JOURNAL OF FUNCTIONAL FOODS XXX (2012) XXX–XXX

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Effect of green mate in overweight volunteers: A randomized placebo-controlled human study

Hwa Jung Kim[a,1], *Jeongah Ko*[b,1], *Charlotte Storni*[c,*], *Hong Ji Song*[d], *Young Gyu Cho*[e]

[a]*Department of Clinical Epidemiology and Biostatistics, Asan Medical Center, University of Ulsan College of Medicine, 86 Asanbyeongwon-gil, Songpa-gu, Seoul 138-736, Republic of Korea*

[b]*Korea National Training Center, Korea Olympic Committee, 223-19 Kongneung-dong, Nowon-gu, Seoul 139-804, Republic of Korea*

[c]*Frutarom Switzerland Ltd., Rütiwisstrasse 7,8820 Wädenswil, Switzerland*

[d]*Department of Family Medicine, Hallym University Sacred Heart Hospital, College of Medicine, Hallym University, 896 Pyeongchon-dong, Dongan-gu, Anyang-si, Gyeonggi-do 431-070, Republic of Korea*

[e]*Department of Family Medicine, Seoul Paik Hospital, College of Medicine, Inje University, 85 Jeo-dong 2-ga, Jung-gu, Seoul 100-032, Republic of Korea*

ARTICLE INFO

Article history:
Received 20 July 2011
Received in revised form
13 December 2011
Accepted 16 December 2011
Available online xxxx

Keywords:
Mate
Ilex paraguariensis A. St.-Hil.
Obesity
Weight loss
Clinical study
Anti-obesity

ABSTRACT

Overweight and obesity have become a global epidemic and they may impair health. Traditional use and growing evidence indicate that mate (*Ilex paraguariensis* A. St.-Hil.) may be helpful in losing excessive weight and fat. The present randomized, double-blind, placebo-controlled study evaluated efficacy and safety of an extract from green mate in 60 overweight subjects aged 20–39 years during 6-weeks. Body composition was measured by Dual-Energy X-ray Absorptiometry (DEXA) at baseline and after 6 weeks. Body weight, body mass index (BMI), waist circumference (WC) and various safety parameters were monitored. After 6 weeks, subjects taking mate experienced a significantly greater reduction of percent of body fat (−0.3% vs. +0.6%, $p = 0.04$) and fat mass (−0.5 kg vs. +0.2 kg, $p = 0.04$) than placebo. No significant differences were observed in other measurements. No adverse events occurred and all safety parameters were within normal ranges during the study in both groups. Thus, taking green mate extract reduced body fat after 6 weeks, while the treatment was safe and well tolerated.

1. Introduction

The prevalence of overweight and obesity has been increasing rapidly and becoming a global epidemic. Overall, 23.2% of the world's adult population in 2005 was overweight, and 9.8% was even obese (Kelly, Yang, Chen, Reynolds, & He, 2008). The estimated total numbers of overweight and obese adults in 2008 were 1500 million and around 500 million, respectively (WHO, 2011). By 2030, the respective number of overweight and obese adults is projected to be 1.35 billion and 537 million

* *Corresponding author:* Tel.: +41 44 782 64 64; fax: +41 44 782 64 66.
E-mail addresses: rsvp@amc.seoul.kr (H.J. Kim), nanadoc@naver.com (J. Ko), cstorni@ch.frutarom.com (C. Storni), hongjisong5@gmail.com (H.J. Song), jacobel@hanmail.net (Y.G. Cho).

[1] Both authors contributed equally to this work.

Abbreviations: BMI, body mass index; DEXA, Dual-Energy X-ray Absorptiometry; WC, waist circumference; WHR, waist to hip ratio; BF%, body fat percentage; BFM, body fat mass; LBN, lean body mass; HDL, high density lipoprotein cholesterol; LDL, low density lipoprotein cholesterol; ITT, intention-to-treat; SD, standard deviation.

1756-4646/$ - see front matter
doi:10.1016/j.jff.2011.12.005

Please cite this article in press as: Kim, H.J. et al., Effect of green mate in overweight volunteers: A randomized placebo-controlled human study, *Journal of Functional Foods* (2012), doi:10.1016/j.jff.2011.12.005

individuals, respectively, without adjusting for secular trends (Kelly et al., 2008). Obesity does not only result in a heavier population, moreover it is becoming a major health concern as it increases the risk of diabetes (Aucott, 2008; Nguyen, Magno, Lane, Hinojosa, & Lane, 2008), dyslipidaemia (Nguyen et al., 2008), hypertension (Nguyen et al., 2008), coronary artery disease (Flint et al., 2009) and ischemic stroke (Kurth et al., 2002). These findings have resulted in an increased interest in dieting, also because losing weight improves health (Fontaine & Allison, 2001). Nevertheless, approximately 80% of those who try to lose weight by dieting fail to maintain the initial weight loss (Ayyad & Andersen, 2000). The effects of obesity treatment can be maximized when diet control is accompanied by exercise and lifestyle changes. Furthermore, a variety of functional food and dietary supplements are available to help those who want to lose weight (Pillitteri et al., 2008). However, the efficacy and safety of such products are not always scientifically proven. As the food supplement market is regulated more strictly, clinical evidence and safety aspects become an absolute must for functional foods and food supplements.

Mate, *Ilex paraguariensis* A. St.-Hil., is a South American herb that is traditionally prepared as a tea and used, among others, for weight reduction (Alikaridis, 1987). Although mate became known worldwide owing to its traditional use, the scientific evidence for its effects is scarce. However, research has recently been expanding and some studies suggest that mate may have beneficial effects in the management of obesity (Heck & De Mejia, 2007). Newly, a characterized extract from *I. paraguariensis* A. St.-Hil. was shown to suppress appetite and prevent diet-induced obesity in rats, evidencing its possible anti-obesity activity (Pang, Choi, & Park, 2008). Thus, this study intended to examine the efficacy of this green mate extract on body weight, body fat reduction and several other parameters connected to overweight. Additionally, the safety of treatment with the extract was assessed.

2. Materials and methods

2.1. Study design

The study was a randomized, double-blind, placebo-controlled, 6-week, prospective, parallel group trial conducted at the Obesity Research Institute of the Seoul Paik Hospital, Inje University in Korea. The protocol was approved by the institutional review board of the hospital (Approval number: 2005-005).

2.2. Study participants

Subjects were women, aged 20 to 39 years, with a body mass index (BMI) $\geqslant$ 25 kg/m^2 without any comorbidity, and who had not received any other weight control therapy within the last 3 months were recruited from the internet. All eligible subjects who were in good health according to their medical history, physical examination, and routine laboratory tests and signed written informed consent were enrolled. Exclusion criteria were history of allergic reactions to medications or food, pregnancy and lactation, use of medication that could interfere with the conduct of the study (e.g. medications that affected body weight or lipid-lowering drugs), a history of alcohol or drug abuse within the past year, participation in another clinical study. Inclusion and exclusion criteria are listed in detail in Table 1.

Table 1 – Inclusion and exclusion criteria for selection of study participants.

Inclusion criteria
Gender: women
Age: 20–39 years
Body mass index: $\geqslant$25 kg/m^2
Exclusion criteria
Hypertension defined by BP $\geqslant$ 140/90 mm Hg
Diabetes defined by fasting blood glucose $\geqslant$ 126 mg/dL or random blood glucose $\geqslant$ 200 mg/dL or treated with oral hypoglycemic agents or insulin
History of neoplastic disease within the past 5 years
Allergic disease including bronchial asthma
Psychiatric disorder including major depression, schizophrenia, alcohol abuse or substance-abuse
Cardiac disease, cerebrovascular disease, renal disease, gout
Liver disease, gallbladder disease, gastrointestinal disease
Significant musculoskeletal diseases that can interfere with exercise
History of surgical procedure during 6 months prior to study start
Pregnancy or lactation
Participation in a weight loss program during 3 months prior to study start
Current use of drugs or herbal preparations that can alter body weight (diuretics, anti-obesity agents, anti-depressant drugs, glucocorticoids, oral contraceptive, female hormones, etc.)

2.3. Interventions

2.3.1. Non-pharmacological intervention

Diet and exercise counseling was provided by a trained dietician to every participant in order to maintain a 1500 kcal/day balanced diet (Poston, Haddock, Dill, Thayer, & Foreyt, 2001) and do sufficient exercise every day to consume 250 kcal/day. A printed sheet with information about energy content of foods and amount of energy expended through different physical exercises was distributed to the participants. The subjects were instructed to record all food intakes and physical activities in a diary during the study period.

2.3.2. Study products

Study products were hard gelatine capsules containing 334 mg of green mate powder extract (active) or corn (placebo) and excipients pro capsula, weighing 400 mg in total. The green mate extract was obtained from Frutarom Switzerland Ltd., Wädenswil, Switzerland (commercial name of the extract: Finomate™ EFLA®920). The extract was manufactured from dried green leaves of *I. paraguariensis* A. St.-Hil. by extraction with 15% (m/m) ethanol followed by a patented filtration procedure (EFLA®Hyperpure, EP 0 730 830 B1) and drying. The drug to extract ratio (DER) was 4–6:1 (by weight). Characteristic components of the extract were caffeoylquinic acid (chlorogenic acid derivatives) 20–40% (m/m), caffeine 2–4% (m/m), theobromine 0.3–1.2% (m/m), triterpenic saponins > 1% (m/m). The batch

used had a content of 28.2% caffeoylquinic acid, 2.4% caffeine, 0.36% theobromine and 2.4% triterpenic saponins. Participants in the mate and the placebo group received three times daily 3 capsules, to be ingested 30 min before meals. The daily dosage of the study product was therefore 3000 mg green mate extract during 6 weeks.

2.4. Sample size and Randomization with double blinding

Sample size estimation was calculated using a one-sided two-sample *t*-test. Group sample sizes of 30 and 30 achieve 53% power to detect a difference in body weight of 3.3 kg and 85% power to detect a difference in body fat mass of 2.6 kg with a significance level (alpha) of 0.05.

Subjects were randomly assigned to the mate product or the placebo group by an automated randomization system. Participants received capsules with identical appearance and taste in accordance with the allocation code after randomization with a 1:1 allocation ratio between groups. To maintain double blinding, the allocation was managed by an investigator with no clinical involvement in the trial, whereas study manager and data analyst were kept blinded to the allocation. All data of subjects were strictly managed according to code until the study was finished. Absolute secrecy of all individual information was maintained.

2.5. Measurements

Measure of vital signs, anthropometric measures and serological tests were performed during clinic visits at baseline and after 3 and 6 weeks. Anthropometric measures included height, weight, waist circumference (WC), and hip circumference. Body composition analysis determined by Dual-Energy X-ray Absorptiometry (Prodigy® DEXA Lunar, GE Healthcare, Madison, WI, USA) estimated body fat percentage (BF%) body fat mass (BFM) and lean body mass (LBM) and was performed at baseline and after 6 weeks. Efficacy outcomes were body weight, BMI, WC, BF%, BFM and LBM.

Additionally at baseline, information concerning socioeconomic factors, age, sex, occupation, educational level and income, was collected using a general questionnaire. The general health status of the subjects was also assessed with a questionnaire about medical history, family history and lifestyle. Daily intake of nutrients was assessed with a 24-h dietary recall questionnaire at 0, 3 and 6 weeks. Subjects' compliance with food diary recording, exercise amount, and intake of study product was monitored weekly by phone in between clinic visits or directly by interview during visit.

Total cholesterol, HDL-cholesterol, LDL-cholesterol, triacylglycerol, glucose and uric acid were measured in order to study metabolic changes as subsidiary items for the assessment of the potential weight control effect.

Safety outcomes were blood pressure, pulse rate, and electrocardiogram (ECG), liver function tests (serum level of protein, albumin, aspartate aminotransferase (AST), alanine aminotransferase (ALT), alkaline phosphatase and total bilirubin), renal function tests (blood urea nitrogen (BUN) and creatinine), complete blood count (CBC), calcium, phosphorus and serum electrolytes to determine overall nutritional status, and adverse events either reported by subjects or observed by investigator.

2.6. Statistical analysis

Collected data were analyzed in accordance to intention-to-treat (ITT) analysis ($n = 30$ per group). Student's *t*-test was used to compare every measurement between groups at each visit. Paired *t*-tests were used to examine differences within each group between 0 and 6 weeks. Analysis of Covariance (ANCOVA) was performed to examine mean decreases for efficacy outcome variables by groups after 6 weeks. Each test was conducted with a one-tailed significance level of 0.05. SAS ver. 9.1 was used.

3. Results

3.1. Participants flow

Seventy-three subjects were recruited, sixty subjects met the eligibility criteria and were enrolled in the study. After six weeks, fourteen subjects (30%) had dropped out of the study for personal reasons or because of difficulty in continuation of diet. Twenty-two subjects in the placebo and twenty-four subjects in the mate group finished the clinical trial.

3.2. Baseline characteristics

The clinical data of the ITT population, consisting of 60 subjects, who were randomly assigned to each group, were analyzed and are presented in Table 2. No significant differences in analytical values of anthropometric and laboratory measurements between groups were found. The mean daily energy intake as estimated by the 24-h dietary recall at baseline was different between the two groups (1589.8 kcal vs. 1440.2 kcal; $p = 0.04$). To take this difference into consideration, baseline daily energy intake was included as covariate in analyses of efficacy outcomes.

In contrast, there were no differences in total energy and macronutrient intake between the two groups at 3 and 6 weeks (data not shown).

3.3. Efficacy results

Table 3 summarizes the efficacy outcome variables by visits and group. After 6 weeks, BF% and BFM in the mate group had decreased more than in placebo group and the differences were statistically significant ($p = 0.05$ and 0.03, respectively). Changes in weight and BMI in the mate group were larger than those of the placebo group but not statistically significant.

Fig. 1 shows the mean decreases for efficacy outcome variables by groups after 6 weeks, after the mean change of each efficacy variable was adjusted for baseline value of each variable and baseline daily energy intake. BF% in the mate group significantly decreased by 0.3%, whereas in the placebo group it increased by 0.6% ($p = 0.03$). BFM in the mate group significantly decreased by 0.5 kg, whereas in the placebo group it increased by 0.2 kg ($p = 0.05$). LBM showed a non-significant

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Table 2 – Baseline characteristics of subjects (n = 60), mean ± SD.

	Placebo group (n = 30)	Mate group (n = 30)	p-value
Sex	Female	Female	
Age (years)	28.0 ± 4.8	27.0 ± 5.1	0.47
Height (cm)	162.5 ± 6.3	159.9 ± 5.1	0.08
Weight (kg)	72.9 ± 6.6	70.2 ± 7.1	0.10
BMI (kg/m^2)	27.5 ± 1.9	27.4 ± 1.6	0.45
BFM (kg)	25.3 ± 4.0	24.1 ± 3.4	0.43
LBM (kg)	42.4 ± 8.6	42.8 ± 4.6	0.41
BF (%)	36.5 ± 4.0	36.0 ± 4.2	0.33
WC (cm)	90.8 ± 5.3	87.7 ± 12.0	0.10
Total cholesterol (mg/dL)	182.1 ± 25.5	182.1 ± 34.0	0.47
Triacylglycerol (mg/dL)	89.2 ± 33.6	95.6 ± 46.8	0.28
HDL-cholesterol (mg/dL)	50.1 ± 10.8	49.0 ± 9.7	0.29
Glucose (mg/dL)	83.1 ± 5.7	83.1 ± 9.3	0.49
AST (IU/L)	18.5 ± 3.3	19.2 ± 3.6	0.20
ALT (IU/L)	15.8 ± 6.3	16.1 ± 7.7	0.43
SBP (mmHg)	111.0 ± 10.3	112.3 ± 9.7	0.34
DBP (mmHg)	70.3 ± 7.2	70.0 ± 7.4	0.43
Energy intake (kcal/d)	1589.8 ± 296.7	1440.2 ± 272.5	0.04

BMI: body mass index, BFM: body fat mass, LBM: lean body mass, BF%: body fat percentage, WC: waist circumference, HDL: high density lipoprotein, AST: aspartate aminotransferase, ALT: alanine aminotransferase, SBP: systolic blood pressure, DBP: diastolic blood pressure.

Table 3 – Efficacy outcome variables by group and visit.

	Placebo group		Mate group		p-value
	n	Mean ± SD	n	Mean ± SD	
Weight (kg)					
Baseline	30	72.9 ± 6.6	30	70.2 ± 7.1	0.10
3 weeks	24	72.2 ± 6.5	24	69.0 ± 9.1	0.07
6 weeks	22	72.0 ± 6.5	24	68.7 ± 8.2	0.07
BMI (kg/m^2)					
Baseline	30	27.5 ± 1.9	30	27.4 ± 1.6	0.45
3 weeks	24	27.3 ± 1.8	24	26.9 ± 1.8	0.17
6 weeks	22	27.2 ± 1.8	24	26.7 ± 1.8	0.19
WC (cm)					
Baseline	30	90.8 ± 5.3	30	87.7 ± 12.0	0.10
3 weeks	24	90.8 ± 6.12	24	89.4 ± 5.9	0.21
6 weeks	22	90.8 ± 6.2	24	88.5 ± 5.9	0.10
BF (%)[a]					
Baseline	30	36.5 ± 4.0	30	36.0 ± 4.2	0.33
6 weeks	22	37.6 ± 3.2	24	35.6 ± 3.6	0.05
BFM (kg)[a]					
Baseline	30	25.3 ± 4.0	30	24.1 ± 3.4	0.43
6 weeks	22	26.1 ± 4.4	24	23.5 ± 3.0	0.03
LBM (kg)[a]					
Baseline	30	42.4 ± 8.6	30	42.8 ± 4.6	0.41
6 weeks	22	43.1 ± 4.0	24	42.5 ± 5.0	0.32

BMI: body mass index, WC: waist circumferences, BF%: body fat percentage, BFM: body fat mass, LBM: lean body mass.

[a] Body fat%, body fat mass, lean body mass were measured by DEXA at baseline and 6 weeks.

decrease in the placebo group compared to the mate group (0.9 kg vs. 0.5 kg; p = 0.18).

The changes in total cholesterol, triacylglycerol, HDL-cholesterol and glucose are shown in Table 4. Although the differences in the levels of cholesterol, triacylglycerol and HDL-cholesterol between the two groups were not statistically significant after 6 weeks, the mean cholesterol level of the mate group was lower than that of the placebo group (172.3 mg/dL vs. 183.2 mg/dL; p = 0.09). No significant changes were seen in the blood glucose levels of both groups.

3.4. *Safety results*

All safety parameters were within normal ranges at baseline and at study end in both groups (data not shown). They included blood pressure, ECG, liver and renal function tests,

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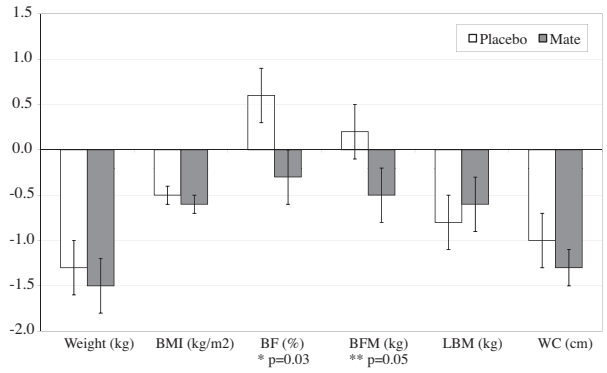

Fig. 1 – Mean changes for efficacy outcome variables after 6 weeks. Effect of treatment with green mate extract or placebo on each efficacy outcome after 6 weeks from study start. Values shown are means ± SD. Values are adjusted for the baseline value of each variable and baseline daily energy intake. Negative values correspond to decreases from baseline. Positive values correspond to increases from baseline. BMI: body mass index, BF%: body fat percentage, BFM: body fat mass, LBM: lean body mass, WC: waist circumference.

Table 4 – Serum lipids and glucose by group and visit.

	Placebo group		Mate group		*p*-value
	n	Mean ± SD	*n*	Mean ± SD	
Total cholesterol (mg/dL)					
Baseline	30	182.1 ± 25.5	30	182.1 ± 34.0	0.47
3 weeks	24	184.5 ± 25.6	24	178.6 ± 32.5	0.25
6 weeks	22	183.2 ± 21.2	24	172.3 ± 31.6	0.09
Triacylglycerol (mg/dL)					
Baseline	30	89.2 ± 33.6	30	95.6 ± 46.8	0.28
3 weeks	24	85.3 ± 24.0	24	94.1 ± 42.5	0.17
6 weeks	22	89.8 ± 32.7	24	98.5 ± 44.5	0.23
HDL cholesterol (mg/dL)					
Baseline	30	50.1 ± 10.8	30	49.0 ± 9.7	0.29
3 weeks	24	47.0 ± 11.5	24	46.3 ± 22.9	0.41
6 weeks	22	48.5 ± 11.4	24	45.1 ± 10.8	0.15
Glucose (mg/dL)					
Baseline	30	83.1 ± 5.7	30	83.1 ± 9.3	0.49
3 weeks	24	78.6 ± 5.6	24	81.1 ± 7.5	0.09
6 weeks	22	79.6 ± 7.6	24	79.1 ± 9.8	0.42

HDL: high density lipoprotein.

haematologic tests and serum electrolytes. No adverse events were reported during the study.

4. Discussion

Obesity is a major health concern in many developed and developing countries. Interest in a healthy diet is also increasing, causing many obese and overweight people to seek a variety of diet products. Their main purpose is the reduction of their body weight, which should be obtained by body fat reduction and not by LBM reduction in order to maintain health. This study showed that participants taking a green mate extract obtained a significantly greater reduction of BF% and BFM compared to those in the placebo group ($p < 0.05$). As the dietary energy intake was comparable between both groups, and the participants followed similar exercise instruction, it may be concluded that this effect is related to the ingestion of the green mate extract. Additionally, the reduction of LBM was larger in the placebo group than in the mate group, even though the difference was not significant. This is an appreciated effect as reduction of LBM is one of the undesirable effects of losing weight. Body weight loss was achieved by both groups without significant differences. Therefore, the main result of this study is the favorable effect on body composition in overweight people.

Despite previous research providing supportive evidence of the weight reducing potential of mate, this is the first controlled trial showing that an anti-obesity effect may be ascribed to the ingestion of this herb. In a previous placebo-controlled clinical trial, mate was contained in a supplement together with other ingredients such as green tea, asparagus, black tea, guarana and kidney bean extracts (Opala, Rzymski, Pischel, Wilczak, & Wozniak, 2006). This study also showed reduced body fat by those taking the supplement.

The extract manufactured from mate leaves contained characteristic components such as caffeoylquinic acids, caffeine, theobromine and triterpenic saponins. The mechanisms of action of mate on fat reduction, while not directly known, may be due to the effects of its single components as investigated in previous studies. Caffeine was found to enhance noradrenaline-induced lipolysis in adipose tissue (Han, Takaku, Li, Kimura, & Okuda, 1999). Caffeoylquinic acids inhibit maltase and prolong the absorption of caffeine (Czok & Lang, 1961; Gracza & Ruff, 1987). Saponins delay intestinal absorption of dietary fat by inhibiting pancreatic lipase activity, which shows their hypolipidemic effects (Han, Zheng, Xu, Okuda, & Kimura, 2002; Xu, Han, Zheng, Lee, & Sung, 2005; Zhao et al., 2005). Polyphenols, that are present in mate as caffeoyl-derivatives, account for the high antioxidant capacity of mate (Arçari et al., 2011; Berté, Beux, Spada, Salvador, & Hoffmann-Ribani, 2011; Filip & Ferraro, 2003; Schinella, Troiani, Dávila, de Buschiazzo, & Tournier, 2000) and other beverages such as green tea (Seeram et al., 2006). However, polyphenols have also been reported to interact synergistically with caffeine to augment and prolong sympathetic stimulation of thermogenesis (Dulloo, Seydoux, Girardier, Chantre, & Vandermander, 2000; Greenway & Heber, 2004), the process in the body that produces heat by expending energy and burning fat.

The potential thermogenic properties of mate are known and were investigated in a clinical setting by (Martinet, Hostettmann, & Schutz, 1999). This study evaluated the acute effects of oral administration of 12 commercially available plant preparations, aimed at treating human obesity. Only after treatment with a green mate extract a change in respiratory quotient (RQ) was shown, which indicates a rise in the proportion of oxidized fat that may lead to decreased body fat. The results suggest the positive potential of mate leaves in the treatment of obesity.

In terms of metabolic benefits, it is known that mate tea can also affect other aspects of lipid metabolism. An *I. paraguariensis* extract was reported to inhibit the progression of atherosclerosis in cholesterol-fed rabbits, although it did

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not decrease the serum cholesterol (Mosimann, Wilhelm-Filho, & da Silva, 2006). A reduction in serum concentrations of cholesterol and triacylglycerols could be observed in rats fed a high-cholesterol diet after ingestion of mate extracts (Stein et al., 2005). In the present study, a reduction of total cholesterol by the green mate extract was observed, although the difference with placebo was not statistically significant. Additionally, from previous studies it was assumed that antioxidants in extracts of *I. paraguariensis* A. St.-Hil. inhibit LDL oxidation *in vitro* and *in vivo*, exhibiting a potency comparable to that of ascorbic acid (Gugliucci, 1996; Gugliucci & Stahl, 1995). Whether metabolic benefits from weight reduction can be produced via long-term treatment with mate products remains to be demonstrated.

Another study reported that a preparation containing mate may reduce energy intake and increase satiety, while inducing weight loss (Andersen & Fogh, 2001). Such an effect was not shown in the present study, where the energy intake of the subjects during the trial was relatively well controlled and stable. A weight loss effect could not be demonstrated definitively, although weight and BMI diminished more in the mate group than in the placebo group. This might be due to a low statistical power in this study because of the limited sample size. While our study was limited to a population restricted by age and gender, such a follow-up study should also address the variety of the overweight population. Due to the limited sample-size, the gender restriction was introduced to included participants in order to better control for gender-related differences in response to the study product. As a consequence, participants were all females.

Analysis of the safety outcomes evidenced that the extract was safe and well tolerated at the dosage used in this study. Therefore, with respect to safety, our results are consistent with past research in showing no serious, deleterious consequences with the use of mate products (Pittler, Schmidt, & Ernst, 2005). Although specific safety concerns related to the intake of mate tea have been raised, recent research indicate that this association is not due to the consumption of the herb itself but to contaminants in processed mate and to the high temperature of tea preparations. Therefore, proper process technology and good quality insure safety of mate preparations (Heck & De Mejia, 2007). The mate preparation used in this study fulfils this high quality standard: the plant material was gently dried, the preparation was not submitted to high temperatures during processing, and was manufactured in GMP-qualified facilities.

Based on the above, it can be stated that the reductions of BF% and BFM in the group taking mate were significantly greater than those in the placebo group, which suggests that supplementation with green mate extract can support weight loss in overweight volunteers when combined with a balanced diet and regular physical activity. This hypothesis, as well as the possible effects of a long-term application of the extract should be further studied in suitable obesity models.

Acknowledgements

This study was supported by Frutarom Switzerland Ltd. We thank Tania Perrinjaquet-Moccetti and Marian Verbruggen for critically reviewing the manuscript.

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Please cite this article in press as: Kim, H.J. et al., Effect of green mate in overweight volunteers: A randomized placebo-controlled human study, *Journal of Functional Foods* (2012), doi:10.1016/j.jff.2011.12.005

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