*Topical Review Article*

Journal of Evidence-Based Complementary & Alternative Medicine
18(4) 309-313

DOI: 10.1177/2156587213496818
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# Green Coffee for Pharmacological Weight Loss

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**Abstract**

This review article evaluates if clinical data support the use of green coffee for weight loss. A literature search was conducted that yielded 5 clinical trials and 1 meta-analysis. Studies were evaluated for quality in accordance to clinical practice and US Food and Drug Administration guidelines. The amount of weight loss ranged from approximately 1 to 8 kg, with the meta-analysis finding a statistically significant difference in body weight, with a mean difference of −2.47 kg between green coffee and placebo (95% confidence interval = −4.23 to −0.72). The duration of trials varied between 4 and 12 weeks, and the dose of chlorogenic acid varied from 81 to 400 mg. Few published studies were in compliance with the US Food and Drug Administration guidelines. Despite the potentially clinically significant weight loss achieved in some published studies, all held significant limitations. Green coffee extract is not recommended as a safe or effective treatment for weight loss.

**Keywords**

green coffee, weight loss, obesity, chlorogenic acid

Received March 14, 2013. Received revised May 3, 2013. Accepted for publication June 14, 2013.

## Introduction

More than one third of the United States is considered obese, according to the Centers for Disease Control.[1] Obesity is known to contribute to comorbid conditions such as diabetes, hypertension, dyslipidemia, respiratory problems, and many other diseases, all of which may become life threatening. Patients are classified as obese if their body mass index is greater than or equal to 30 kg/m$^2$ and overweight if their body mass index is between 25 and 29.9 kg/m$^2$.[2] Since 1960, there has been a dramatic increase in the portion of the population classified as overweight or obese.[3]

The Federal Trade Commission has stated that at any given time, 70 million Americans are seeking weight loss, and in 2000, $35 billion was spent on dietary supplements with the intent of promoting weight loss.[4] With companies advertising weight loss supplements, with many claims being false or misleading, the Federal Trade Commission warns of potential risk to patients, as this may take the place of education patients could be receiving from health care professionals. In a comparison from 1992 to 2001, the amount of false or misleading advertisements related to weight loss supplements has dramatically increased. The US Food and Drug Administration has also questioned claims that dietary supplements cause significant weight loss.[5]

In 2007, US Food and Drug Administration created the "Guidance for Industry: Developing Products for Weight Management."[6] It is recommended that Phase III clinical trials assessing the efficacy and safety of medications for the use of weight loss are randomized, double-blind, and placebo-controlled. To assess the safety of the medications, it is recommended that at least 3000 subjects be given the active medication while at least 1500 subjects receive placebo, both for at least 12 months. It is also recommended that a lifestyle modification program be implemented into the trial. Primary endpoints should assess the amount of weight loss and the proportion of patients losing 5% of baseline body weight compared to placebo. It is expected that an efficacious agent would result in a mean weight reduction of 5% over 6 months. Secondary endpoints should look at metabolic parameters, such as blood pressure, pulse, lipids, glucose levels, hemoglobin A1C, and waist circumference.

Parameters suggested by the US Food and Drug Administration correlate with published obesity treatment guidelines.[3] Guidelines for initial management recommend implementing lifestyle modifications such as diet modification, exercise, and behavioral changes. If lifestyle modifications are not

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**Table 1.** US Food and Drug Administration–Approved Medications for Weight Loss.[7]

| | Over the Counter | Prescription |
|---|---|---|
| Orlistat (Alli, Xenical) | X | X |
| Phentermine (Adipex) | | X |
| Diethylpropion (Tenuate) | | X |
| Phentermine/Topiramate (Qsymia) | | X |
| Lorcaserin (Belviq) | | X |

successful, pharmacotherapy is an option. If severely obese, bariatric surgery can be considered if other options have failed.[3] Guidelines only recommend weight loss drugs when used in combination with diet and exercise for patients with a body mass index greater than or equal to 30 kg/m$^2$ with no obesity-related comorbidities (eg, diabetes mellitus, cardiovascular disease) or for those with body mass index greater than or equal to 27 kg/m$^2$ if the patient has obesity-related diseases. The US Food and Drug Administration approved prescription and nonprescription medications for obesity are listed in Table 1.

Currently, green coffee is being marketed for "natural" weight loss as a drink and in various solid oral dosage forms. This product has gained national interest and has appeared in the lay media, including *The Dr. Oz Show*.[8] In the weeks following a segment featuring green coffee on *The Dr. Oz Show*, with claims that it can help women lose 2 pounds per week based an in-house study, it was among the most popular Internet searches.[9]

Green coffee, classified as a dietary supplement, refers to raw, nonroasted coffee.[10] Chlorogenic acids, natural antioxidants present in large amounts in green coffee, are the active ingredients in green coffee thought to promote weight loss. Chlorogenic acid is present, to some extent, in roasted coffee, although much of it is destroyed in the roasting process. The most common chlorogenic acids are 5-O-caffeoylquinic acid, 2-O-caffeoylquinic acid, and 4-O-caffeoylquinic acid. Studies have been conducted to assess chlorogenic acid bioavailability and have shown that they are highly absorbed and metabolized when present in coffee.[11] The mechanisms of action of the chlorogenic acids, which are present in green coffee, include modulating glucose metabolism, lowering postprandial glucose, reducing glucose absorption through the intestines, and inhibiting fat accumulation. While caffeine may also promote weight loss, green coffee has a measured caffeine content similar to regular brewed coffee.[12] Studies suggest that chlorogenic acids, along with caffeine consumption, may impair glucose absorption rates.[13] According to the Natural Medicine Comprehensive Database, green coffee is considered "possibly safe" if used orally and appropriately.[12] Although little safety information exists regarding green coffee specifically, potential adverse drug events of green coffee include those related to high doses of caffeine, such as agitation, anxiety, arrhythmia, diuresis, headache, insomnia, and vomiting. Excessive caffeine exposure may also result in catecholamine release leading to acid/base, serum glucose, and serum potassium changes that could have serious cardiac implications.

Due to the wide availability of products containing green coffee and increasing popularity due to media exposure, it is expected that pharmacists and other health care professionals will encounter patient questions regarding these products. The objective of this review was to determine if clinical data support the use of green coffee for the purpose of weight loss.

## Data Sources, Selection, and Extraction

A literature search using PubMed (1966 to November 2012) and International Pharmaceutical Abstracts (1976 to November 2012) was conducted using the terms green coffee, chlorogenic acid, and weight loss. The search was limited to English language articles. References of results were reviewed for additional relevant articles. Clinical trials, meta-analyses, or case reports involving the use of green coffee in humans were included in the review. The search identified 5 clinical trials and 1 meta-analysis, all of which are reviewed in the following section. Studies were assessed for accordance with US Food and Drug Administration guidance for weight loss trials.

## Data Synthesis

In a prospective crossover trial, 16 subjects aged 22 to 46 were randomized to receive GCA, a commercial product containing green coffee extract, orally in a high dose of 350 mg 3 times daily, a low dose of 250 mg 2 times daily, and placebo 3 times daily.[14] Patients received each of these treatments for 6 weeks with a 2-week washout period in between treatments. The total duration of the trial was 22 weeks, and the subjects had a mean baseline body mass index of 28.22 $\pm$ 0.91. The objective of the trial was to assess the efficacy and safety of green coffee. The primary outcomes assessed were changes weight, body mass index, and percent body fat. Secondary outcomes were blood pressure and heart rate.

Few baseline characteristics were reported; mean weight and body mass index were 77 kg and 28 kg/m$^2$, respectively.[14] Following 22 weeks of treatment, the authors found a statistically significant difference in primary endpoints, favoring a beneficial effect of GCA in weight ($-8.04$g $\pm$ 2.31 kg), body mass index ($-2.92 \pm 0.85$ kg/m$^2$), and percent body fat ($-4.44 \pm 2\%$) compared to baseline (mean 76.69 kg $\pm$ 9.91, 28.22 $\pm 0.91$ kg/m$^2$, and 28.13% $\pm$ 4.95%). The authors concluded that GCA provides more weight loss than the US Food and Drug Administration–approved drugs on the market.

The primary limitation of this study was use of a crossover design. This study design is likely not optimal for measuring time-sensitive endpoints such as weight and body mass index. It is difficult to attribute weight loss to a specific dose or treatment, especially when the duration of each treatment arm was so brief. Evidence of this is shown in figures suggesting decreases in weight and body mass index were most dramatic during the first 6 weeks of treatment, regardless of treatment assignment. Additionally, the results in the

treatment group were statistically significant compared to baseline measurements, not a direct comparator, increasing risk for type I error. The milligram dose of caffeine in GCA was not identified, although it was stated that caffeine was included. Studies have shown that caffeine consumption can also decrease weight in patients and may also reduce the risk of developing metabolic syndrome. This makes it imperative to state the caffeine content so that weight loss can be attributed to the correct ingredient in GCA.[15,16] The study also had unclear blinding and lifestyle modifications. Finally, a specific primary endpoint and associated sample size calculations were not defined.

In a second prospective clinical trial, 62 volunteers were randomized to receive 4 weeks of Coffee Shape, a product with 81 mg of chlorogenic acid per serving, or Nescafe Expresso, a brewed coffee control.[17] Each group consumed 1 serving of assigned coffee per day. The objective of the study was to evaluate the effect that Coffee Shape has on weight. Outcome measures assessed were weight, waist, bust, and hip size. A primary outcome was not identified, and a sample size calculation was not conducted. Patients were advised to maintain their original diet and physical exercise; however, baseline information was not provided regarding this.

At baseline, patients in the treatment group had a mean starting weight of approximately 77 kg in both groups. After 4 weeks, patients in the treatment group had a mean reduction in weight by 1.35 $\pm$ 0.81 kg versus 0.12 $\pm$ 0.27 kg in placebo ($P < .05$). The average waist measurement decreased by 1.9 versus 0.01 inches, hips decreased by 1.3 versus 0.2 inches, and bust decreased by 1.25 versus 0.15 inches. Inferential statistics were only calculated for weight loss.

A notable limitation of this article is inconsistency of results presented. The raw data of reduction in weight and measurements for patients taking Coffee Shape differed in tables reporting the same endpoints, with no information identifying which numbers were used in statistical calculations. Additionally, the reported changes in bust, hip, and waist measurement are suspect considering patients only lost approximately 1.35 kg. No descriptive information regarding the measurement process was provided including blinding and consistency of those measuring the subjects. Coffee Shape is currently marketed in the United States but not recommended in patients with hypertension or diabetes; there were no criteria excluding these patients from the study. Finally, the clinical significance of an approximate 1 kg reduction in weight, relative to placebo, is minimal.

In a prospective clinical trial, 50 volunteers age 19 to 75 years were randomized in a 3:2 ratio to receive 60 days of treatment with Svetol, a capsular green coffee extract preparation, 200 mg orally twice daily or matching placebo.[19] Patients included in the study had a body mass index greater than 25 kg/m$^2$ and amenability to a "bland low caloric diet." Patients were excluded for history of gastrointestinal diseases, including cancer and infection, alcohol use, and use of medications for weight loss. The objectives of this study were to investigate whether Svetol could limit development of overweight and obesity, as well as related metabolic conditions. A primary endpoint was not identified.

Baseline characteristics of patients were not described, except for that they were similar in terms of weight and muscle mass to fat mass ratio.[18] Following 60 days of treatment, investigators report a reduction of 4.97 $\pm$ 0.32 kg in the treatment group compared to 2.45 $\pm$ 0.37 kg in the placebo group ($P < .001$). Body mass index was reduced by 1.9 $\pm$ 0.1 kg/m$^2$ in the treatment group and by 0.9 $\pm$ 0.1 kg/m$^2$ in the placebo group. It should be noted that all variability was presented as standard error of the mean. The authors found no difference in self-rating of physical appearance.

The primary limitation of this study is that authors did not describe whether investigators or participants were blinded to treatment assignment.[18] Additionally, the authors did not name a primary endpoint or perform a power calculation to determine sample size. Similarly, despite identifying study of development of overweight, obesity, and metabolic conditions as objectives of this study, the authors did not discuss any endpoints or results relating to these issues. The primary results discussed were changes in body weight, body mass index, and muscle mass to fat mass ratio. These results may be misleading as variability was described using standard error of the mean rather than standard deviation. Standard error of the mean produces small values that may cloud the true variability of study results. Very little information regarding baseline characteristics, such as weight, body mass index, presence of metabolic conditions, and so on, was provided. It is unclear whether the study results would apply to an overweight, obese, or morbidly obese population. Additionally, the authors did not address safety (eg, adverse event reporting) in their methods or results. Finally, the product was only assessed for 60 days, providing no information regarding long-term safety and efficacy. On a related note, the authors did not assess whether patients regained lost weight after discontinuing the product. The authors concluded that this product has a role in the management of obesity; however, the results do not address the limitations discussed.

In a prospective clinical trial, 30 volunteers were randomized in a 1:1 ratio to receive treatment with Coffee Slender, a coffee product with 200 mg green coffee extract per cup, or placebo as Nescafe Gold Norwegian blend coffee.[19] Each group consumed 5 cups of the assigned coffee per day for a total of 12 weeks. Patients included in the study were nonsmoking coffee drinkers with body mass index of 27.5 to 32 kg/m$^2$. The objective of this study was to evaluate the effect of green coffee extract on the overweight; a primary endpoint was not identified.

At baseline, patients in the treatment group had a mean starting weight of 85.2 $\pm$ 4.5 kg and body mass index of 29.2 $\pm$ 2.5 kg/m$^2$ compared to 84.3 $\pm$ 4.3 kg and 29.9 $\pm$ 2.4 kg/m$^2$ in the placebo group.[19] After 12 weeks, patients in the treatment group had a mean reduction in weight of 5.4 $\pm$ 0.6 kg ($P < .05$) and body mass index of 3.6 $\pm$ 0.3 kg/m$^2$ ($P < .05$) relative to baseline. Patients in the placebo group had a mean reduction in weight of 1.7 $\pm$ 0.9 kg and body mass index of 0.7 $\pm$ 0.4 kg/

$m^2$; neither of these results were statistically significant relative to baseline. No treatment-related adverse effects were reported.

As seen in the previous study, the primary limitation of this study is that authors did not describe whether study authors or participants were blinded to treatment assignment.[19] Additionally, the authors did not name a primary endpoint or perform a power calculation to determine sample size. Rather than directly comparing mean weight and body mass index between groups following 12 weeks of treatment, the authors compared the resulting mean values with baseline data for each group individually, increasing the risk for Type I error. Additionally, the authors indicated use of a Student *t* test (for parametric data) or Mann–Whitney test (for nonparametric data); tests designed to compare paired data would have been more appropriate. It should also be noted that the study only assessed overweight patients. These results would not apply to the obese or morbidly obese populations. Similar to the previous study, the authors only assessed use of green coffee for a 12-week period, leaving long-term safety and efficacy, as well as ability to maintain weight loss following discontinuation, as unanswered questions.

A meta-analysis evaluated 3 trials previously reviewed in this article (Coffee Shape, Svetol, and Coffee Slender).[10] The objective of this meta-analysis was to assess the efficacy of green coffee with regard to weight loss. There were significant differences between the 3 trials with regard to heterogeneity, with an $I^2$ statistic of 97%. Variable endpoints were conducted in individual trials, and therefore, the only data reported in this meta-analysis was weight loss. The analysis found a statistically significant difference with regard to body weight with a mean difference of −2.47 kg between green coffee and placebo (95% confidence interval = −4.23 to −0.72). The authors concluded that the clinical relevance is unknown and a more rigorous trial assessing the true efficacy of green coffee with regard to weight loss should be conducted.

A primary limitation of the meta-analysis is the variability of the included trials. Duration ranged from 4 to 12 weeks, and the daily dose of chlorogenic acid varied from 81 mg to 400 mg.[10] The variations in duration can significantly skew the data of this meta-analysis as weight may be considered time sensitive, with more cumulative weight loss over a greater amount of time. Thus, comparing the mean weight loss over differing durations yields a result that cannot be accurately interpreted. The meta-analysis included only trials that were double-blind and placebo controlled. However, 2 of the articles (Coffee Shape and Coffee Slender) used a potentially active comparator rather than a placebo, considering the possibility that caffeine can aid in weight loss. Additionally, the clinical trials stated that they were double-blinded, but on review, there was no description on whether investigators or participants were truly blinded. As stated in the GCA and Coffee Shape trials, data were inconsistent. Therefore, it should be noted that the accuracy of the meta-analysis data is uncertain as well.

Finally, the most publicized study of green coffee was conducted by *The Dr. Oz Show* where 100 women, aged 35 to 49 with body mass index of 25 to 45 $kg/m^2$ were either given 400 mg capsules of green coffee bean extract or placebo 3 times a day.[8] Participants were told to keep a journal of their food consumption and to not change their diet while on the study. Exclusion criteria included pregnancy, history of heart attack or stroke, and diabetes. The reported results were a mean loss of 2 pounds in the green coffee group, with an average loss of 1 pound in placebo over a 2-week time period. No other information regarding the trial is available. Beneficial information that was not provided includes whether or not there was randomization, blinding, or similar baseline characteristics, especially with regard to mean baseline weight of each group. It should also be noted that the dose used was higher than previous trials. The show concluded that green coffee could be beneficial for those 18 years or older, who are also healthy and wanting to lose weight. However, given the inclusion and exclusion criteria stated above, the recommendations from *The Dr. Oz Show* do not reflect the true external validity of the study.

## Conclusion

Current literature regarding green coffee for the use of weight loss is limited to 4 small clinical trials. All studies found statistically significant reductions in weight compared to baseline or a direct comparator. However, in most studies, the clinical significance of this reduction was minimal. All these trials have significant limitations. Key limitations, overall, included lack of blinding, direct comparisons, and safety assessment. Additionally, the studies did not assess comprehensive endpoints, had very low sample size, and did not include lifestyle modifications. Finally, none of the studies assessed whether weight was regained on discontinuation. As seen in Table 2, when compared to the standards that the US Food and Drug Administration has set for trials looking at weight loss medications in order to properly assess safety and efficacy, the studies reviewed are below the benchmark of a properly designed trial. While adherence to US Food and Drug Administration guidelines is only one measure of study design appropriateness and other tools are available, it is a good baseline standard for weight loss studies. The clear deficiencies in the available literature make this a particularly relevant benchmark.

Well-designed trials demonstrating the efficacy and safety of green coffee for the use of weight loss are needed before it can be recommended for routine use. These trials should be powered to evaluate the efficacy of green coffee for weight loss in comparison to placebo or US Food and Drug Administration–approved medications, depending on the population studied, and should be double-blinded. Additionally, confounding factors such as diet and exercise should be described and equally conducted in treatment arms. Following published guidelines, lifestyle modifications should be initiated first in a patient interested in weight loss followed by pharmacotherapy that is US Food and Drug Administration approved. Green coffee extract is not recommended as a safe or effective treatment for weight loss.

**Table 2.** Comparison of US Food and Drug Administration Recommendations for Weight Loss Medications Versus Available Studies.

| | Study Design | Duration | Primary Endpoint | Secondary Endpoints |
|---|---|---|---|---|
| FDA Recommendations[6] | Randomized, double-blind, placebo-controlled; >3000 receive active medication, >1500 receive placebo | 1 year | Amount of weight loss; proportion of patients losing 5% of baseline weight versus placebo | Metabolic parameters |
| Vinson et al[14] | Randomized, double-blind, placebo-controlled, crossover; 16 patients | 22 weeks | Weight, body mass index, percent body fat | Changes in blood pressure and heart rate |
| Ayton Global Research[17] | Randomized, double-blind; 62 volunteers | 4 weeks | Weight | Waist, bust, and hip size |
| Dellalibera et al[18] | Randomized, placebo-controlled; 50 volunteers | 60 days | Not identified | Not identified |
| Thom et al[19] | Randomized; 30 volunteers | 12 weeks | Not identified | Not identified |
| *The Dr. Oz Show*[8] | 100 female volunteers | Not identified | Weight | Not identified |

## Author Contributions

RDB generated the idea for this review. RDB and RB jointly designed and conducted the literature search, evaluated the studies, and analyzed the results.

## Declaration of Conflicting Interests

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

## Funding

The authors received no financial support for the research, authorship, and/or publication of this article.

## Ethical Approval

This study is exempt from oversight by human subjects research protection as there were no human subjects involved.

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