions. Blood and urine samples were analyzed at the labo of Medlatec Hospital.

**2.8. Data processing and analysis**.

Interview, physical activity, blood biochemistry and anthropometric data are imported using Epidata 3.1 software. All metrics are aggregated and analyzed using Stata 14.1 MP software. Use the When squaring test with the categorical variable. Accreditation Student Unpaire T (Independent Test t). Student T-test: Test Wilcoxon ranksum (Mann Whitney) test and Wilcoxon signrank test with continuous random variable with no standard distribution. Evaluating the effectiveness of the intervention, using the following indicators: ARR index (absolute risk reduction): NNT index: (number of patients requiring treatment to reduce one case).

2.9. Ethics in research.

The study was reviewed and approved by The Scientific Council and the Medical Ethics Council in Biomedical Research No. 130/VDD-QLKH, dated March 22, 2016 of the Institute of Nutrition

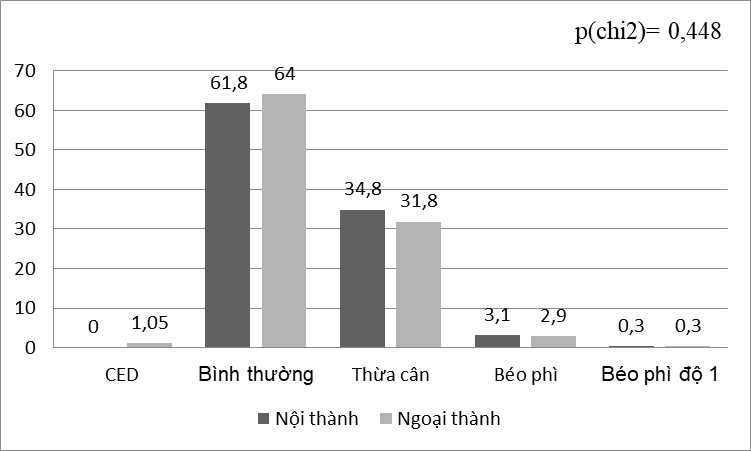
**Chapter 3.** **RESEARCH RESULTS**

3.1. Overweight and obesity among women 40-65 years old in Ha Dong district and Chuong My district, Hanoi.

Table 3. 1. Anthropometric characteristics of subjects according to the study location.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Index** | **Inner city** | | **Suburban** | | **General** | | **p** |
| n | (± SD) | n | (± SD) | n | (± SD) |
| **Age (years)** | 293 | 55 ± 7,2 | 380 | 50,9 ± 7,8 | 673 | 52,7 ± 7,8 | **0,000** |
| **Weight(kg)** | 293 | 57,4 ± 7,1 | 380 | 56,5 ± 6,7 | 673 | 56,9 ± 6,9 | 0,127 |
| **Height (cm)** | 293 | 153,4 ± 5,6 | 380 | 154 ± 5,5 | 673 | 153,7 ± 5,5 | 0,187 |
| **Waist circumference (cm)** | 293 | 85,2 ± 6,5 | 380 | 85,1 ± 6,9 | 673 | 85,1 ± 6,7 | 0,940 |
| **Hip circumference (cm)** | 293 | 93,5 ± 5,3 | 380 | 92,5 ± 5,7 | 673 | 92,9 ± 5,5 | **0,025** |
| **BMI (kg/m2)** | 293 | 24,4 ± 3,0 | 380 | 23,9 ± 3,0 | 673 | 24,1 ± 3,0 | **0,032** |

*p (t-test)*



%

Figure 3.1. Prevalence of overweight and obesity by NC location (n = 673).

In suburban areas, the prevalence of chronic energy deficiency (CED) of diabetes is 1.05%, the overweight rate is 31.8%, the obesity rate is 2.9% and the obesity rate is 0.3%. For urban areas, the overweight rate accounted for 34.8%, obesity accounted for 3.1% and grade I obesity accounted for 0.3%. There was no difference between urban and suburban areas with (p=0.448).

The overall prevalence of diabetes, chronic energy deficiency (CED) was 0.59%, the prevalence of overweight accounted for 33.14%, obesity was 2.97% and grade I obesity was 0.3%

# Table 3.2. The combined ratio of abdominal obesity (waist circumference > 80 cm) with overweight (BMI ≥ 23 kg/m2) of the study subjects.

|  |  |  |  |
| --- | --- | --- | --- |
| **Index** | **BMI < 23(kg/m2)**  **n (%)** | **BMI ≥ 23(kg/m2)**  **n (%)** | **Total**  **n (%)** |
| **Not yeta belly** | 119(44,1) | 29(7,2) | 148(22,0) |
| **Abdominal obesity** | 151(55,9) | 374(92,8) | 525(78,0) |
| **General** | 270(100) | 403(100) | 673(100) |
| *p* (χ2) | **0,000** | | |

Atotal of 673 subjects were: 270 subjects with a BMI of <23 (kg/m2), up to 55.9% had abdominal obesity and 44.1% were not abdominal fat; Of the 403 subjects with a BMI of ≥23 (kg/m2), only 7.2% were non-abdominal fat and 92.8% were abdominal obesity, a statistically significant difference with *p* = 0.000.

**3.2. Evaluation of the effectiveness of intervention to improve overweight, obesity and change some biochemical indicators in women 40-65 years old with Calorie Limit supplements in Ha Dong district and Chuong My district, Hanoi.**

From 673 cross-sectional subjects, 112 subjects were selected who were eligible for inclusion in the intervention, of which 14 subjects (8 subjects in the placebo control group and 6 subjects in the supplementary group signed a consent form to participate, but no longer co-participated in the study before starting the supplement; therefore, And 48 control subjects and 50 intervention group subjects began taking the experimental supplement. During the intervention period, the intervention group had 02 subjects who had to be treated for hypertension, 03 subjects allergic to the intervention product; 02 control subjects for personal reasons did not continue to participate in the study. After 12 weeks of intervention, the study was completed on schedule with 46 subjects in the control group and 45 and the intervention product group. At the end of the intervention, at the time of opening the product label to determine the product code used for each group, we found that 1 subject in the intervention group was mistakenly allocated to the control group. This subject was excluded from the analysis of the results. This subject was excluded from the analysis of the results. Therefore, included in the product effectiveness analysis were 46 subjects in the control group and 44 subjects in the intervention product group**.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Table 3.3. The anthropometric values and nutritional status of the 2 study groups at the time of T0. | | | | |
| **Index** | **Unit** | **Control group**  n (46) | **Intervention** groups  n (44) | **p** |
| (± SD) | (± SD) |
| **Age** | year | 51,1 ± 5,4 | 52,8 ± 5,0 | 0,140 |
| **Height** | Cm | 153,4 ± 4,6 | 152,4 ± 5,4 | 0,360 |
| **Weighed** | kg | 59,8 ± 4,7 | 59,9 ± 5,6 | 0,890 |
| **BMI** | kg/m2 | 25,4 ± 1,6 | 25,8 ± 1,6 | 0,290 |
| **PBF** | % | 36,0 ± 2,6 | 36,5 ± 2,4 | 0,310 |
| **Total fat area** | cm² | 328,7 ± 45,6 | 329,8 ± 55,3 | 0,920 |
| **Visceral fat area** | cm² | 118,8 ± 35,5 | 124,7 ± 33,3 | 0,420 |
| **The area of subcutaneous fat** | cm² | 208,7 ± 39,5 | 204,8 ± 37,4 | 0,640 |
| **Waist circumference** | cm | 86,5 ± 3,7 | 86,3 ± 3,8 | 0,800 |
| **hip circumference** | cm | 96,1 ± 3,3 | 96,1 ± 4,0 | 0,96 |
| **Waist/hip ratio** |  | 0,9 ± 0,037 | 0,899 ± 0,031 | 0,81 |

*P: (t-test)*

At the time before the intervention, it was shown that anthropometric indicators such as height, weight, body mass index (BMI), body fat percentage (PBF), total fat area, visceral fat area, subcutaneous fat area, waist circumference, hip circumference and waist/hip ratio of the 2 control groups (NC) and intervention group (NCT) were similar, All differences were not statistically significant (P > 0.05 – T-test).

**3.2.1. Effectively improve overweight and obesity in women 40-65 years old with Calorie Limit supplements in Ha Dong district and Chuong My district, Hanoi.**

# Table 3.4. Changes in weight and BMI of the 2 study groups after 12 weeks.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Index** | **Research Team** | **T4 - T0** | **T8 - T0** | **T12 - T0** | **p\*** | **p****\*\*** |
| **Weight** (kg) | NCT (44) | -0,6 ± 0,64 | -1,02 ± 0,84 | -1,4 ± 0,95 | **0,000** | **0,000** |
| NC (46) | -0,24 ± 0,62 | -0,26 ± 0,81 | -0,3 ± 1,12 | 0,823 | 0,611 |
| p (NCT ss NC) | | **0,009** | **0,000** | **0,000** |  |
| **BMI** (kg/m2) | NCT (44) | -0,26 ± 0,27 | -0,44 ± 0,35 | -0,6 ± 0,39 | **0,000** | **0,000** |
| NC (46) | -0,11 ± 0,28 | -0,11 ± 0,35 | -0,13 ± 0,48 | 0,890 | 0,674 |
| p (NCT ss NC) | | **0,011** | **0,000** | **0,000** |  |

*\*: t-test: comparison between T4 and T8. \*\*t-test: comparison between T4 and T12.*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Table 3.5. Changes in the subjects' waist and hip circumference according to the research team. | | | | | | |
| **Index** | **Research Team** | **T4 - T0** | **T8 - T0** | **T12 - T0** | **p\*** | **p\*\*** |
| **Waist circumference**  (cm) | NCT (44) | -1,77 ± 1,75 | -3,18 ± 1,87 | -4,41 ± 2,14 | **0,000** | **0,000** |
| NC (46) | -0,21 ± 1,08 | -0,17 ± 1,39 | -0,2 ± 2,07 | 0,678 | 0,968 |
| p (NCT ss NC) | | **0,000** | **0,000** | **0,000** |  |
| **hip circumference**  (cm) | NCT (44) | -0,25 ± 0,71 | -0,34 ± 0,74 | -0,53 ± 1,02 | 0,179 | 0,054 |
| NC (46) | 0,04 ± 0,58 | 0,16 ± 0,87 | 0,29 ± 1,18 | 0,316 | 0,119 |
| p (NCT ss NC) | | **0,043** | **0,005** | **0,001** |  |

*\*: t-test: comparison between 2 times T4 and T8. \*\*t-test: comparison between T4 and T12. (NCT ss NC): Comparative intervention group with control group*

|  |  |  |  |
| --- | --- | --- | --- |
| Table 3.6. Evolution of abdominal obesity rate (VE > 80cm) of 2 study groups after 12 weeks. | | | |
| **Timing** | **NCT (44)**  **(n; %)** | **NC (46)**  **(n; %)** | **p** |
| **T0** | 44 (100) | 46 (100) |  |
| **T4** | 38 (90,5) | 45 (97,8) | 0,137 |
| **T8** | 35 (79,6) | 45 (97,8) | **0,006** |
| **T12** | 33 (75,0) | 45 (97,8) | **0,001** |

*p(chi2).*

The prevalence of abdominal obesity in diabetic subjects at the start of the intervention (T0) was 100%, at 12 weeks it was 75%, the difference between the intervention group and the control group was statistically significant (p = 0.006 – chi2 test).

Figure 3.2. Evolution of central fat rates of 2 study groups after 12 weeks.

The core fat prevalence of the two study groups at12 weeks, in the intervention group, decreased to 93.2%, lower than the rate in the control group of 100%.

Figure 3.3. The change in total fat area according to the study group.

Figure 3.4. Variation in visceral fat area by NC group.

Figure 3.5. Variation in subcutaneous area by NC group.

**3.2.2. Effect of improving some biochemical indicators in women 40-65 years old with Calorie Limit supplements in Ha Dong district and Chuong My district, Hanoi.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Table 3.7. The effect of the product on the blood glucose - lipid status of the study subjects. | | | | | |
| **Index** | |  | | --- | | **Group**  **research** | | **T0**  (± SD) | **T4**  (± SD) | **T8**  (± SD) | **T12**  (± SD) |
| **Glucose** (mmol/L) | NCT (44) | 4,7 ± 0,3 | 4,7 ± 0,2 | 4,7 ± 0,2 | 4,6 ± 0,3 |
| NC (46) | 4,6 ± 0,4 | 4,8 ± 0,4 | 4,9 ± 0,4 | 4,9 ± 0,5 |
| p (NCT ss NC)\* | | 0,248 | **0,020** | **0,000** | **0,002** |
| **HbA1c**  (%) | NCT (44) | 5,5 ± 0,3 | 5,4 ± 0,3 | 5,3 ± 0,2 | 5,2 ± 0,2 |
| NC (46) | 5,6 ± 0,3 | 5,4 ± 0,2 | 5,5 ± 0,2 | 5,6 ± 0,3 |
| p (NCT ss NC)\* | | 0,448 | 0,085 | **0,003** | **0,000** |
| **Insulin**  (UI) | NCT (44) | 7,8 ± 4,4 | 7,8 ± 3,2 | 7,7 ± 2,6 | 7,5 ± 2,4 |
| NC (46) | 8,9 ± 4,7 | 9 ± 4,6 | 9,1 ± 4,3 | 9,2 ± 3,9 |
| p (NCT ss NC)\* | | 0,270 | 0,179 | 0,078 | **0,019** |
| **Triglycerid**  (mmol/L) | NCT (44) | 2,2 ± 1,1 | 2,2 ± 0,8 | 2,1 ± 0,7 | 1,9 ± 0,6 |
| NC (46) | 2,2 ± 1,5 | 2,3 ± 1,3 | 2,4 ± 1,5 | 2,5 ± 1,5 |
| p (NCT ss NC)\* | | 0,906 | 0,499 | 0,196 | **0,029** |
| **Cholesterol toàn phần**  (mmol/L) | NCT (44) | 5,0 ± 0,9 | 5,0 ± 0,8 | 4,9 ± 0,7 | 4,8 ± 0,7 |
| NC (46) | 4,9 ± 0,8 | 5 ± 0,7 | 5,2 ± 0,7 | 5,2 ± 0,7 |
| p (NCT ss NC)\* | | 0,425 | 0,782 | 0,158 | **0,008** |
| **HDL**  (mmol/L) | NCT (44) | 1,2 ± 0,3 | 1,2 ± 0,2 | 1,2 ± 0,2 | 1,2 ± 0,2 |
| NC (46) | 1,1 ± 0,2 | 1,1 ± 0,2 | 1,1 ± 0,1 | 1,1 ± 0,2 |
| p (NCT ss NC)\* | | 0,103 | 0,142 | **0,037** | 0,058 |
| **LDL**  (mmol/L) | NCT(44) | 3,0 ± 0,7 | 3,0 ± 0,6 | 2,9 ± 0,5 | 2,7 ± 0,5 |
| NC (46) | 2,8 ± 0,7 | 3,0 ± 0,7 | 3,0 ± 0,8 | 3,1 ± 0,8 |
| p (NCT ss NC )\* | | 0,389 | 0,882 | 0,268 | **0,002** |

*p\*: Independent* T-Test*.*

*(NCT ss NC**): comparative intervention group with control group.*

# Table 3.8. Changes in serum triglycerides, cholesterol, LDL-C of 2 study groups during 12 weeks of intervention.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Index** | **Group**  **research** | **T0**  **(n, %)** | **T4**  **(n, %)** | **T8**  **(n, %)** | **T12**  **(n, %)** |
| **Triglycerid**  (mmol/L) | NCT (44) | 27 (61,4) | 32 (74,4) | 30 (68,2) | 25 (56,8) |
| NC (46) | 23 (51,1) | 29 (64,4) | 28 (62,2) | 30 (66,7) |
| p (NCT ss NC)\* | | 0,330 | 0,311 | 0,555 | 0,339 |
| **Cholesterol**  (mmol/L) | NCT (44) | 22 (50,0) | 20 (46,5) | 23 (52,3) | 19 (43,2) |
| NC (46) | 19 (42,2) | 18 (40,0) | 26 (57,8) | 26 (57,8) |
| p (NCT ss NC)\* | | 0,462 | 0,538 | 0,602 | 0,169 |
| **LDL-C**  (mmol/L) | NCT (44) | 30 (68,2) | 32 (74,4) | 34 (77,3) | 35 (79,6) |
| NC (46) | 38 (84,4) | 39 (86,7) | 40 (88,9) | 38 (84,4) |
| p (NCT ss NC)\* | | 0,071 | 0,146 | 0,143 | 0,547 |

*p (chi2). (NCT ss NC): Comparative intervention group with control group.*

The rates of elevated serum triglycerides, cholesterol, and LDL-C of study participants in both groups after 12 weeks of intervention showed no difference.

|  |  |  |  |
| --- | --- | --- | --- |
| Table 3.9. HDL-C changes in 2 study groups over 12 weeks of intervention. | | | |
| **Timing** | **NCT (44)**  **(n ,%)** | **NC (46)**  **(n ,%)** | **p** |
| **T0** | 14 (31,8) | 9 (20,0) | 0,203 |
| **T4** | 8 (18,6) | 13 (28,9) | 0,258 |
| **T8** | 4 (9,1) | 15 (33,3) | **0,005** |
| **T12** | 1 (2,3) | 16 (35,6) | **0,000** |

*p (chi2)*

**Table 3.10.** **Reduced incidence** of **Metabolic Syndrome (HCCH) of 2 study groups after 12 weeks of intervention***.*

|  |  |  |  |
| --- | --- | --- | --- |
| **Timing** | **NCT (44)**  **(n ,%)** | **NC (46)**  **(n ,%)** | **p** |
| **T0** | 17 (38,6) | 11 (24,4) | 0,149 |
| **T4** | 13 (31,0) | 14 (31,1) | 0,987 |
| **T8** | 10 (22,7) | 13 (28,9) | 0,507 |
| **T12** | 5 (11,4) | 14 (31,1) | **0,023** |
| **Preventive effect of the product on the condition of Metabolic Syndrome** | | | |
| **ARR (CI 95%)** | 0,139(-0,007 – 0,286) | | 0,090 |
| **NNT (CI 95%)** | ( - ) | | |
| **The therapeutic effect of the product on the condition of Metabolic Syndrome** | | | |
| **ARR (CI 95%)** | 0,492(0,16 – 0,824) | | **0,010** |
| **NNT (CI 95%)** | 2,033(1,396 – 8,697) | | |

*p (chi2)*

The results showed that by the end of the study, the incidence of HCCH of diabetes in the new intervention group was statistically significantly lower than that of the control group. When evaluating the effectiveness of the intervention by the number of people requiring treatment (NNT), the results showed that treating only 2 people was able to reduce 1 case of HCCH among patients who had HCCH before participating in the study.

Chapter 4. DISCUSSION

**4.1. Overweight and obesity in women 40-65 years old in Ha Dong district and Chuong My district, Hanoi.**

The study results showed that the study participants were up to 36.4%underweight, obese (BMI ≥ 23 kg / m2), there was no difference between inner city and suburban as well as the age of participation in the study (p > 0.05 – chi2 test). In 2005, the census on overweight and obesity showed that the TCBP rate (BMI ≥ 23 kg/m2) of women in the age group of 45-54 was 24.1% and in the age group of 55-64 was 24.6%. Theprevalence of abdominal obesity of diabetes accounted for 78%, the ratio between inner city and suburban was different with (p = 0.011) the group of people aged ≤ 50 had a rate of abdominal obesity of 69.6%, less than the group over 50 years old of 83.3%, the difference between the 2 age groups was statistically significant (p = 0.000). Thecentral obesity rate (WHR ≥ 0.8) of diabetes is very high at 98.1%. This rate is higher when compared to the central obesity rate of urban 55-64 yearold women living in 2005 of 88.65%. The study showed that 36.4% of subjects had TCBP and 63.6% did not have TCBP, and in the absence of TCBP, 0.6% of subjects had chronic energy deficiency (BMI < 18.5 kg/m2), at least over 90% of subjects had a normal BMI but had central obesity. Theresults showed that up to 92.8% of the study subjects had abdominal obesity, and almost all of the non-abdomen were those who lacked energy or were very thin. The prevalence of abdominal obesity among adult females in the community is very high (88.65% in 55-64 year old in 2005, the number that needs attention is body mass index (BMI) rather than just waist circumference or waist/butt ratio.

When comparing abdominal obesity between subjects with a BMI of < 23 kg/m2 and those with a BMI of ≥ 23kg/m2, the results showed that out of a total of 673 subjects, 270 subjects with a BMI of <23(kg/m2), 55.9% had abdominal obesity. Meanwhile, the prevalence of abdominal obesity in the BMI group ≥ 23 (kg/m2) was 92.8% (in 403 subjects). The prevalence of abdominal obesity in the BMI group ≥ 23 (kg/m2) was nearly 1.7 times higher than that of BMI < 23 (kg/m2), a statistically significant difference. The prevalence of non-abdominal obesity in the BMI group ≥ 23 (kg/m2) was 7.2%, while the rate in the BMI group <23 (kg/m2) was 44.1%, which was 36.9% higher than in the BMI group ≥ 23 (kg/m2), statistically significant difference with p = 0.000. Our findings are consistent with previous research findings. There is a strong linear correlation between waist circumference and BMI. It can be seen that the waist circumference index is necessary and important to assess the nutritional status of women in the age group of 40-65 years.

4.2. Effectiveness of Calorie Limit after 12 weeks of intervention.

At the beginning of the intervention, the anthropometric indicators (height, weight, body mass ratio (BMI), fat percentage (PBF), total fat area, subcutaneous fat area, visceral fat area, waist circumference, buttocks, waist/buttocks ratio (WHR) of the 2 study groups were similar, all the differences were not YNTK with (p > 0.05 – t-test). The ages of the two study groups also did not differ as the average age of the intervention group was 52.8 ± 5.0 years compared to the mean age of the control group of 51.1 ± 5, 4 years old. The study found that the nutritional value of the diets of the two study groups was similar, all without YNTK. At the start of the study, the incidence of metabolic syndrome and the incidence of metabolic syndrome components of the two study groups were similar to the difference without YNTK (p > 0.05 – t-test).

The results of the study showed that the two study groups were similar in all the research indicators that the research team had collected at the time of the start of the intervention.

***Control for confounding factors in physical activity and diet control of study subjects.***

The confounding factors did not change during the study participation such as age group, gender, living area, placebo effect, etc. has been controlled through study design. However, many other factors can affect the results of the study.

The research team assessed the nutritional value of diets and physical activity of all study subjects during all four times. The results of the diet study showed almost no difference in dietary nutritional value between the two study groups at all time of the diet assessment. When inter-chalem dietary nutritional value was considered, showing that the nutritional value of inter-batch diets was similar, there was no major variation in the participants' diets.

In the study, the team used step per day index to assess participants' physical activity. The step count was recorded for 3 days, excluding the release date and the collection date to assess the physical activity level of the study participants. The results showed no difference in physical activity between the two groups nor within a study group between all assessments. From the results of the actual diets and physical activity of the participants, it can be confirmed that the actual diets as well as physical activities of the 2 groups were completely similar during the study period. It can be seen that the weight loss effect of the research product is due to the intervention method of the study, not due to some other random factor that we have not controlled or taken into account.

***The intervention effect of the product on the weight, waist circumference, buttocks, waist/butt ratio of the study subjects.***

In the study, the weight of the intervention group at the start of the intervention study was higher than the weight in the control group (59.9 ± 5.5 kg and 59.4 ± 4.7 kg), this difference was not YNTK (p = 0.664 – t-test). After 4 weeks of intervention, the weight of both groups decreased with YNTK. The weight of the intervention group decreased from 59.9 ± 5.5 kg to 59.3 ± 5.6 kg (p = 0.000 – t-pairing test). In the control group, weight decreased from 59.4 ± 4.7 kg to 59.2 ± 4.7 kg (p = 0.012 - t- pairing test), the difference between the 2 groups at the time of T4 after deployment is still without YNTK (p = 0.908 – t-test). At the next evaluation, T8, the control group's weight remained unchanged, while the study group's weight continued to decrease to 58.9 ± 5.4 kg, the difference from the start of the study was YNTK (p = 0.000 - t-pairing test). However, the difference between the 2 study groups at the time of T8 was still not YNTK (p = 0.783 – t-test). At the last assessment, at the time of T12, the weight in the control group was almost unchanged from the previous time. In the intervention group, the average weight of the study subjects decreased to 58.5 ± 5.3 kg compared to 58.9 ± 5.4 kg at T8, the difference from the beginning of the study was having YNTK (p = 0.000 - t-pairing test), the difference between 2 groups without YNTK.

As can be seen, the weight loss effect of the research product is quite impressive. In 2015, author Jonathan Sackner-Bernstein with a meta-analysis based on 17 different studies from 1797 overweight and obese adults with a follow-up of less than 1 year, showed that it was associated with significantly more weight loss (Δ = -2.0 kg, 95% CI): -3.1, - 0.9) by eating reduced carbohydrates and reducing dietary fat. Using a reduced-carb diet resulted in an average loss of 2 kg over the course of the study, which is significantly higher than the results in this study.

The variability of waist circumference, butt circumference and waist/butt ratio also show. The waist circumference index of the intervention group continuously decreased over the study periods, from 86.3 ± 3.8 cm at T0, to 84.5 ± 3.9 cm after T4, to 83.1 ± 3.5 cm after T8, and finally to 81.9 ± 3.6 cm at the end of the intervention (T12), all differences when compared to the start of the intervention have YNTK (p = 0.000 - t-pairing test). In controls, the subjects' waist circumference decreased only slightly after 4 weeks of the start of the study, from 86.4 ± 3.7 cm to 86.2 ± 3, 6 cm, but subsequent times were virtually unchanged with levels of 86.2 ± 3.8 cm at T8 and levels of 86.2 ± 4.1 cm at the end of T12, all differences were absent when compared to the start of T0 intervention (p > 0.05 – t-pairing test). When comparing between the 2 groups, after only 4 weeks of intervention, the difference between the 2 groups began to have YNTK (p = 0.036 – t-test) and this difference continued to increase at the next 2 times as YNTK levels continued to increase (p = 0.000 – t-test) at both times.

On further analysis, the results also showed that the reduction in waist circumference from the T4 time of the intervention group (-1.77 ± 1.75) cm was higher than that of the control group (-0.21 ± 1.08) cm with YNTK. After that, the waist circumference reduction of the intervention group continued to increase, the waist circumference reduction of the control group leveled off almost unchanged, by the time T12 was reduced (-4.4 ± 2.14) cm in the intervention group and in the control group was (-0.2 ± 2.07) cm.

In 2011, author Amagase and colleagues conducted a study evaluating the waist-reducing effect of Lycium barbarum fruit juice on overweight and obese adults. The results showed that after only 14 days of using Lycium barbarum fruit juice product, the waist circumference of the subjects in the intervention group was reduced by 5.5 ± 0.8 cm, this reduction was YNTK (p < 0.01). So it can be seen that Lycium barbarum reduced waist circumference faster and more when compared to the Calorie Limit product in this study. However, the drawbacks of Lycium barbarum fruit juice compared to Calorie Limit products are: the study subjects must use fresh juice in fairly large amounts (up to 120ml) that can change the daily eating habits of the study subjects. The second is that transporting, storing, and distributing fresh fruit juices is obviously a lot more difficult and expensive when compared to the tablet form of the Calorie Limit product.

A meta-study evaluating the weight loss and metabolic syndrome effects of plant extract products from 279 different clinical trial studies. The results showed that the waist circumference reduction of the study subjects in the intervention group was -1.71 SMD (Standardized Mean Different), the waist circumference reduction was -4.41 ± 2.14 cm, when converted to SMD would be equivalent to -2.06, so it can be seen that the waist reduction effect of Calorie Limit products is higher than the average of 279 types of reduced products plant-based scales in Moloud's study.

***The effect of the product's intervention on the indicators of assessing the state of body fat of the study subjects.***

Computerized Tomography (CT), is the gold standard for evaluating the area of belly and visceral fat. At the start of the intervention to the end of the intervention, the reduction in total body fat area measured at L4, L5 of the intervention group decreased significantly, to -9.9 cm2, while in the control group the opposite occurred, when the total body fat area increased by 3.7 cm2. The total body fat area of the intervention group decreased (-9.9 cm2) due to a decrease (-5.8 cm2) in visceral fat and a decrease in (-3.9 cm2) in subcutaneous fat. In controls, a total fat are increase of 3.7 cm2 was mostly due to an increase of 4.5 cm2 visceral fat, while subcutaneous fat decreased slightly (-0.4 cm2).

There are very few studies evaluating the effectiveness of products by body fat area index. Most of the studies conducted were conducted in Japan. In 2015, Nagatomo studied the effectiveness of reducing belly fat in obese patients (25 < BMI <30) by giving 100mg of rosehip extract once daily for 12 weeks. As a result, the index of subcutaneous fat area in the abdominal area of the intervention subjects decreased significantly compared to the control group.

In 2018, author Susumu Yoshino and colleagues, a study evaluated the abdominal fat loss effect of Kaempferia parviflora extract on abdominal obesity of TCBP people. The results showed that the intervention group reduced 4.3 ± 1.4 cm2 of visceral fat. This result was similar to the visceral fat reduction effect of the calorie limit product used in this study.

***The effect of the product on blood biochemical indicators and the incidence of HCCH of the study subjects.***

The Calorie Limit product statistically significantly reduced the fasting intravenous glucose index of the intervention subjects compared to controls at 4 weeks after use of the product (p = 0.020–independent t-test) and continued to decrease at subsequent data collections (down from 4, 7 ± 0.3 mmol/L to 4.6 ± 0.3 mmol/L. TheHbA1c number in the intervention group also decreased significantly from the 8th week after the intervention, at the time the average TbA1c of 5.5 ± 0.3 to T8 decreased to 5.3 ± 0.2 and at the end of the intervention decreased to 5.2 ± 0.2 the decrease after 12 weeks was statistically significant with (p = 0.000).

A meta-study of 26 different studies by author Reza Tabrizi on 1890 subjects on the effectiveness of curcumin consumption, showed that curcumin reduced fasting blood glucose at -0.78 SMD. Thus, Curcumin has a slight advantage when compared to the ability to lower blood glucose when compared to this ability of Calorie Limit products.

This study also assessed triglycerides, total cholesterol, LDL-C, and HDL-C. In these indicators, HDL-C scores remained virtually unchanged throughout the study period, across 4 different assessments. Triglycerides, total cholesterol, and LDL-C are similar. These indicators decreased steadily in the intervention group, while in the control group, these indicators increased steadily, however, statistically significant differences were observed only at the end of the intervention (p > 0.05 – independent t-test). The research results are similar to the results of testing 1 number of other naturally derived weight loss support products, author Bokura has tested and proven Chitosan has the ability to reduce total cholesterol and LDL - C.

The results showed that the incidence of metabolic syndrome in the intervention group decreased steadily and consistently with each evaluation, from 38.6% at the time of the study to 11.4% at the end of the study. While this figure in the control group increased slightly from 24.4% at the start of the study to 31.1% at the end of the study. The difference with YNTK was observed only at the end of the study (p = 0.023 - test When squared).

Further research, the results showed that for subjects who did not have HCCH at the time of the start of the study, the use of the product or not using the product did not significantly affect the progress of the study subjects. The absolute odds (ARR) of the incidence of HCCH of these 2 groups after intervention was only 13.9% without YNTK (p = 0.09 - test When squared). However, when only subjects were considered who had HCCH at the start of the intervention, the use of the product significantly reduced the incidence of HCCH in the intervention group compared to the control group after 12 weeks of the study. Given that the absolute odds (ARR) of the incidence of these two groups after 12 weeks of study was 49.2% with YNTK (p = 0.010 - test When squared) and the number of people requiring treatment to reduce 1 case (NNT) was approximately 2 (Ci 95%: 1.396 - 8.697), we can conclude that Calorie Limit is a product worth using to treat HCCH for sick people. In the author's ability to search for literature, almost no intervention studies using plant-based products assessed the subjects' ability to improve HCCH, but only evaluated the effectiveness of the product on each component of HCCH, which somewhat limited the author's ability to compare the results of the study with those of the study other research in the world.

**Advantages and novelty of the study.**

The study has provided valuable scientific information on the status of TCBP in women aged 40-65 years.

Having an additional product to reduce body weight still ensures normal living, not too strict about nutrition as well as physical activity.

**Limitations of the study.**

The study was designed based on the funding framework and duration of the project, so the intervention period was 12 weeks, so any long-term effects of taking the supplement have not yet been fully evaluated.

Improved effects on lipids and glucose metabolism by dietary intake were also suggested in this study. However, parameters related to glucose and lipid metabolism were not assessed as the main criteria. Therefore, this natural active ingredient supplement is considered to inhibit the absorption of glucose and lipids from food, so the impact on lipid and glucose metabolism should be evaluated in the future.

CONCLUSION

1.Overweight and obesity in women 40-65 years old in Ha Dong district and Chuong My district, Hanoi.

The cross-sectional survey of 673 study subjects who were women aged 40-65 years showed that:

The prevalence of overweight and obesity among women aged 40-65 years with a BMI of ≥ 23 kg/m2 at the study site was (36.41%). This rate is similar across age groups and living regions.

The average BMI of the study subjects was 24.1±3.0 kg/m2.

More than three-quarters (78%) of the study subjects had abdominal obesity (waist circumference > 80cm) and most (98.1%) had central obesity (WHR ≥ 0.8). The prevalence of abdominal obesity in the group with a BMI of < 23 (kg/m2) accounted for 55.9%; and the group with a BMI of ≥ 23 (kg/m2) accounted for (92.8%).

The proportion of study subjects using weight loss drugs accounted for 2.7%; Inner-city areas had a statistically significant higher utilization rate than suburbs with p=0.003.

**2. Effective intervention** **of food supplements containing natural active ingredients Calorie Limit, improving overweight, obesity and changing some biochem ical indicators in women 40-65 years old.**

Subjects who used Calorie Limit products during the 12-week study of the intervention group had improvements in weight status, visceral fat, subcutaneous fat in the abdomen, and reduced incidence of Metabolic Syndrome.

The effectiveness of the product supported weight reduction for the study subjects when the average intervention group lost 1.4 ± 0.95 kg of weight, while the average control group lost only 0.3 ± 1.12 kg of weight. The difference between the 2 groups was statistically significant with p = 0.000.

For waist circumference, the product helped the intervention subjects reduce their waist circumference by an average of 4.41±2.14 cm compared to the control group's average reduction of 0.2 ± 2.07 cm. The difference between the 2 groups was statistically significant with p = 0.000.

With visceral fat and abdominal subcutaneous fat, subjects in the intervention group lost an average of 5.8 cm2 of visceral fat and 3.9 cm2 of abdominal subcutaneous fat compared to the start of the study, a statistically significant difference with p = 0.000 and p = 0.010. While subjects in the control group increased an average total of 3.7cm2 in both of these indicators.

The total body fat area measured at L4, L5 of the intervention group decreased by 9.9 cm² meaningfully with (p = 0.000), the control group increased by a total of 3.7 cm² the difference was not statistically significant.

The effect of calorie limit after 12 weeks of intervention resulted in statistically significant reductions in biochemical indicators of blood glucose (mmol/L), HbA1c (%), insulin (UI), triglycerides (mmol/L), cholesterol (mmol/L), LDL-C (mmol/L), the mean of indicators in the intervention group decreased accordingly (4,7 ± 0,3; 4,6 ± 0,3); (5,5 ± 0,3; 5,2 ± 0,2); (7,8 ± 4,4; 7,5 ± 2,4); (2,2 ± 1,1; 1,9 ± 0,6); (5,0 ± 0,9; 4,8 ± 0,7); (3,0 ± 0,7; 2,7 ± 0,5).

Evaluation of the effectiveness of intervention through the NNT index (the number of people who need intervention to reduce one case): shows that the product is effective in treating the study subjects to reduce the incidence of HCCH when only 2 people need to be treated, 1 case is reduced after only 12 weeks of using the product (NNT ≈ 2; CI95%: 1,396 – 8,697) Statistically significant reduction.

# RECOMMENDATIONS

Through the research results of the topic, we have some recommendations as follows:

1. For groups of subjects with high rates of abdominal obesity and central obesity, high body mass index needs more attention, developing appropriate intervention strategies such as lifestyle medicine.

2. Calorie limit supplements have the effect of supporting body weight reduction, especially reducing visceral fat, abdominal wall fat, controlling metabolic syndrome component factors, so it is necessary to strengthen communication and advice about products to the right target groups.

3. Follow-up studies on a larger scale and longer time are needed to evaluate the effectiveness of dietary supplements Calorie limit containing natural active ingredients on lipid and glucose metabolism of the body in subjects with abdominal obesity rate, central fatness, high body mass index.