

Clinical Report

Efficacy and acceptability of the Kilokiller food supplement intended to combat obesity in subjects suffering from arterial hypertension and hypercholesteremia.

Final report

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1. Context and General purpose

Obesity is a major international social problem affecting all countries. According to the World Health Organization, 7% of the world's population is affected. It is estimated that 300 million people will be obese worldwide in 2025. The number of obese subjects increases by 10% every 10 years (Chazova I.E, 2001; Belialov N.A. et al.; 2003; Izogenova N.F. et al., 2005).

Several scientific studies describe obesity as an epidemic due to its worldwide propagation (Seidell J. et al., 1997; Kurzmarski R. et al., 1994), but of a non-infectious type. In parallel, obese subjects are two times more likely of developing cardiovascular disease. For this reason, it would appear appropriate to conduct this study in a centre with expertise in cardiology liable to recruit a population affected by obesity.

Laboratoires Nutrisanté wish to evaluate a food supplement called Kilokiller, which they claim has a weight and fat mass loss action in overweight patients.

The purpose of this study was to evaluate the efficacy and tolerance of a food supplement accompanied by the consumption of Kilokiller, over 3 sessions.

2. Materials and methods

2.1. Product

2.1.1. Definition

Manufacturer: PVI, Parc d'Activité Sud Loire – 85612 Montaigu Cedex – France

Distributor: Ermatech, Vyatskaya street 27, str.16 127015 Moscow

Regulatory categories: food supplement according to the directive 2002/46 EC dated 10 January

2.1.2. Presentation

Carton containing 3 tubes of 14 tablets

- **Kilokiller morning**
- **Kilokiller lunchtime**
- **Kilokiller evening**

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2.1.3. Composition

Kilokiller morning

Ingredients:

Acidifier: citric acid; sweetener: sorbito; acidity corrector: sodium bicarbonate; citrus flavour; maltodextrin; carrier: polyethylene glycol; vitamins: C, E, B3; extracts of: green coffee, olive leaf, common ash, kola, mate, cynorhodon, wild pansy, cherry stem, meadowsweet, green tea; sweetener: saccharin; vitamins: B5, B6, B2, B1, B12, B9, B8.

Nutritional Value	For 1 tablet	For 100 g
Energy value	6 kcal 28 kJ	231 kcal 986 kJ
Proteins	0,0 g	0,1 g
Carbohydrates including - Sugars	0,98 g 0,00 g	34,8 g 0,0 g
Fats	0,00 g	0,0 g
Vitamin E	10 mg (100% RDA*)	357 mg
Vitamin C	60 mg (100% RDA*)	2143 mg
Thiamin B1	1,4 mg (100% RDA*)	50 mg
Riboflavin B2	1,6 mg (100% RDA*)	57 mg
Niacin B3	18 mg (100% RDA*)	643 mg
Vitamin B6	2 mg (100% RDA*)	71 mg
Folate B9	200 µg (100% RDA*)	7143 µg
Vitamin B12	1 µg (100% RDA*)	36 µg
Biotin B8	0,15 mg (100% RDA*)	5 mg
Pantothenic acid B5	6 mg (100% RDA*)	214 mg

*RDA = Recommended Daily Allowance

Claims	For 1 tablet 2,8 g	For 100 gr
Green coffee extract	20 mg	0,71 g
Olive leaf extract	20 mg	0,71 g
Common ash extract	20 mg	0,71 g
Kola nut extract	20 mg	0,71 g
Mate extract	20 mg	0,71 g
Cynorhodon extract	20 mg	0,71 g
Wild pansy extract	20 mg	0,71 g
Cherry stem extract	20 mg	0,71 g
Meadowsweet extract	20 mg	0,71 g
Green tea extract	20 mg	0,71 g

Kilokiller lunchtime

Ingredients:

Sweetener: sorbitol; acidifier: citric acid; acidity corrector: sodium bicarbonate; cider vinegar; apple and citrus pectins; guar gum; maltodextrin; apple flavour; carrier: polyethylene glycol; sweetener: saccharin; colouring agents: caramel, riboflavin; anticaking agent: silicon dioxide.

Nutritional value	For 1 tablet	For 100 g
Energy value	6 kcal 26 kJ	219 kcal 936 kJ
Proteins	0,01 g	0,3 g
Carbohydrates including - Sugars	0,93 g 0,00 g	33,9 g 0,0 g
Fats	0,00 g	0,1 g

Nutritional value (unless nutritional claim)

Claims	For 1 tablet 2,75 g	For 100 g
Cider vinegar	150 mg	5,45 g
Apple pectin	120 mg	4,36 g
Citrus pectin	120 mg	4,36 g
Guar gum	120 mg	4,36 g

Kilokiller evening

Ingredients:

Acidifier: citric acid; sweetener: sorbitol; acidity corrector: sodium bicarbonate; red fruits flavour; carrier: polyethylene glycol; extracts of: pineapple, cocoa, orange peel, papaya, grape marc; sweetener: aspartam; mineral: chromium chloride; emulsifier: soya lecithin.

Nutritional Value	For 1 tablet	For 100 g
Energy value	7 kcal 31 kJ	256 kcal 1093 kJ
Proteins	0,02 g	0,8 g
Carbohydrates including - Sugars	1,08 g 0,00 g	38,5 g 0,0 g
Fats	0,00 g	0,0 g
Chromium	25 µg	892 µg

Claims	For 1 tablet 2,8 g	For 100 g
Pineapple extract	50 mg	1,78 g
Cocoa extract	50 mg	1,78 g
Orange peel extract	50 mg	1,78 g
Papaya extract	50 mg	1,78 g
Grape marc extract	50 mg	1,78 g

2.1.4. Safety certificate

Certificate No. 1836 dated 14/08/06 issued by the Federal Health centre located at 19-a, Vartchavskoy street **117105, Moscow**

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2.2. Population study

2.2.1. Inclusion criteria

- The women recruited in the study are women between 18 and 45 years of age, with a Body Mass Index (BMI) greater than 25.
- Women who have given their free and informed written consent.
- The women had to be cooperative, informed of the duration of the examinations.

2.2.2. Exclusion criteria

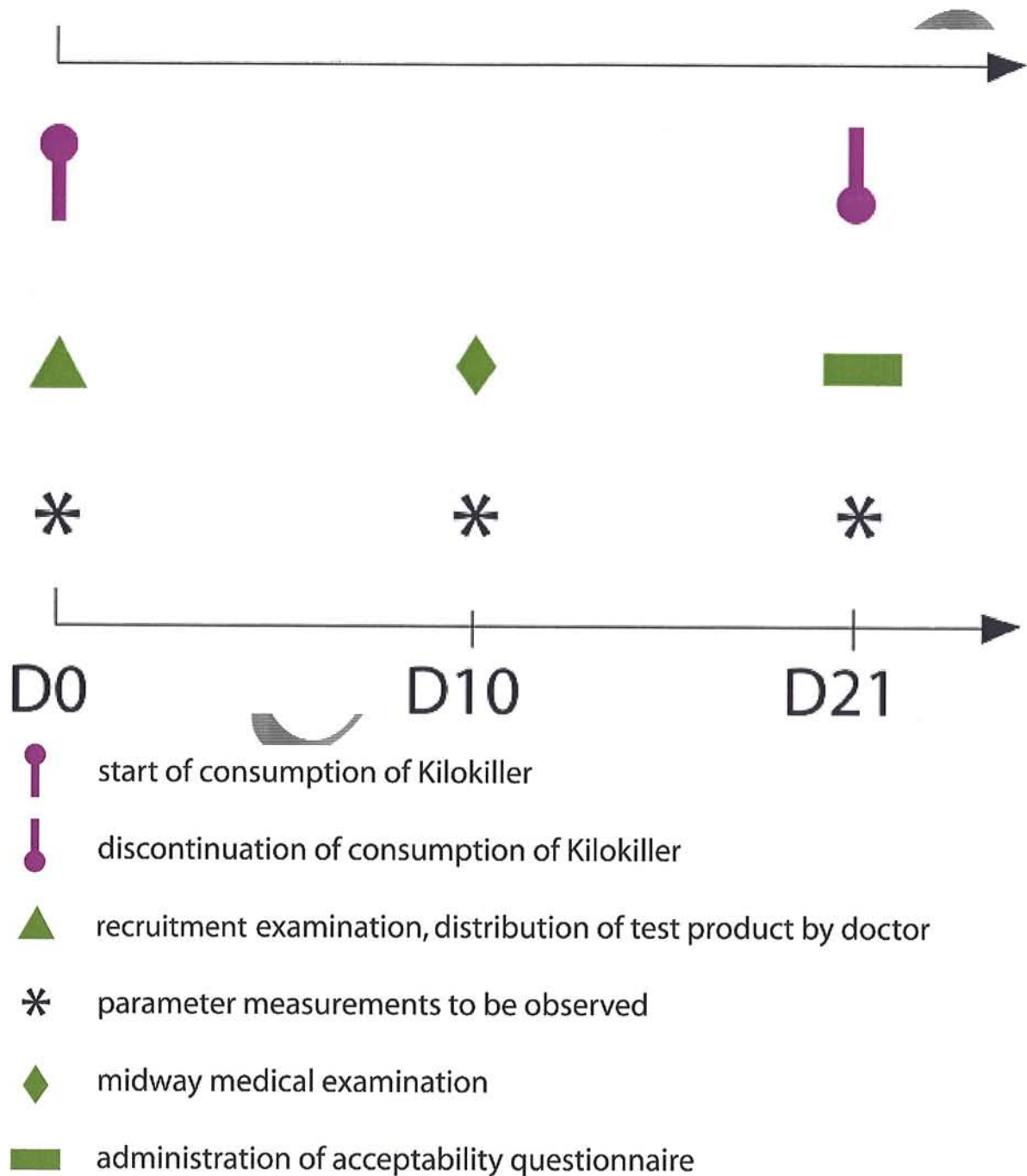
- The women following a basic systemic medical treatment in progress or finished since less than one month, and likely to influence the results. Women suffering from rare or chronic diseases.

2.2.3. Evaluation criteria

- Weight measured on D0, D10, D21
- Variation in body mass index (BMI)
- Variation in fat mass
- Thigh circumference measurement
- Acceptability questionnaire

2.2.4. Plan study

The protocol procedure is represented schematically below:



3. Results

3.1. Purpose and summary of study plan

The purpose of this study was to evaluate the efficacy and tolerance of a diet accompanied by the consumption of Kilokiller, over a 3-week period. It consisted of an open trial.

The women underwent 3 medical examinations at the Tver' city cardiology centre on D0, D10, D21.

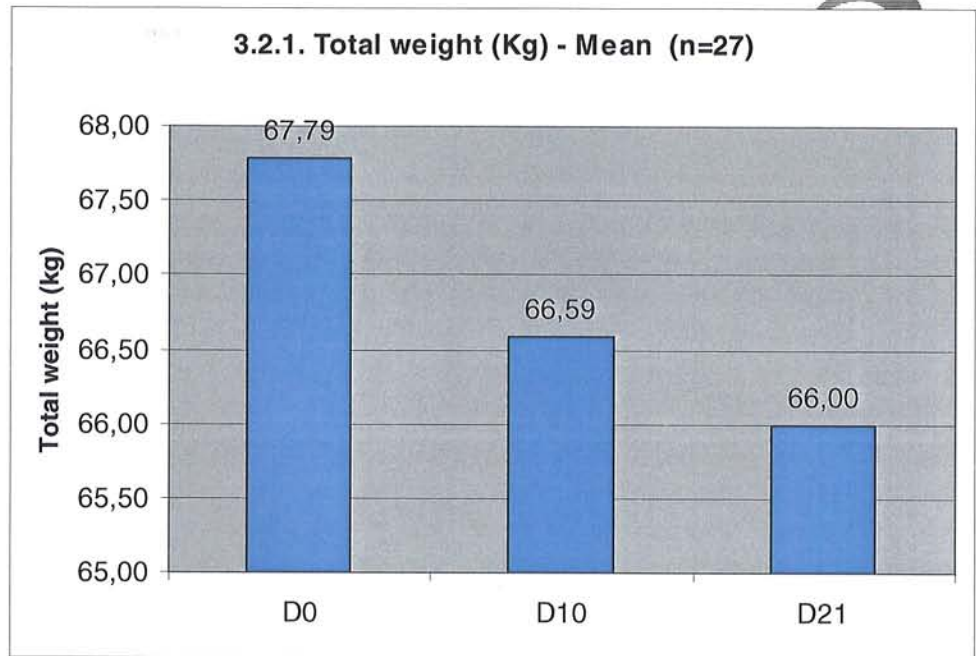
On D0, after signing a consent form, the volunteers were weighed, measured and the perimeter of their right thigh recorded. The fat mass was read on "Tanita" BF 576 impedance meter scales. Finally, a blood test was conducted on D0 and D21. During the laboratory tests, particular attention was focused on the glucose and protein levels in the blood. In the case of high levels, the food supplement made it possible to normalise their levels, and in the case of satisfactory levels, they did not decrease their indices.

The results do not indicate any liver dysfunction. Cholesterol measurements display an average decline from 1.62 ± 0.07 mmol/l; $p < 0.001$.

3.2. Evolution of parameters measured

3.2.1. Total weight

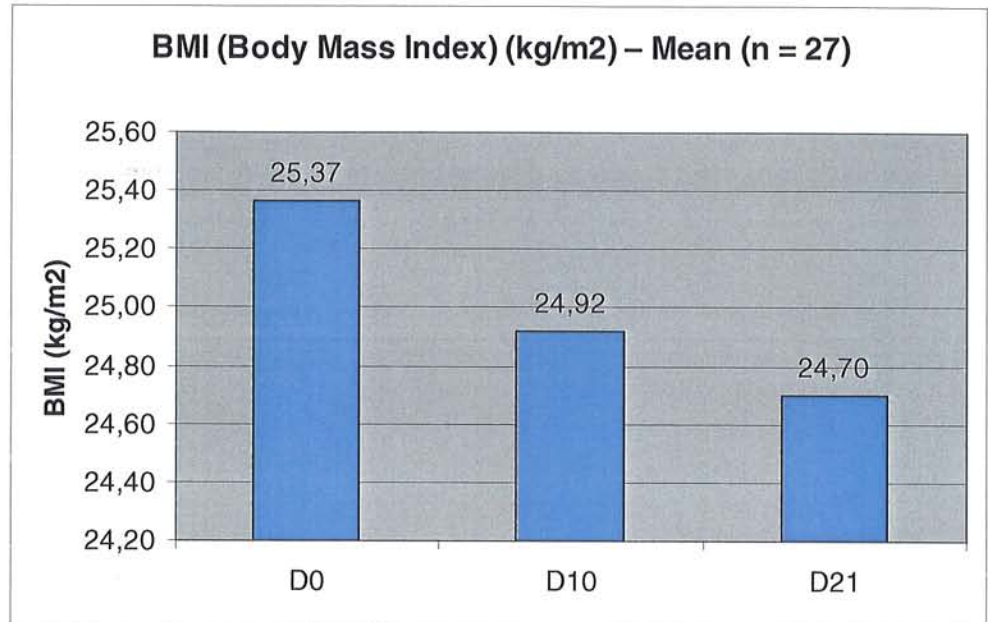
96% of the volunteers lost weight homogeneously over the 20 days, as shown in the figure below:



The mean weight loss of 1.79 kg (2.6%) is significant ($p < 0.0001$), with a maximum loss of 4.9 kg.

3.2.2. Body Mass Index

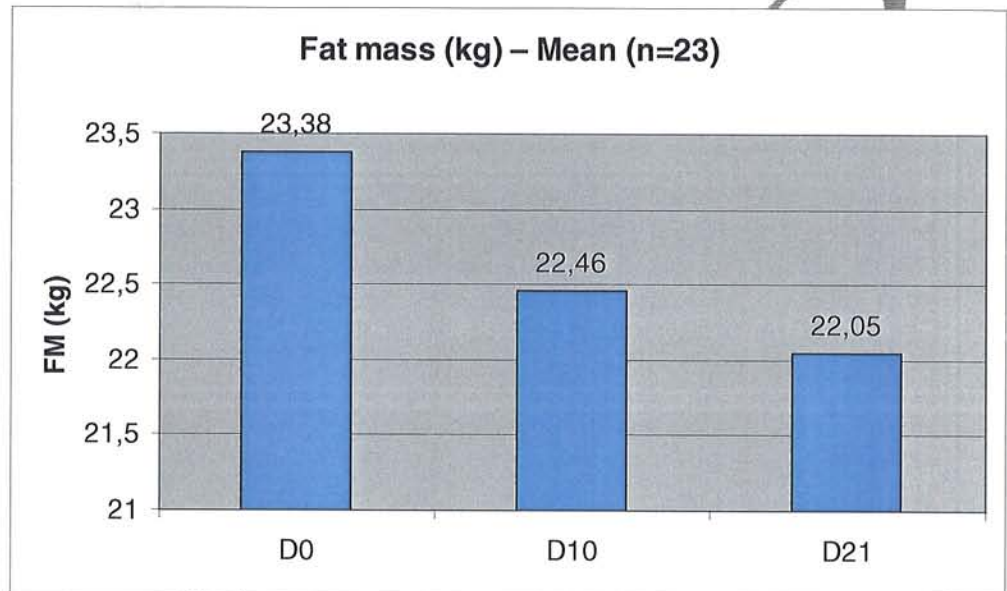
The weight loss naturally has repercussions on the body mass index:



The mean loss was 0,67 kg/m² (2.6%), with a maximum loss of 1.76 kg/m². The difference between D21 and D0 is significant ($p < 0.0001$).

3.2.3. Fat mass

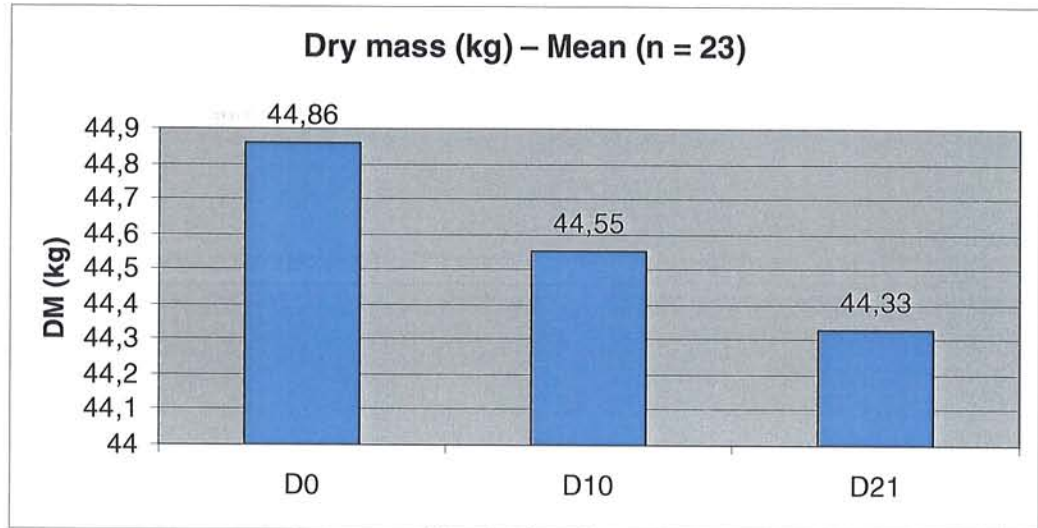
The volunteers were weighed on Tanita BF 576 impedance meter scales; this made it possible to obtain the proportion of fat mass and dry mass. For 4 volunteers, a weighing error meant that the FM/DM data are incorrect; for this reason, the results below relate to 26 subjects.



It is interesting to note that a mean loss of 1.33 kg (5.7%) was obtained on the fat mass (significant between D0 and D21, $p < 0.0001$). For these 26 volunteers, the fat mass loss represented 71.5% of the total body weight, which is very satisfactory as it demonstrates that the diet enabled the loss of mainly adipose tissue.

3.2.4. Dry mass

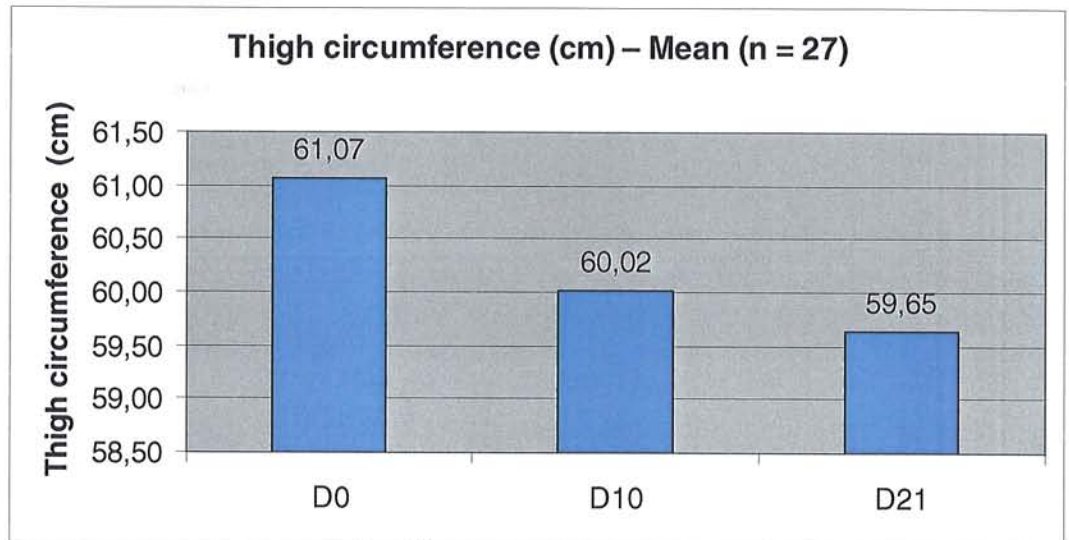
For the same reasons as those given above, the graph below only accounts for 25 volunteers :



The mean dry mass loss is 0.53 kg (1.18%), which, with reference to the total weight loss of the 23 volunteers, represents 28.5%.

3.2.5. Thigh circumference

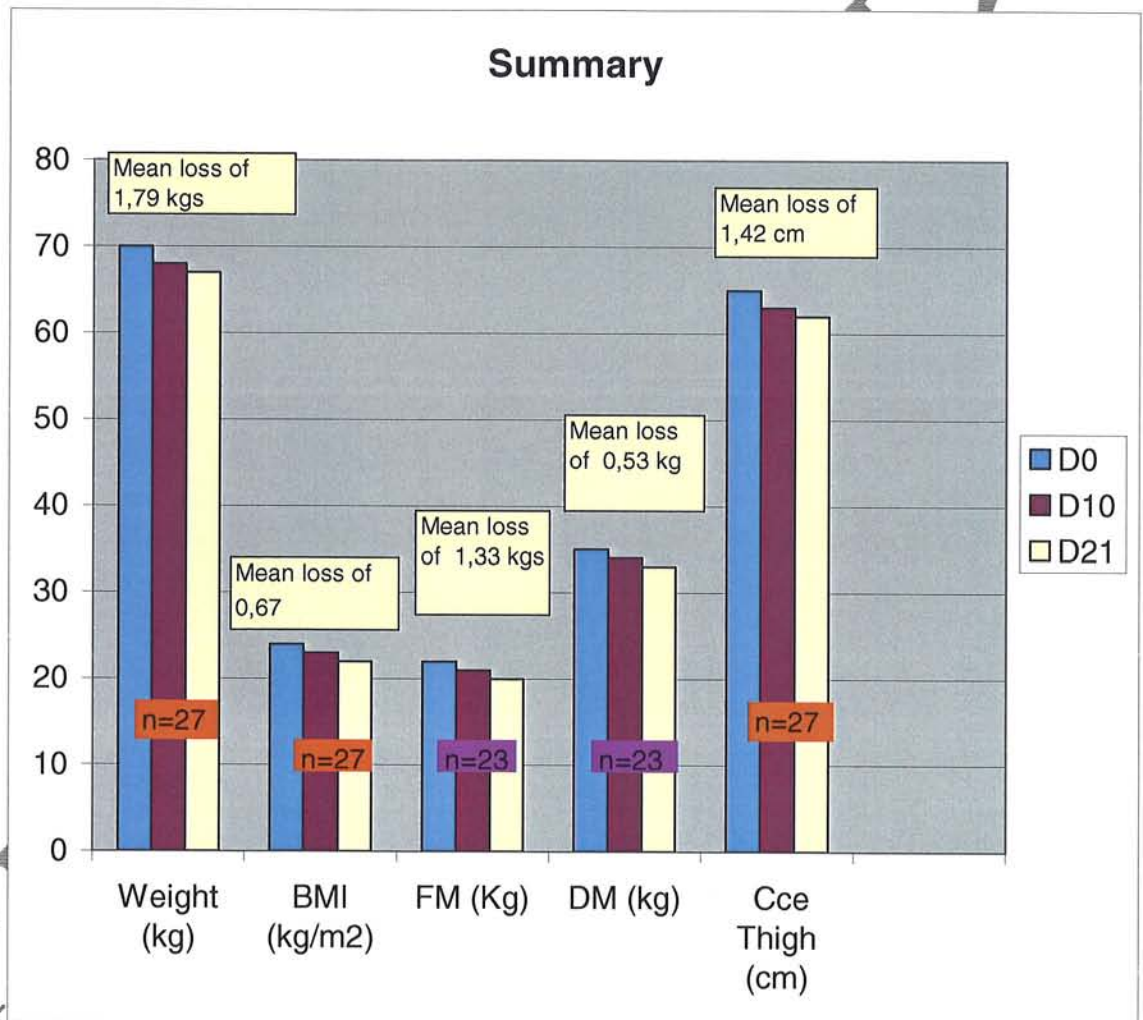
The thigh circumference measurement was always made at the same place (top right thigh) using a circumferential measuring tape.



A mean loss of 1.42 cm (2.3%) in the thigh circumference was observed. This decrease in the thigh circumference was observed for 81% of the volunteers.

3.2.6. Summary

In terms of clinical measurements, the results are extremely satisfactory as they demonstrate that 96% of the women lost weight and 81% obtained a substantial thigh circumference loss. In addition, the diet enables the loss of essentially fat mass and not dry mass.



3.3. Tolerance

No adverse events were observed after 20 days of use of Kilokiller. The product was tolerated perfectly.

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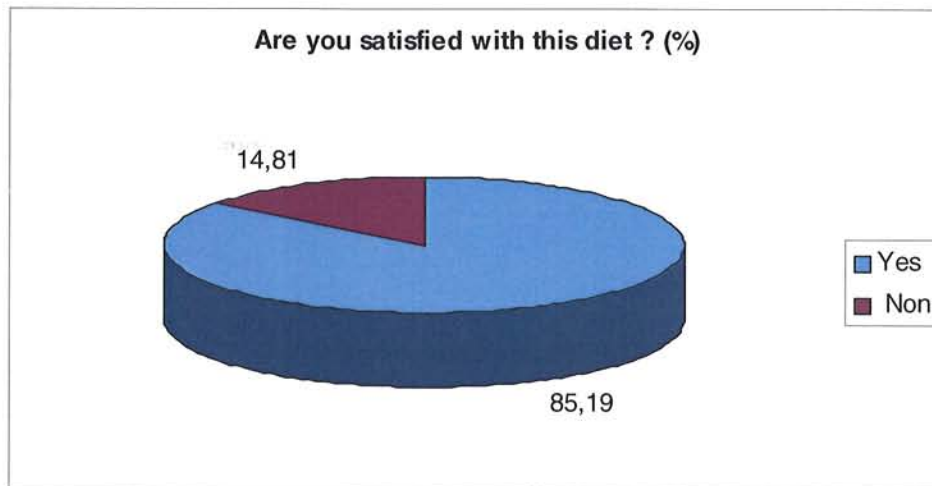
3.4. Perceived efficacy

At the last examination on D21, a questionnaire relating to the diet was given to the volunteers in order to assess the degree of satisfaction. The questionnaire results are given in the following pages.

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3.4.1. Diet easy to follow

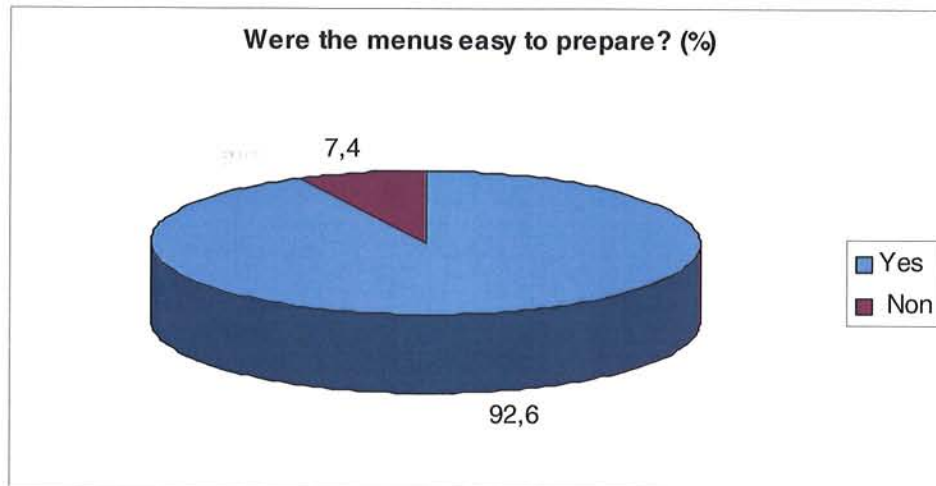
The following question was asked: "was it easy to follow the diet?"



Overall, the women found it easy to follow the diet. Although they gave positive responses, some criticised the diet for having a low proportion of meat and starchy foods. One volunteer reported 2 fainting spells.

3.4.2. Preparation of proposed menus

The following question was asked: "Were the menus easy to prepare?"

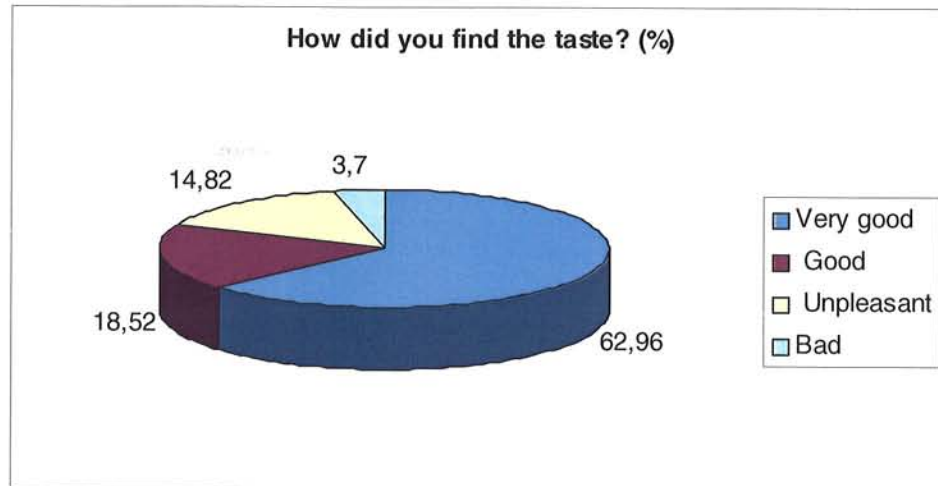


All the volunteers were extremely satisfied by the fact that a 3-week diet was proposed in addition to the product to be consumed, as this enables a more overall "treatment" than dietary recommendations alone.

They all noted the originality of the recipes proposed. Two subjects noted that some of the recipes were relatively expensive.

3.4.3. Taste of drink after reconstitution

The following question was asked: "How did you find the taste?"



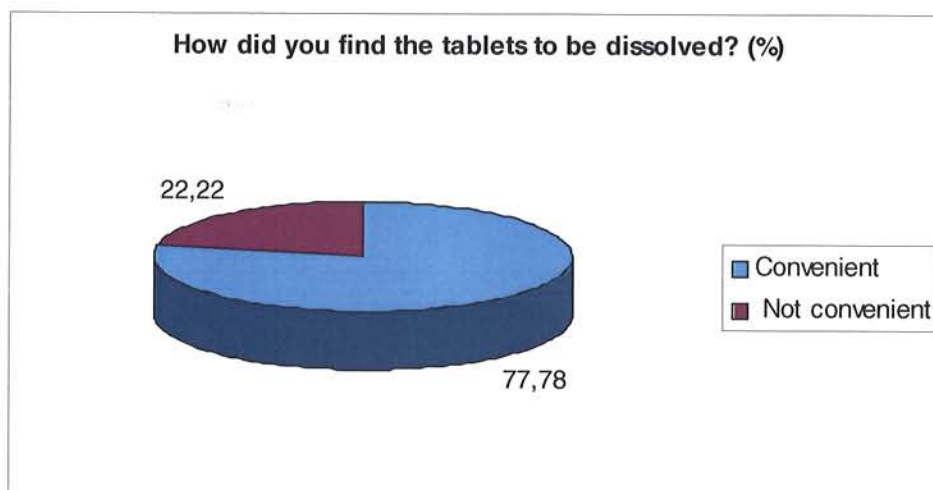
The results are very satisfactory as, for almost 78% of the volunteers, the taste was considered to be pleasant (good or very good). Only one volunteer found it to be bad. Of those who liked the taste, one subject found the drinks to be too sweet while another found them not sweet enough.

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3.4.4. Convenience

The following question was asked: "Are the tablets to be dissolved...?"

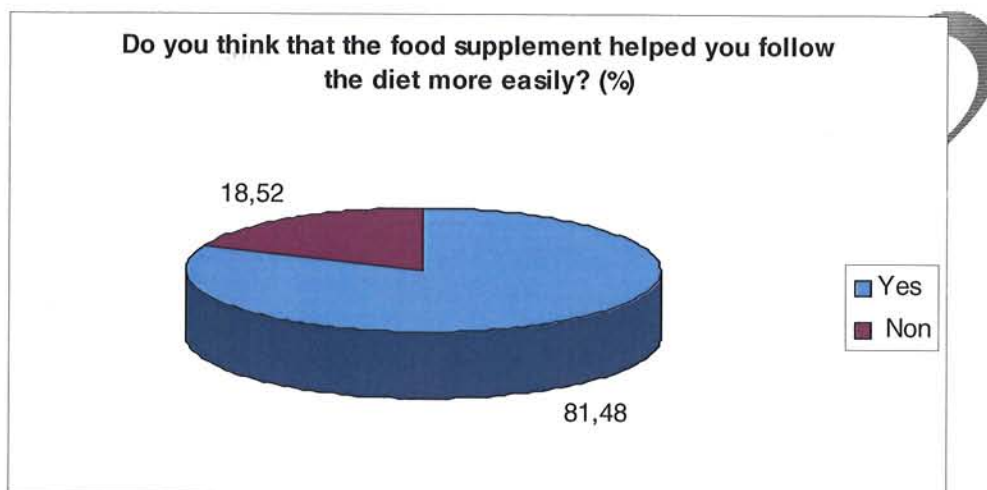
How did you find the tablets to be dissolved? (%)



Therefore, overall, the responses were very favourable for this form. Of those who did not find the tablets convenient, the cause was difficult dissolution in water and some difficulty pouring the solution into a bottle of water; in fact, the volunteers reconstituted the drink in a 500 ml bottle in order to be able to drink at all times.

3.4.5. Role of the nutritional supplement in the diet

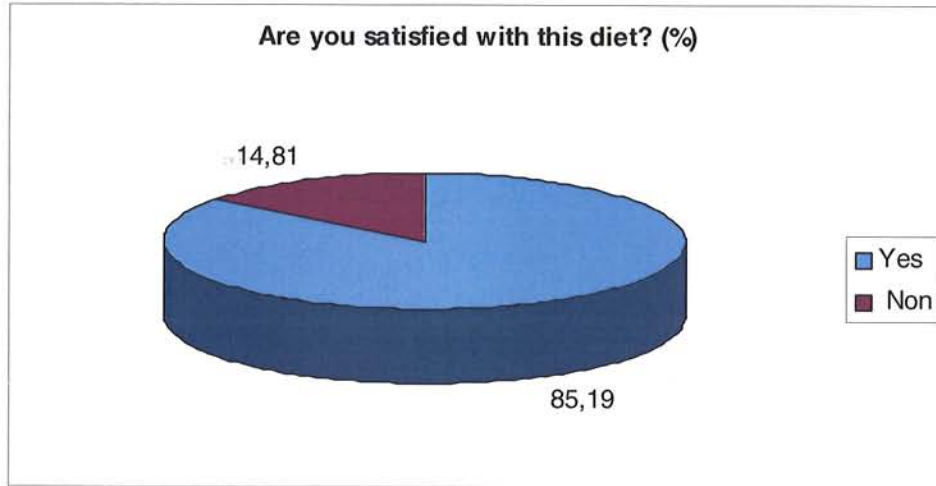
The following question was asked: "Do you think that the food supplement helped you follow the diet?"



Therefore, the vast majority of volunteers considered the consumption of the product to be beneficial in following the diet. When asked how the product helped them, almost 73% of them replied that the solution increased or extended the satiating effect and that they were less tempted to nibble.

3.4.6. Overall satisfaction

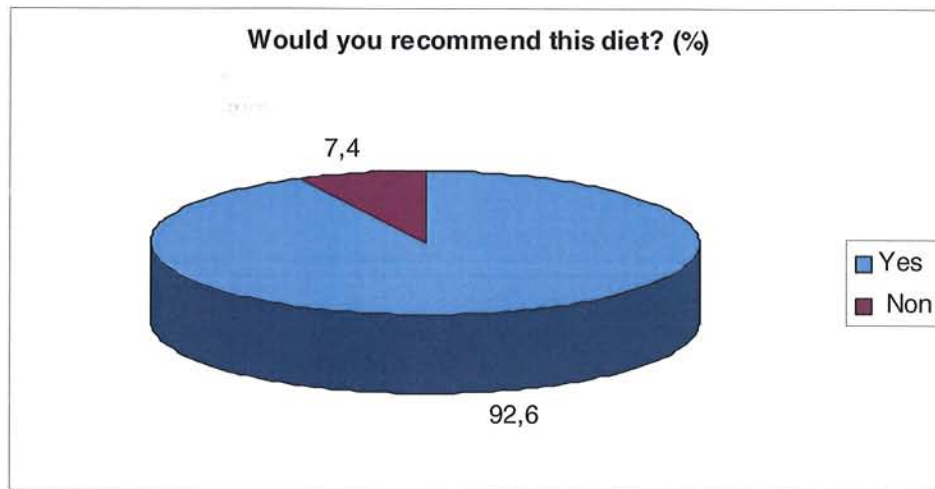
The following question was asked: "Are you satisfied with this diet?"



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3.4.7. Is the diet worth recommending?

For an optimal evaluation of the volunteers' satisfaction, the following question was asked: "Would you recommend this diet?"



Almost 93% gave a positive response to this question. Some suggested including starchy foods in the diet proposed.

4. Conclusion

The slimming treatment proposed by Laboratoires Nutrisanté combines the consumption of a nutritional supplement with a diet. The 30 volunteers tested this treatment for 20 days. The results were very satisfactory in terms of weight loss and overall satisfaction. In fact, 96% of the volunteers lost weight (1.8 kg on average) and the impedancemetry analysis demonstrated that the loss essentially consisted of fat mass loss (over 70%). In terms of overall satisfaction, besides some remarks relating to the low proportion of starchy foods in the proposed diet, 85% were satisfied and almost 93% would recommend the diet.

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