

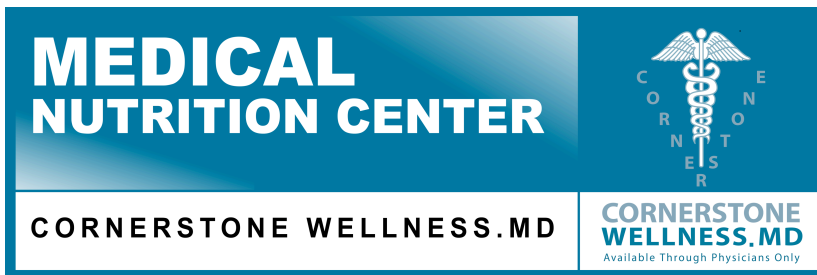
MEDICAL NUTRITION CENTER



CORNERSTONE WELLNESS.MD

CORNERSTONE
WELLNESS.MD
Available Through Physicians Only

- ❖ **The only all-natural physician program that addresses the underlying cause of metabolic syndrome through nutritional support**
- ❖ **The only fat loss program that uses bioimpedance based body composition and metabolic analysis to insure fat loss and maintenance of muscle mass to prevent drop in basal metabolic rate**
- ❖ **The only fat loss program completely run by office staff**
- ❖ **The only fat loss program in which diagnostics are covered by health insurance**
- ❖ **The only fat loss program that uses patented algorithmic software to produce a customized diet, exercise and supplement plan for each patient based on body composition and metabolic analysis**
- ❖ **The only fat loss program that trains physicians' office staff in the physicians' office on existing patients**



Cornerstone Meal Replacement

- + Only all natural, physician only meal replacement available anywhere**
- + Only whey/pea formula providing best amino acid profile**
- + Highest protein content per serving available, preventing muscle loss with calorie restriction**
- + Highest protein to carbohydrate ratio of any physician only meal replacement**
- + Highest levels of vitamin and minerals of any meal replacement**
- + Only meal replacement that contains most recent recommendations of vitamin D3 of 800IU daily**
- + Contains no soy which is high in phytoestrogens that can sabotage weight loss efforts and has been linked to tumors in estrogen sensitive tissues in lab animals and thyroid dysfunction in humans**
- + Vitamins and minerals are presented in most bioavailable forms**
- + Least expensive of any physician only meal replacement on a per protein gram basis**
- + Only meal replacement containing medium chain triglycerides for satiety and energy**
- + Contains no soy, wheat, gluten, egg or yeast**



MetAssist

- + Contains hydroxycitric acid from Garcinia Cambogia that decreases hepatic liponeogenesis, decreases glucose absorption from ileum and increases serotonin levels 44%**
- + Contains most bioavailable and potent form of chromium, chromium polynicotinate (glucose tolerance factor) which increases insulin receptor quantity and affinity and therefore reduces serum glucose and HBA1C**
- + Contains Gymnema Sylvestrie, which according to the NIH shows “good scientific evidence” for controlling serum glucose levels in diabetics. This alkaloid also blocks sensation of sweetness helping to curb cravings for sweets. It has also been shown to lower triglycerides and LDL**
- + Contains green tea which is thermogenic and has antioxidant qualities**

OmegaHealth

- + Molecularly distilled which is highest purification technique available with no measureable levels of mercury or other heavy metals, PCBs or dioxins**
- + A full 600 mg of EPA and DHA in a natural occurring 2:1 ratio per capsule**
- + Enteric coated to citrus flavored to prevent aftertaste and burping**
- + Omega 3 oils have unquestionable proven efficacy in prevention of coronary artery disease as well as treatment efficacy in numerous neuropsychiatric conditions and inflammatory and auto-immune disorders**

The Cornerstone Nutrition Program

Introduction:

The major reason why 95% of low calorie diets don't result in long term fat loss is that with significant calorie restriction muscle tissue is lost along with fat. Because the metabolic rate at which one burns calories at rest is primarily dependent on the existing amount of muscle, any loss of muscle on a low calorie diet would therefore sabotage any fat loss efforts.

The best way to combat this fat loss sabotage is to consume more protein during dieting which will largely prevent muscle from being depleted. Protein has a much higher appetite blocking effect compared with fat or carbohydrates. The best way to take in large amounts of protein without significantly increasing intake of fat or carbohydrate is with the use of high protein meal replacement milk shakes. Every single scientific study has shown that diets based on the use of two high protein meal replacement shakes results in greater long term weight loss, less hunger, better compliance and greater health benefits than low calorie diets with food alone.

In addition to a high protein meal replacement program, there are certain nutritional supplements which can aid in fat loss efforts and ensure maintenance of good energy levels and overall healthfulness. Appetite suppressing pharmaceutical drugs result in minimal and often temporary weight loss and have many side effects.

The core group of nutritional supplements that comprise the Cornerstone Wellness Program are all backed by numerous scientific and medical studies. They are safe and effective and will allow you to meet your fat loss needs as well as your overall health and wellness goals.

Cornerstone High Protein Meal Replacement

Every single published medical study that has examined meal replacements as a tool for fat loss has demonstrated superiority over usual diets with regards to fat loss, improvement in physiologic parameters such as blood lipids, hyperglycemia, elevated blood pressure and other sequelae of overweight and metabolic syndrome, ease of use, satiety and patient satisfaction (1,2,3,4,5,6,7). This fact is undisputable, even in studies going out four and even ten years. The rapid early weight loss and improved energy levels provides significant reinforcement for patients many of who have failed any of the dozens of diets available. Also undisputed is that supplementation with low calorie, high protein meal replacements prevent loss of lean body mass, which often occurs with low calorie diets, thereby maintaining lean body mass which is the main determinant of basal metabolic rate insuring against cycling or yo-yoing once the diet is discontinued(8). Typically the patient wholly or partially replaces two meal per day during the induction phase and continues with one meal during maintenance and then can go back to two shakes for a short period if and when weight gradually increases.

The Cornerstone meal replacement is a physician dispensed, high potency formula developed by nationally recognized physicians and nutritionists which exceeds every other available product with regards to protein content, vitamin and mineral levels, medium chain triglyceride content and is all natural with no artificial ingredients. The protein source is 70% whey and 30% immature green pea (yellow pea) the highest quality vegetable protein source available. By combining an animal protein source with vegetable source the amino acid profile is improved considerably. Twenty three grams of protein (31 grams when combined with milk) insures that the patient receives enough protein to prevent lean muscle loss while reducing calories.

Two shakes a day ensures a full 800 IU of Vitamin D3 per shake, which exceeds the most recent DRI for this key Vitamin (serum levels of which have been shown to be inversely proportional to BMI), as well as 400% of the RD of most vitamins (100% for fat soluble) as well as a full complement of minerals and trace minerals including 60% of the RD for magnesium. Medium chain triglycerides are added to improve energy and satiety. Betaine, known to decrease homocysteine levels is included, as are citrus bioflavonoids which support vascular health. Fiber and a probiotic blend aid in digestion and dysbiosis. At only 150 calories, 23 grams of protein and less than 8 grams of carbs, Cornerstone has the highest protein to carb ratio in the industry. With 2 grams of healthy MCTs the shake approximates the 30-40-30 ratio recommended by the Zone diet. The cost per meal is on the low side but cost per gram of protein, the most precise value parameter, is by far the lowest (see accompanying chart) of all the physician prescribed meal replacements. Naturally flavored with vanilla bean or Dutch chocolate, the powder when mixed with cows, goats, rice or almond milk provides a delicious and refreshing low calorie, high protein, extremely nutritious whole meal.

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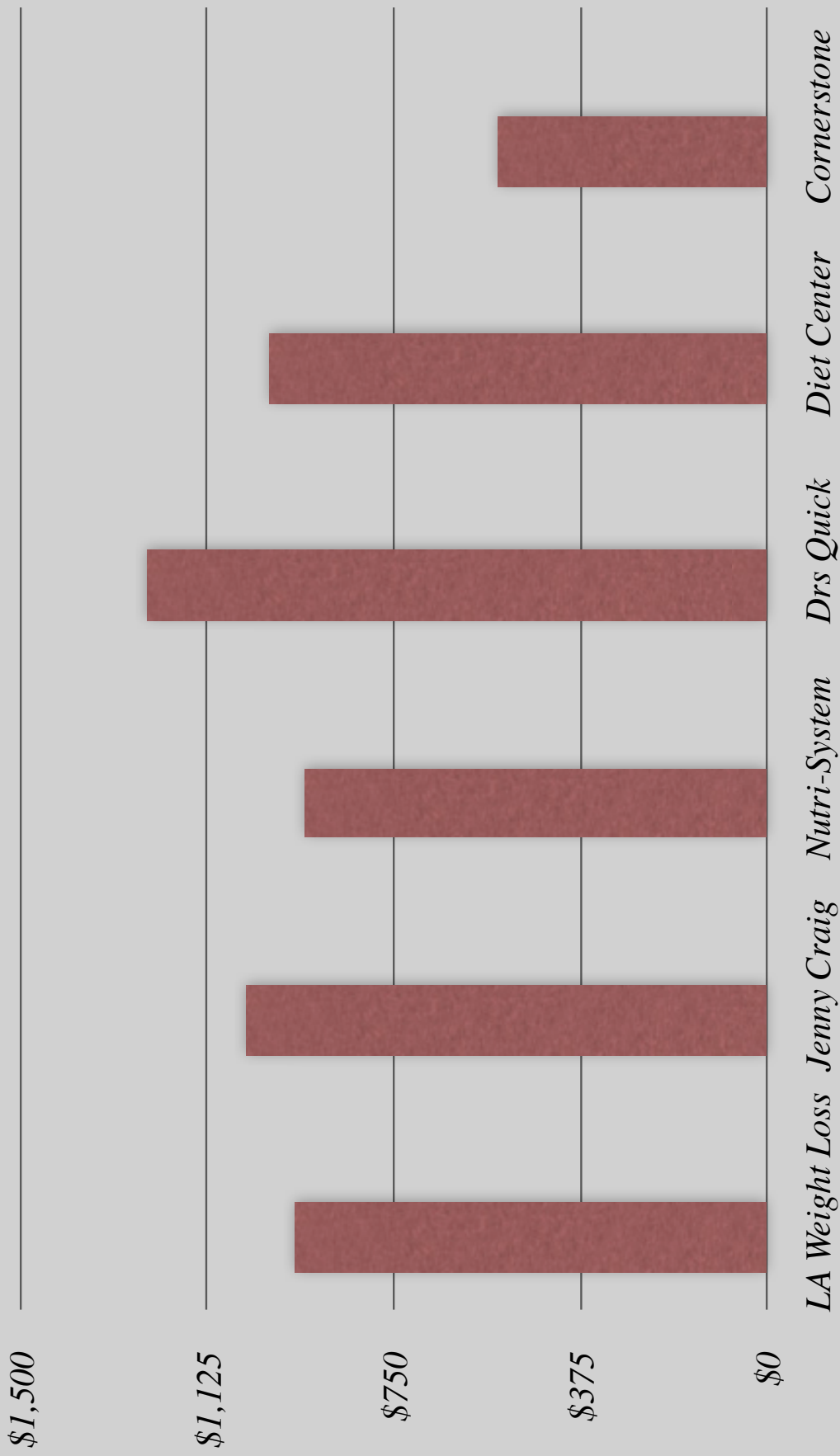
Meal Replacement Comparison

superior

inferior

Meal Replacement	protein source	cal	protein gram	carb gram	prot carb	artificial ingred	% RDA Vitamins	Vit D3 IU	Trace Minerals	MCT	cost gram prot	cost meal	physician only
Cornerstone	whey pea	150	23 (31)	7.8	3	no	50-400%	800	yes	yes	0.10	\$2.20	yes
Optifast	casein	160	14	20	0.7	yes (soybean oil)	20-30%	50	no	no	0.21	\$3.00	yes
Medifast	soy milk solids	90	11	13	0.9	yes (HFCS)	20-35%	60	no	no	0.19	\$2.07	no
Metagenics UltraMeal Plus 360	soy	160	15	24	0.6	no	50-400%	40	no	no	0.22	\$3.36	no
HMR 500	milk solids egg	120	10	16	0.6	yes (sacharin)	30-35%	40	no	no	0.22	\$2.43	no
Nutrimed (Robard)	casein soy	100	15	8	2.1	yes (trans fat)	20-30%	40	no	no	0.16	\$2.40	yes
Herbalife	soy whey	90	9	13	0.7	yes	25%	40	no	yes	0.13	\$1.20	no
Slimfast	milk solids	110	10	18	0.6	yes	25-35%	90	no	no	0.17	\$1.65	no

What 20 lbs Will Cost You



MetAssist

Most patients on a physician directed weight/fat loss program have one or more measurable metabolic abnormalities including but not limited to elevated serum glucose, triglycerides, cholesterol, LDL, leptin and decreased HDL. The main active ingredients in MetAssist namely hydroxycitric acid, chromium polynicotinate, and green tea have been shown alone and in combination to improve the above physiologic parameters in humans and laboratory animals in addition to synergistically increasing fat loss.

Hydroxycitric acid is isolated from the Southeast Asian fruit *garcinia cambogia*. The mode of action appears to be the competitive inhibition of the enzyme ATP-citrate lyase, which catalyzes the conversion of citrate and coenzyme A to oxaloacetate and acetyl-CoA, primary building blocks of fatty acid and cholesterol synthesis (1). One 8 week study on 60 obese patients demonstrated a 5% reduction in weight on HCA, as well as a statistically significant reduction in food intake, total cholesterol, LDL, triglycerides, leptin and an increase in HDL and urinary fat metabolites (2). Other studies have shown increase in serum free fatty acid concentrations and a decrease in respiratory quotient suggesting increased fat oxidation and a decrease in de novo liponeogenesis (3,6). Another study showed a 38% reduction in serum leptin a 45% increase in serotonin, a decrease in LDL and triglycerides of 14% and 7% respectively and a 5% reduction in BMI (4). Further studies demonstrated decreased intestinal uptake of glucose by the intestinal mucosa with HCA ingestion (5).

Chromium polynicotinate has been studied extensively as well. Its mechanism of action involves increased insulin binding, increased insulin receptor number and increased insulin receptor phosphorylation (6). It improves serum glucose, insulin, cholesterol, and hemoglobin A1C in a dose dependent manner (7). A study in patients on sulfonylureas showed improvements in insulin sensitivity and glucose control and significantly attenuated weight gain and visceral fat accumulation on chromium as compared to placebo (8).

Green tea in addition to containing powerful antioxidant polyphenols called catechins, has significant fat loss properties as well (9). Green tea has been showed in multiple studies to be thermogenic and to specifically promote fat oxidation and this property is independent of its caffeine content (10).

Gymnema Sylvestrie, according to the NIH, shows “good scientific evidence” for controlling blood sugar levels in patients with diabetes. Gymnema also blocks the sensation of sweetness from sugary foods helping curb craving of sweets. It has also been shown to lower triglycerides and LDL.

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OmegaHealth

OmegaHealth is an enteric coated, ultra refined omega3 supplement which provides a full 600 mg of EPA and DHA in a 2:1 ratio per capsule. It is molecularly distilled which is the most advanced purification method available to remove all toxins including mercury, dioxin and PCBs to within measurable limits. The enteric coating prevents the typical fishy aftertaste and eructation which is the main reason why patients discontinue this life saving supplement. Omega 3 supplementation has been found extremely useful in the prevention and treatment of heart disease, hypertriglyceridemia, inflammatory syndromes such as RA, Crohns disease, and neurological conditions such as depression, ADD/ADHD as well as others. The following is an excellent review from the 2005 Journal of the American Board of Family Practice (*The Journal of the American Board of Family Practice* 18:28-36 (2005) entitled Practical Applications of Fish Oil (Omega 3 Fatty Acids) in Primary Care Practice.

There are 2 classes of essential fatty acids, the Omega-6 and Omega -3 fatty acids (FA). -3 FA, found primarily in fatty fish with high oil content, consists of both eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). Research has shown increasing evidence for anti-inflammatory, antithrombotic, antiarrhythmic and antiatherogenic effects of fish oil.[1,2,3,4,5](#) Fish oil is the most significant source of dietary -3 FA. The terms will be used interchangeably.

Arachidonic acid, an -6 FA, is converted into inflammatory prostaglandins and leukotrienes via the enzymes cyclooxygenase and lipoxygenase, respectively. Increased intake of -3 FA reduces incorporation of arachidonic acid into cell membranes, thereby promoting a net anti-inflammatory response. Indeed, fish oil has been shown to significantly decrease potent inflammatory markers, including leukotrienes, prostaglandins, interleukins, and tumor necrosis factor.[6,7](#) The inhibition of arachidonic acid by -3 FA also produces a potential antithrombotic effect by decreasing production of thromboxane A2. Membrane stabilization in cardiac tissue by -3 FA confers potential antiarrhythmic effects,[8](#) whereas triglyceride-lowering effects are caused by the reduction and secretion of very low density lipoprotein particles from the liver.[5](#) With its unique and varied mechanism of actions, the potential uses of fish oil have been studied in various clinical situations.

Cardiovascular Disease

The benefits of fish oil in cardiovascular disease provide the strongest and most compelling evidence favoring its use in practice. Numerous observational studies have shown that -3 FA enriched diets are associated with reduction of cardiovascular mortality, myocardial infarction, and sudden death. Higher fish intake was associated with decreased incidence of coronary artery disease and cardiovascular mortality in several prospective cohort studies.[9-11](#) Another large prospective cohort study reported a marked reduction in sudden cardiac death associated with dietary fish intake.[12,13](#) Putting it in perspective, a minimum of one fish meal a week was associated with a 52% reduction in sudden cardiac death. Some observational trials do not show a beneficial relationship for fish intake. This may be related to differences in background cardiovascular risk, fish intake, or lifestyle behaviors of study populations and study definitions of sudden death and fish intake.[14](#) Although the intake of fish oil in these studies was not sufficient to produce a marked anti-inflammatory or triglyceride-lowering effect, both antiarrhythmic properties and membrane stabilization of cardiac tissue by fish oils has been proposed as its mechanism of action.[8](#)

Randomized clinical trials add to the growing evidence—especially for secondary prevention of cardiovascular disease. A randomized placebo-controlled trial showed that supplementing patients with recent history of a myocardial infarction (MI) with 1.8 g of fish oil for 1 year decreased total cardiac events by 29% [number needed to treat (NNT) = 10 for 1 year; $P < .05$]. Both total cardiac deaths and nonfatal MI were also reduced by 48% (NNT = 8.1 for 1 year; $P < .01$ and NNT = 9.8 for 1 year; $P < .01$; respectively)¹⁵ [level of evidence-1 (LOE)]. The Diet and Reinfarction Trial (DART),¹⁶ randomized 2033 men with myocardial infarction into different dietary groups. Men randomized to fatty fish diet had a 29% reduction in the 2-year all-cause mortality compared with those who did not receive this advice (NNT = 28 for 2 years; $P < .05$). Most of the benefits resulted from the reduction of cardiovascular deaths (NNT = 27 for 2 years; $P < .01$) (LOE-1). The GISSI¹⁷ trial randomized 11,324 Italian men who had suffered a myocardial infarction within 3 months. Compared with the control group, patients supplemented with fish oil 850 mg showed a 15% reduction in the primary endpoints (death, nonfatal myocardial infarction and stroke) after 3.5 years (NNT = 48 for 3.5 years; $P = .008$) (LOE-1). It is striking that most of the benefit was derived from a 30% reduction in cardiac mortality and a 45% reduction in sudden death. Mortality reduction was significant in just 3 months of fish oil therapy—even in light of optimal pharmacologic therapy with antiplatelet agents, angiotensin inhibitors, and lipid lowering therapy.¹⁸ Finally, a meta-analysis¹⁹ and a recent systematic review²⁰ launched by the Agency for Health Care Research and Quality (AHRQ), found favorable effects of fish oil on cardiovascular and overall mortality. With this mounting evidence, the American Heart Association,¹⁴ recommends 1 g of fish oils in all patients with documented coronary artery disease via diet or through supplementation after consultation with their physician [strength of recommendation (SOR)-A]

Hypertriglyceridemia

High triglycerides have been recognized as an independent risk factor for coronary artery disease. The Third Report of the Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (ATP III),²¹ recommends treating hypertriglyceridemia more aggressively. However, medications to treat hypertriglyceridemia (such as fibric acid derivatives and niacin) are limited and can have serious side effects. Even with medications, hypertriglyceridemia can be difficult to treat without using a combination of drugs.

A review of over 70 clinical trials²² and a recent systematic review by the AHRQ²³ have demonstrated the consistent and potent triglyceride lowering effects of fish oil supplementation. In an early trial, mean triglycerides were reduced 79% (from 1432 to 282 mg/dL) using 20 g of fish oil. ($P < .01$).²⁴ More recently, in patients with severe hypertriglyceridemia (mean = 919 mg/dL), 3.4 g of fish oil showed a triglyceride reduction 45% compared with controls ($P < .0001$).²⁵

Although studies are limited, combination therapy with a statin seems to be safe and the results additive. Adding 3 g of fish oil to 40 mg of pravastatin reduced triglycerides an additional 33%.²⁶ Another study, combining 3.4 g of fish oil daily in patients with persistent hypertriglyceridemia on 10 to 40 mg simvastatin, showed additional reduction in triglycerides by 20% to 30%, without serious adverse effects.²⁷ Another trial, however, using 10 mg of atorvastatin and 1.7 g of fish oil, did not show significant difference from baseline. This trial may have been limited by their lower dosage of fish oil and the higher background fish consumption by the patients.²⁸

Overall, there is a dose-dependent lowering of triglycerides with higher fish oil supplementation. Although on average, low density lipoprotein (LDL) cholesterol rose 10 mg/dL and high-density lipoprotein 3 mg/dL, these were nonsignificant.²³ There were no significant changes in total cholesterol. Use of 2 to 4 g of fish oil, which lowers triglycerides by 20% to 50%, may be recommended for patients with mild or persistent hypertriglyceridemia to reach ATP III goals (SOR-A) ^{14,21}

Rheumatoid Arthritis □ In patients with rheumatoid arthritis (RA), over 15 clinical trials and 2 meta-analyses favor the use of fish oil.^{29,30} Fish oil supplementation consistently shows modest clinical

improvement and reduction of nonsteroidal anti-inflammatory drug (NSAID) use in randomized clinical trials. One trial compared approximately 2.8 g of fish oil versus placebo in 64 patients with stable RA. In 3 months, the fish oil group showed significant reduction of NSAID use compared with placebo. This effect peaked at 12 months and was not associated with any clinical deterioration (LOE-2).[31](#) A double-blind placebo-controlled trial showed that fish oil supplementation of 130 mg/kg/day decreased the number of tender joints, duration of morning stiffness, pain, and global arthritis activity versus placebo (LOE-2).[32](#)

Reduction of tumor necrosis factor, interleukin levels, and other anti-inflammatory mediators has been hypothesized as the main effect of -3 FA in RA. However, others recognize the importance and synergistic effects of a higher intake of -3 FA in conjunction with lower dietary intake of -6 FA. A double-blind placebo controlled trial using lower doses of fish oil (40 mg/kg; average, 2.3 g) in a background of low dietary -6 showed clinical improvement compared with placebo over 15 weeks ($P < .02$) (LOE-2).[33](#) Clinical improvements were similar to studies using higher doses. Another recent randomized controlled trial showed clinical benefits, reduction of NSAID, and corticosteroid use with low-dose fish oil supplementation (30 mg/kg; average, 2 g) in patients with diets low in -6 FA.[34](#) Effects were significant at 3 months and peaked at 6 to 8 months (LOE-1)

For the family physician, although fish oil supplementation may benefit clinical symptoms of RA, its potential to reduce or even eliminate NSAID use[35](#) may be the most useful in clinical practice. NSAIDs, although highly effective for pain control, has serious side effects that often limits its use. Overall, doses of 2.6 to 6 g (or weight-based) of fish oil given for a minimum of 8 to 12 weeks is optimal (SOR-A) [32,36](#)

Mothers and Infants

Omega-3 FA use in pregnancy has shown promise in prolonging gestation and the prevention of preterm labor.[37](#) A randomized double-blind controlled trial showed that supplementation with eggs enriched with 133 mg of DHA prolonged gestation by 6 days compared with women given regular eggs ($P < .01$).[38](#) Looking at women at high risk for preterm delivery, a multicenter study supported the use of fish oil in prolonging gestation.[39](#) Women supplemented with 2.7 g of fish oil showed significantly reduced preterm delivery rates, increased mean birth weight by 209 g, and increased duration of pregnancy by 8.5 days compared with the control group (LOE-1). Fish oil's inhibition of arachidonic acid and its subsequent reduction of prostaglandins have been thought to be a potential mechanism of action.

In 2002, the Food and Drug Administration (FDA) approved supplementation of both -3 and -6 FA in infant formula. Both are potentially important in fetal and infant neural development, in that DHA and arachidonic acid have been shown to be incorporated into brain and retinal cell membranes—particularly during the third trimester and early infant life. In both preterm and term infants, evidence consistently shows benefit of visual improvement at 4 months compared with infants fed nonsupplemented formula.[40,41](#) Systematic analysis and meta-analysis have shown that higher DHA content of formula is significantly related to improved visual acuity (LOE-1).[42,43](#) However, benefit beyond 4 months is controversial. One recently completed trial showed visual improvement at 12 months in term infants given formula supplemented with -3 FA compared with nonsupplemented formula.[44](#) Another study showed sustained increase in intelligence at 4 years of age in children whose mothers were supplemented with fish oil from 18 weeks of pregnancy to 3 months postpartum (LOE-2).[45](#)

It is important to emphasize that breast-fed infants have outperformed infants fed -3/-6 FA enriched formula in visual acuity measures. Although increasing dietary intake of fatty fish during the antepartum or breast-feeding period is a potentially attractive alternative to fish oil supplementation, it

is unclear how much dietary -3 FA intake is essential to maintain the benefit of DHA in breast milk.[46](#) Concerns of mercury content in fish also cloud its potential health benefits.[47](#)

With fish oils' potential benefits in reduction of preterm labor, and improved neural and retinal growth for infants, it is prudent to recommend up to 2 low-mercury fish meals a week for women of childbearing age (SOR-C).[48](#) For infants, whereas breast milk continues to be superior over any formula, -3 FA enriched formula should be considered in mothers who are not breast-feeding or have contraindications to breast-feeding.[49](#) It may be especially beneficial for preterm infants (SOR-B).

Other Conditions □ With its potential anti-inflammatory actions and membrane stabilization properties, fish oil supplementation has been studied in a wide spectrum of conditions. Studies in inflammatory bowel disease,[30,50–52](#) asthma,[53,54](#) atopic dermatitis,[55](#) psoriasis,[56,57](#) renal disease,[30,58,59](#) and psychiatric illnesses[60,61](#) are either inconsistent or the studies are limited. Studies in neurologic disorders such as ischemic stroke[62,63](#) and Alzheimer disease[64](#) are beginning to be explored.

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Meal Replacements For Weight Loss

Information & Research:

What is the Cornerstone Meal-Replacement Shake?

The Cornerstone high protein shake contains 23 grams of protein from a blend of whey and pea protein. It exceeds RDA for vitamins and minerals, contains prebiotic fiber and probiotic flora. The shake contains a 30/40/30 proportion of fat, carbohydrates and protein, which is the recommended percentage promoted by leading nutritional scientists.

How Do Meal Replacements Work?

Meal replacements help people lose weight by providing a controlled amount of calories, protein and fat in a prefixed portion. They simplify meal planning because they are convenient -- easy to store, and requiring little preparation. They are also reasonably priced, usually costing less than the meal they replace. Meal replacements reduce the number of decisions you have to make about what to eat and reduce your exposure to tempting foods that might result in overeating.

Many effective weight loss meal plans that use meal replacements recommend either using them in addition to eating 1 or 2 healthy "grocery" foods meals, or replacing 2 or 3 meals and 1 snack per day to lose weight, and then replacing 1 meal per day to maintain weight.

Using a meal replacement instead of an entire meal or snack can help you to reduce your calorie and fat intake and your blood sugar levels. When you first start using meal replacements, you will likely notice an immediate reduction in your blood sugar levels because you will probably be consuming fewer calories and less carbohydrates than you would with your usual meal.

How Effective Are Meal Replacements?

Recent studies show that meal replacements have an important role to play in the diet of anyone who wants to lose excess body-fat and build healthy lean muscle.

A good example comes from a study published in the *American Journal of Clinical Nutrition*. Researchers from the University Hospital of Ulm in Germany assessed the effects of low-calorie diet combined with meal replacements on weight loss in a group of 100 obese patients.

Half of the group followed a self-selected diet of 1,200 to 1,500 calories per day, which included three meals and two snacks. The other half followed a similar self-directed diet except that they replaced two snacks and two of the three meals with meal replacements (shakes, soups or hot chocolate).

After three months, the people on the self-selected diet lost an average of 2.9 pounds, while the people using meal replacements lost an average of 15.6 pounds.

After the first three months, everyone was asked to replace one meal and one snack per day with a meal replacement. Over the next 24 months, original self-selected diet group lost an average of nine additional pounds, and the original meal replacement group lost an average of another seven more pounds. At the end of the study, the self-selected diet group had a 5.9 percent weight loss, whereas the original meal replacement group had an 11 percent weight loss.

Another study by researchers from the *University of Nevada* report similar results. *Women using meal replacement supplements* were able to maintain a far greater weight loss over the course of a year than those using other methods to control their weight.

Other Selected References on Meal Replacements

In general, published studies and references have concluded that diets including meal replacements (portion-controlled, calorie-restricted meals) produce substantially great weight loss and weight loss maintenance than traditional diets.

On average, **more than three times as much weight is lost and maintained** using meal replacements as compared to traditional diets. . Meal replacements can be used successfully in a variety of settings and with various treatment populations - e.g., by individuals alone, in structured groups, with or without professional support, and with all medical comorbidities. Importantly, meal replacements also improve dietary compliance and overall nutritional intake, and they reduce all measured medical risk factors. Following is a sample of meal replacement references.

Research/Studies: General Weight Loss Success

Blackburn GL, Rothacker DQ. Ten-year self-management of weight using a meal replacement diet plan: comparisons with matched controls. *Obes Res* 2003;11:A103.

There was a 32.6 pound difference between individuals who used a meal replacement plan over 10 years compared to matched controls. Those using meal replacements lost an average of 6 pounds over the 10 years; those not using meal replacements gained 26.6 pounds. Participants were only given information on the use of meal replacements to lose and maintain weight -no other instruction was provided.

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Heymsfield SB, van Mierlo CAJ, van der Knaap HCM, Heo M, Frier HI. Weight management using a meal replacement strategy; meta and pooling analysis from six studies. *Int J Obes* 2003;27:537-549. **This meta-analysis of six studies found significantly greater weight loss in subjects using partial meal replacement plans (PMR) vs.**

conventional reduced calorie diets. The dropout rate was equivalent at 3 months but significantly less in the meal replacement group at one year. The authors concluded that "our findings demonstrate the important potential of well-developed PMR products and plans as a means of weight control."

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Ditschuneit HH, Flechtner-Mors M, Johnson TD, Adler G. Metabolic and weight loss effects of long-term dietary intervention in obese patients. *Am J Clin Nutr* 1999;69:198-204. In a prospective randomized study, **obese patients who used four meal replacements per day** (two meals and two snacks) for three months **lost five times more weight than those who were on a conventional low-calorie diet** (15.6 pounds vs. 2.9 pounds). **Both groups then used two meal replacements** (one meal and one snack) and, on average, **all continued to lose weight long term** (24-month maintenance phase). Additionally, by the end of the study, both groups experienced significant reductions in blood pressure, glucose, and insulin.

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Bray GA. Treatment and secondary prevention of obesity (editorial). *Nutr* 2000;16:384-385. Hill JO. Long-term weight control with meal replacements (editorial). *Nutr* 2000;16:385. In these two editorials the authors supported the effectiveness of meal replacements as a simple and minimal intervention. As Bray noted, the long-term results imply that "the subjects were continuing to treat themselves, which is the hallmark of success for primary treatment of obesity and for secondary prevention of weight regain". Hill concluded that, "in this study, a minimal intervention [i.e., meal replacements] had a significant impact on body weight". Commenting on the practical value of meal replacements, he stated that "we need to evaluate more of these 'real-life' interventions that have the potential to be translated into other settings".

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Wadden TA, Berkowitz RI, Sarwer DB, Prus-Wisniewski R, Steinberg C. Benefits of lifestyle modification in the pharmacologic treatment of obesity. Arch Intern Med 2001;161:218-227. In a one-year randomized trial of 53 obese women, **those who used meal replacements** for four months in conjunction with group lifestyle modification and obesity medications **lost four times more weight than women who used medications alone** (36.5 vs. 8.4 pounds).

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Rothacker DQ, Staniszewski BA, Ellis PK. Liquid meal replacement vs. traditional food: A Potential model for women who cannot maintain eating habit change. J Am Diet Assoc 2001;101:345-347. Seventy-five overweight women were randomized to either a recommended 1200 calorie/day diet of low fat foods or a similar diet with at least one meal replacement per day for one year. There was no other intervention. After 12 weeks, **the meal replacement group lost significantly more weight than the diet group, and, after one year, the meal replacement group maintained their initial weight loss whereas the traditional diet group regained most of their weight loss.** "In this study, having food consumption controlled at one meal was enough to keep the weight from coming back."

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Allison DB, Gadbury G, Schwartz LG, Murugesan R, Kraker JL, Heshka S, Fontaine KR, Heymsfield SB. A novel soy-based meal replacement formula for weight loss among obese individuals: a randomized controlled clinical trial. Eur J Clin Nutr 2003;57:514-522. One hundred obese patients using five meal replacement shakes a day (along with fruits and vegetables) lost significantly more weight after 12 weeks than those following a conventional low calorie diet. The meal replacement group also had a greater change in total and LDL cholesterol.

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Ryttig KR, Rossner S. Weight maintenance after a very low-calorie diet (VLCD) weight reduction period and the effects of VLCD supplementation: A prospective, randomized, comparative, controlled long-term trial. J Int Med 1995;238:299-306. Fifty-two patients who had used a VLCD for 12 weeks were then randomized to a 1600-calorie maintenance diet - one group with and one without the inclusion of two daily liquid supplements. **After one year, the group using two daily supplements kept off more of their weight loss than the group using no supplement.**

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Meal Replacements Safely Used in Type 2 Diabetes

Redmon JB, Ratz SK, Reck KP, Swanson JE, Kwong CA, Fan Q, Thomas W, Bantle JP. One-year outcome of a combination of weight loss therapies for subjects with type 2 diabetes. *Diabetes Care* 2003;26:2505-2511. Overweight individuals with type 2 diabetes lost significantly more weight and improved diabetes control with a combination therapy that included meal replacements compared with a standard weight loss program.

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Yip I, Go VLW, DeShields S, et al. Liquid meal replacements and glycemic control in obese type 2 diabetes patients. *Obes Res* 2001;9(suppl 4):341S-347S. Fiftyseven patients with type 2 diabetes used either meal replacements (two meal replacement shakes and one portion-controlled dinner high in fruits and vegetables per day) or a calorically-restricted diet (American Diabetes Association Exchange Diet) for 12 weeks. Both diets results in significant weight loss demonstrating that meal replacements can be used safely for weight loss in obese type 2 diabetics. The meal replacement group had greater weight and fat mass loss and reductions in fasting glucose compared to the ADA group.

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Li Z, Hong K, Thames G, Minutti C, Heber D. Meal replacements but not individualized exchange plan diets result in reductions in C-reactive protein (hsCRP) levels in obese patients with type 2 diabetes. *Obes Res* 2003;11(suppl):A50. Meal replacement use resulted in greater weight loss over 24 weeks than individualized diet plans in obese patients with type 2 diabetes. This resulted in significant improvements in C-reactive protein, insulin sensitivity, and lipid levels.

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Reynolds LR, Konz ED, Frederich RC, Anderson JW. Rosiglitazone amplifies the benefits of lifestyle intervention measures in long-standing type 2 diabetes mellitus. *Diabetes Obes Metab* 2002;4:270-275. Patients with long-standing, poorly controlled type 2 diabetes requiring insulin therapy participated in a 6-month structured program incorporating meal replacements (three shakes and two prepackaged entrees per day), fruits and vegetables, and physical activity. The average weight loss of 20.2 pounds led to substantial reductions in multiple cardiovascular risk factors along with a 14.1 unit/day average decrease in insulin dose and an average decrease in HbA1c of 1.2 percentage points.

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Reynolds LR, Konz ED, Frederich RC, Anderson JW. Rosiglitazone amplifies the benefits of lifestyle intervention measures in long-standing type 2 diabetes mellitus. *Diabetes Obes Metab* 2002;4:270-275. Patients with long-standing, poorly controlled type 2 diabetes requiring insulin therapy participated in a 6-month structured program incorporating meal replacements (three shakes and two prepackaged entrees per day), fruits and vegetables, and physical activity. The average weight loss of 20.2 pounds led to substantial reductions in multiple cardiovascular risk factors along with a 14.1 unit/day average decrease in insulin dose and an average decrease in HbA1c of 1.2 percentage points.

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Meal Replacements Used Successfully in a Variety of Settings

Ashley JM, St. Jeor ST, Schrage JP, Perumean-Chaney SE, Gilbertson MC, McCall NL, Bovee V. Weight control in the physician's office. Arch Intern Med 2001; 161: 1599-1604. A primary care office intervention that included brief physician/nurse visits and the use of meal replacements was as effective as a traditional group intervention without meal replacements. Furthermore, **overweight women using meal replacements in a traditional lifestyle-based group lost more than twice as much weight and maintained significantly more of the weight loss after one year than women not using meal replacements.** The average weight loss in the meal replacement group was 9.1% of initial body weight, with substantial improvements in medical risk factors.

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Winick C, Rothacker DQ, Normal RL. Four worksite weight loss programs with high-stress occupations using a meal replacement product. Occup Med 2002; 52: 25-30. Nearly 500 employees in **four different occupational groups** who **used meal replacements** (shakes and nutrition bars) on their own, **lost an average of 16 pounds** in 12 weeks. The **retention of weight loss was considerable**, particularly in the airline personnel, 2/3 of whom had retained >80% of their weight loss after one year, and half of these weighed less than at week 12.

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Cho S, Alberding J, Sadler B, Johnson KJ, Clark C. Worksite weight loss program with meal and snack replacement system: twelve week results. Am J Clin Nutr 2002; 75: 383S. Employees at a worksite were randomized to a 1200-calorie/day diet or a similar caloric meal replacement plan. **The meal replacement group lost more weight and showed greater reductions in systolic blood pressure and cholesterol. The participants found the meal replacements "made a weight loss program simple and easy to follow."**

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Goffhelf L, Ringie L, Jacobsen D. Coaching a weight loss group over the telephone: a successful treatment option. Obes Res 2003; 11: A84. Participants in a phone-based weight loss program incorporating meal replacements (3 shakes and 2 prepackaged entrees per day) lost an average of 16 pounds in 6 weeks or 7.5% of initial body weight. These results were virtually identical to those of participants in a clinic using the same weight loss program.

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Meal Replacements Improve Dietary Compliance, Nutritional Intake, and Reduce Risk Factors

Ashley JM, St. Jeor ST, Perumean-Chaney SE, Schrage JP, Bovee V. Meal replacements in weight intervention. *Obes Res* 2001;9 (suppl 4):312S-320S. In the second year (maintenance) of an earlier study, women using meal replacements maintained more weight loss than those not using meal replacements. **Those using meal replacements within the structure of a lifestyle group maintained significantly more weight loss** (8.5% of initial body weight) than all the others. Furthermore, **women using meal replacements in the group showed an increased intake of micronutrients as well as significant increases in vegetable and fruit servings** .

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Flechtner-Mors M, Ditschuneit H, Johnson T, Suchard M, Adler G. Metabolic and weight loss effects of long-term dietary intervention in obese patients: four year results. *Obes Res* 2000;8:399-402. In a continuation of an earlier study, **two meal replacements** (one meal and one snack) **daily were effective in maintaining weight loss and sustaining healthy eating (reduced energy, fat, and cholesterol intake) for a period of four years**. "From the health point of view, the most important observation is that continued use of a meal replacement strategy can improve several important biomarkers of disease risk for an extended time" (e.g., glucose, insulin, lipids, and blood pressure). Furthermore, the continued use of meal replacements prevented weight gain in those who dropped out and then re-entered the program.

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Rothacker DQ, McPartlan L. Improved intakes of calcium with reduced fat in adults using one daily meal replacement shake. *Obes Res* 1999;7 (suppl 1):96S. Food diaries were analyzed on designated meal replacement days (using a meal replacement shake for the first meal of the day) and control days for 117 adults. By **simply adding one meal replacement shake a day** , a significantly greater percent of adults (52% vs. NIH's estimate of 19%) were able to meet the 1000 mg/day guideline for calcium. **The average daily intake of calcium increased by almost 300 mg, while calories and fat were consistently lower**.

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Metz JA, Stern, JS, Kris-Etherton P, et al. A randomized trial of improved weight loss with a prepared meal plan in overweight and obese patients. *Arch Intern Med* 2000;160:2150-2158. This year-long, randomized, clinical trial to test the effect of a prepared meal plan on weight loss included 302 patients with hypertension and dyslipidemia or type 2 diabetes. "The results demonstrate that the prepared meal plan is more effective in inducing weight loss in such subjects than a macronutrient-equivalent UCD (usual care diet). **The greater weight loss in the prepared meal plan group likely reflects, in part, better dietary compliance and thus, greater sustained reductions in energy and fat intake. Furthermore, the prepared meal plan was more effective in improving multiple risk factors and in enhancing quality of life**.

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McCarron DA, Oparil S, Chait A, et al. Nutritional management of cardiovascular risk factors. Arch Intern Med 1997; 157:169-177. The purpose of this multicenter trial (see also Metz above) was to assess the clinical effects of a total dietary plan designed to meet the nutritional recommendations of major U.S. health organizations for cardiovascular risk reduction. The use of prepackaged meals for 10 weeks was compared to a nutritionist-guided self-selected diet in people with hypertension, dyslipidemia, diabetes, or a combination of these conditions. **The prepackaged plan resulted in greater clinical benefits, weight loss, nutritional completeness, and compliance than the self-selected diet.** Most significant was the impact of the food plans on achieving simultaneous reductions in multiple cardiovascular risk factors.

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The results of these studies suggest that meal replacements are a very effective weight-loss strategy both short and long term.