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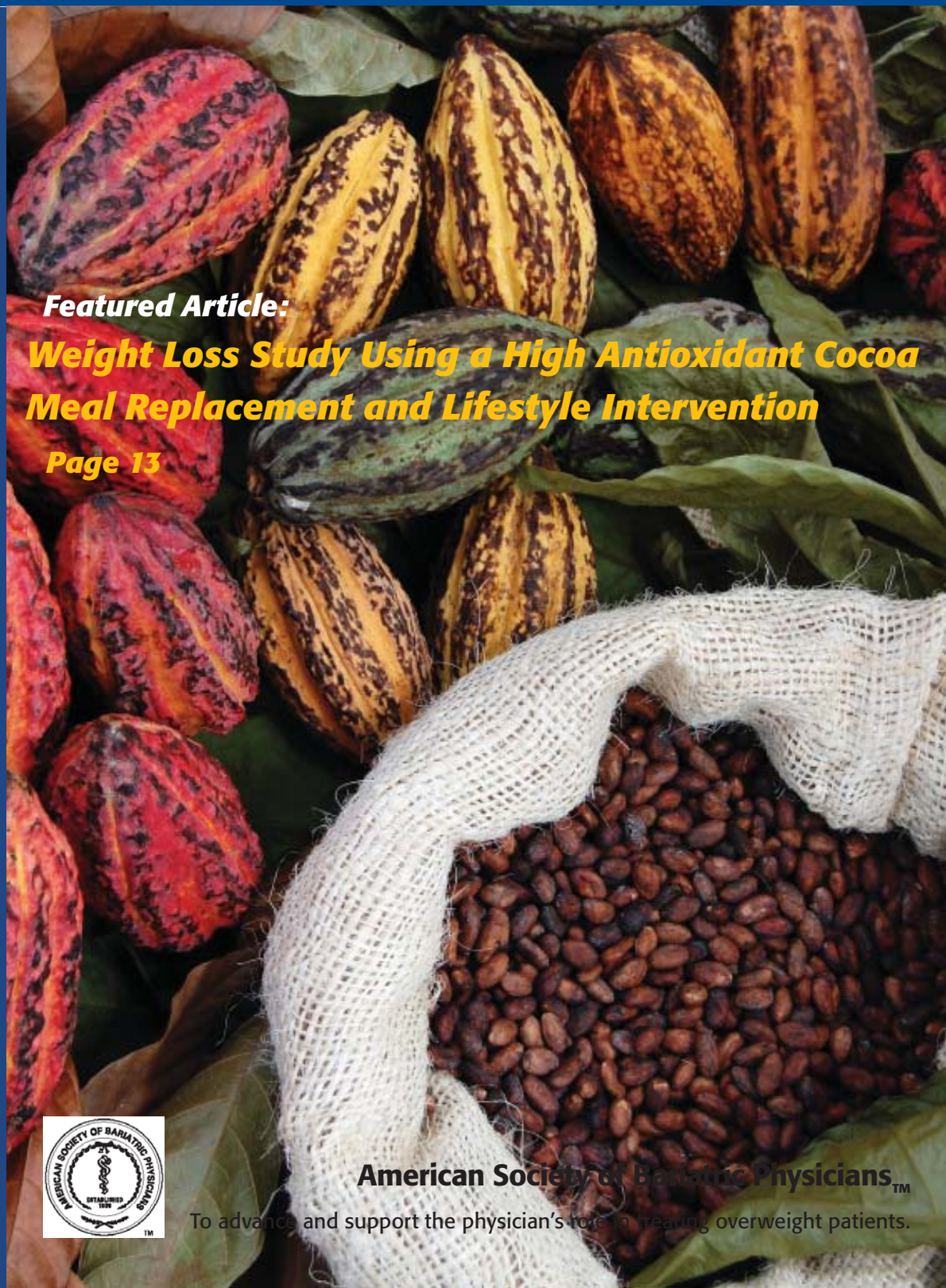
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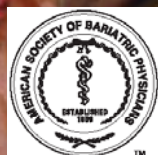
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Weight Loss Study Using a High Antioxidant Cocoa Meal Replacement and Lifestyle Intervention

By Machiel N. Kennedy, MD and Steven E. Warren, MD, DPA, CIME, FABFP, FABHPM, FAPWCA

ABSTRACT

Context: Data supporting weight loss using a high antioxidant meal replacement and lifestyle intervention are sparse.

Objective: To evaluate the effectiveness of a high antioxidant meal replacement made from raw unprocessed cocoa and lifestyle intervention over a 12 week supervised weight loss program.

Design, Setting and Participants: This was a lifestyle intervention trial. A high antioxidant meal replacement was designed using raw unprocessed cocoa with 8 grams of fiber, 21 grams of whey isolate protein, 3 grams of fat from chia oil, and 0.5 grams of sugar. The calories per meal replacement were 190 kcal, but the net calories were about 150 kcal. The participants ranged in age from 26 to 73 years. They were required to participate in a weekly support call with one of the physicians and consume two meal replacements a day and, for the third meal, eat a sensible high protein low carbohydrate meal of their choice totaling 1,200 kcal per day for women and 1,500 kcal per day for men. All of the 50 participants who started completed the study. Each was encouraged to exercise by at least walking. All participants had their meal replacements furnished and monetary rewards were given to the winners of the group. The fifty participants were divided into groups of five and the members of each group monitored each other in addition to the monitoring from the physicians and other staff on a weekly phone call.

Main Outcome Measures: Changes in weight, Body Mass Index (BMI), and waist circumference were evaluated.

Results: Over a 12 week period the average weight loss was 31.3 pounds with an average reduction in waist circumference of 5.8 inches. The percentage weight loss ranged from 6.6% to 24.6% of starting weight. There were no drop outs during the lifestyle intervention study.

Conclusion: Successful weight loss was achieved by

using a high antioxidant meal replacement made from raw unprocessed cocoa along with a monitored program requiring accountability and lifestyle intervention changes. In addition, furnishing product and rewarding participants for their behavior was successful in creating statistically significant weight loss in a group of overweight or obese subjects.

INTRODUCTION

The prevalence of obesity has risen markedly since 1976, now exceeding 30% among US adults. Obesity has well-known associations with morbidity and disability, resulting in unhealthy life-years and increased health care costs. Currently in the US 68% of the population is either overweight or obese.¹

The latest figures from the Centers for Disease Control (CDC) demonstrate that obesity continues to be a significant public health problem in the US. Note the list of health problems associated with weight.

- Coronary heart disease
- Type 2 diabetes
- Cancers (endometrial, breast and colon)
- Hypertension (high blood pressure)
- Dyslipidemia (high total cholesterol or high levels of triglycerides)
- Stroke
- Liver and gallbladder disease
- Sleep apnea and respiratory problems
- Osteoarthritis
- Gynecological problems (abnormal menses, infertility, poly-cystic ovaries)

A very interesting quote from a 2010 article from MD Anderson Cancer Center talking about inflammation and cancer is:²

"This indicates that lifestyle plays a major role in the development of cancer. The important lifestyle factors that affect the incidence and mortality of cancer include to-

bacco, alcohol, diet, obesity, infectious agents, environmental pollutants, and radiation. All of these risk factors are linked to each other through inflammation."

Since it is felt that obesity is related to oxidative stress and inflammation, a weight control trial using a high antioxidant meal replacement might be beneficial.

METHODS

Fifty people were chosen from over 250 applicants. Their age range was from 26 years to 73 years old. People on insulin therapy were excluded and those with a major medical condition the physicians felt were inappropriate for the study were eliminated, also.

The participants were either overweight or obese measured by BMI criteria set by the World Health Organization with >25 defining overweight and >30 defining obesity.³

Exclusionary criteria were insulin dependent diabetes or any medical issue requiring medication that the physicians overseeing the study felt would not be appropriate. The participants were to consume a high anti-oxidant meal replacement shake made from raw unprocessed cocoa by MXI Corporation. The shake had an ORACfn score of 56,500 with 1,128 mg of flavonoids (certified by Brunswick Laboratories). One serving protected over five primary radicals, which was four times the USDA fruits/vegetables average.⁶

The shake was 190 kcal with 21 grams of whey isolate protein, 8 grams of fiber, 3 grams of fat from chia, and 0.5 grams of sugar. Each participant consumed two shakes a day for 12 weeks. In addition the participants consumed a 600 kcal meal. The total calories for women were 1,200 kcal per day and for the men was 1,500 kcal per day. Snacks consisted of chocolate squares or nuggets. If needed, participants could have a 200 kcal high protein snack.⁴

The participants were encouraged to exercise by walking. They were to work their way up to 10,000 steps per day, and they could participate in more vigorous exercise if they desired and it was approved by their primary care physician.

Each participant was encouraged to get at least 7.5 hours of sleep per night.

Each participant was encouraged to drink 1 ounce of water per pound body weight.

The 50 participants were divided into support groups of five people and these groups participated in a physician call for 30 minutes once a week for the 12 weeks.

In addition, each participant completed a food and exercise journal and returned them by fax once a week.

Included in the journal were their calorie consumption, amount of water consumed, a hunger chart, exercise completed, and amount of shakes taken.⁵

The meal replacement shakes and a financial reward were given to the top "losers" of the group.

RESULTS

The average weight loss per participant was 31.3 pounds. In addition, there was an average decrease in waist circumference of 5.8 inches. None of the participants experienced any ill health from the program. The most common complaint was gastrointestinal upset and/or diarrhea.

COMMENTS

The combination of a high ORACfn meal replacement made from raw unprocessed cocoa along with a lifestyle intervention program and financial rewards seems to be a highly effective way of achieving weight loss and weight control in overweight or obese individuals. Since both financial compensation and the lifestyle intervention were provided to all participants, the individual effects on weight loss of receiving monetary compensations vs. the meal replacements cannot be determined.

While measurements of inflammatory markers associated with obesity and other diseases were not measured, it is hypothesized that they would have improved during the course of the study.

Previous testing using cell-based "efficacy" assays that were modified for testing natural products, had shown that one serving of the meal replacement produced positive changes in inflammatory markers.⁶ These tests use live cells to see whether or not products actually work to protect human cells. For the recent testing, anti-inflammation and anti-aging tests which use highly respected NF-kB and SIRT1 markers as performance standards were selected, since both are believed to be involved in weight loss, glucose management, and a host of other wellness factors.^{2, 7, 8} Both tests demonstrated positive results. A single serving of the meal replacement stimulates SIRT1 by approximately 15% and inhibits NF-kB by 34%. Furthermore, there are likely to be cumulative benefits that may result with regular daily consumption of the meal replacement.

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About the Authors

Machiel Kennedy, MD graduated from Indiana University Medical School and is board certified in Family Medicine and Bariatric Medicine. He has over 30 years experience in clinical practice and weight loss management. He has authored four books. The latest book was co-authored with Dr. Steve Warren and is titled *Radically Free, The Anti-inflammatory and Antioxidant Approach to Weight Management*. Dr. Kennedy was as consultant to MXI Corp for this study.

Steven Warren, MD, DPA is a geriatric physician who is board certified in family medicine, hospice and palliative medicine, and wound care. He is actively practicing in several long term care facilities. He has been doing research and lecturing on the health benefits of dark chocolate for the past six years. He owns a weight loss clinic and is motivated to help people lose weight in order to help them avoid chronic health illnesses.

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