LeanMR™ Balanced Fitness Nutrition Shake Mix

Goal

To support weight/bodyfat reduction and maintenance by delivering better, satisfying nutrition in fewer calories throughout the day when integrated into daily menu planning along with traditional food meals. LeanMR (meal replacement) is designed to accomplish this goal by: 1) delivering energy and nutrition within low calories to help increase voluntary daily activities; 2) combining with traditional food meals to increase meal frequency within the necessary calorie allotment for weight/fat reduction or maintenance to support satiety, energy and activities; 3) delivering accurate portion sizes to help correct the otherwise common underreporting of calorie intake that often sabotages weight control; 4) incorporating a high whey isolate protein and unique fiber formula to total calorie ratio to assist in maintaining lean body mass (LBM) and appetite control. Therefore, LeanMR is designed to provide maximum support for LBM, a steady supply of energy, and improved fullness (satiety) within the fewest calories to improve the dieting experience, avoid typical plateaus, and accelerate results when compared to mass market meal replacements (MRs) or dieting without MRs.

Rationale

Meal replacements, or balanced powdered fitness formulas, are used in many ways to help achieve and maintain healthy or desired body composition. However, integrating into standard meal planning (whole/traditional foods) a powdered formula (allows portability/flexibility/accuracy) containing a favorable starting macronutrient and calorie profile that has been shown to support safe and effective weight/bodyfat loss including protecting LBM, may be a short and long-term healthy body composition solution. Once total calorie needs are established based on the body composition goal within an achievable timeframe, 2-3 traditional food meals combined with 1-3 high nutrition/protein shakes (ranges based on total calories allowed) may become a lifetime solution in navigating the environmental barriers to weight control/body composition success.

Background

The obesity/overweight epidemic continues to sweep through developed nations and especially in the United States.[1,2,3] This fact is a testament that there is no one universal solution for proper weight control.[4,5,6] However, one aspect of weight control is clear, the majority of humans living in modern societies must pay attention to their energy consumption and expenditure to manage a healthy body weight throughout a lifetime.[7,8,9,10,11] High protein MR powdered formulas have emerged as a valuable tool within this one unequivocal common denominator (cognitive consumption[12]) that leads to success, by addressing many of the known obstacles to managing bodyfat reduction and maintenance of desired/healthy body composition. Unfortunately, the original perception of what a MR program for weight control constitutes, has stubbornly lingered in the minds of health professionals (HP) while the MR products and programs have significantly diversified. [13] HPs are generally under-educated as to how to use the many forms of "MRs" as part of an economical lifelong weight/bodyfat loss and maintenance solution.[13]

The lingering thoughts of MRs for weight loss, are that a MR program consists of primarily or only liquid meals, leading to rapid weight loss that is unsustainable because people must return to "real food" and behavioral problems that led to weight gain in the first place were not addressed, making weight regain virtually inevitable.[13] That attitude had some basis back in the 70s and 80s,[14,15,16] and while those programs still exist under medical supervision only,[13,17,16] there are currently many more uses of "MR-type products," including integrating them into traditional "whole-food" daily meal planning.[13,18,19,20] Further, other than a necessary medical definition for a form of sustenance that could totally replace whole foods including essential macro and micronutrients, the name MRs, per se, is often a misnomer considering what's available and how some MRs are

used within normal meal planning with consistent success.[13,18,19,20,21,22] In other words, "MRs" wouldn't necessarily replace a meal but may in fact be an additional meal since it is food in powdered form. Therefore, the said food mix can also be added to, such as fruits, vegetables, caloric and nutrient containing fluids, etc., making a complete traditional meal, albeit in a delivery system that eliminates most chewing but maintains a high variety of nutrient value in relatively low calories. To avoid confusion, going forward in this document that supports the use of low calorie, high protein unique nutrition additions to traditional meal planning, we will refer to the formula or product as a convenient nutrient dense fitness food (FF) because the formula's base ingredients (before any additions) easily meet the criteria of a low calorie, nutrient dense healthy food selection, mindful the FF would never be the sole daily food choice. In fact, the addition of the FF into daily planning would improve the nutrient content of any goal based eating plan making achieving desired bodyfat/weight control easier than without the FF.

Barriers to Weight/Bodyfat Control and FF/MR

Dieting (calorie restriction) for weight loss and maintenance is difficult at best.[3,4,23,24,25,26] During normal energy restriction, 25% of weight loss is from lean body mass/fat free mass, (LBM/FFM) [27,28,29,30] and more depending on the magnitude of the deficit.[30,31,32,33,] Although exercise helps protect LBM losses and contributes to health even in the absence of weight loss, by itself exercise is not a weight loss solution, especially at current exercise recommendations.[34,35,36,37,38] As the body mounts its natural evolutionary driven weight loss defenses,[39,40,41,42] weight regain is all but inevitable for the majority of dieters based on the following energy restriction and weight reduction induced variables: 1) need to continuously decrease calorie intake to overcome obligatory plateaus caused by overall weight/LBM reduction and exercise induced fitness improvements (both conditions can lead to a slower metabolism/ metabolic adaptations);[37,38,43,44,45,46,47] 2) conscious and unconscious energy/movement level decreases (e.g. daily fatigue, less NEAT, etc.)[39,40,41] 3) increases in appetite/cravings[30,48,49,50,51,52,53] 4) environmental obstacles including social influences (e.g., easy access to palatable foods, advertising, family gatherings,[10,11,26,32,54,55,56] time constraints, inability to increase daily/exercise activities, etc.);[10,11,32,54,57] 5) as mentioned above, exercise alone has been consistently shown be an ineffective weight loss solution primarily due to the amount and time needed to achieve and sustain weight loss.[34,35,36,37,38,58,59,60]

Meal replacements or what we are referring to for our purposes as fitness foods, (FF) have become a modern day viable solution for many of the challenges and barriers to successful weight control.[13,18,19,20,21,22,61] Therefore LeanMR has been designed to be a better FF than competitors by incorporating ingredients and macronutrient ratios (high whey protein, low fat) that best address obstacles to success including mood disturbance, fatigue, stress and/or diet dissatisfaction.[62] Used individually, MRs, low carbohydrate-low glycemic index (GI) diets, high protein intake and types of proteins used, and moderate fat consumption, have all shown positive effects on diet and weight maintenance outcomes and therefore all factors have been incorporated in the LeanMR formula integration with daily meal planning.[4,63]

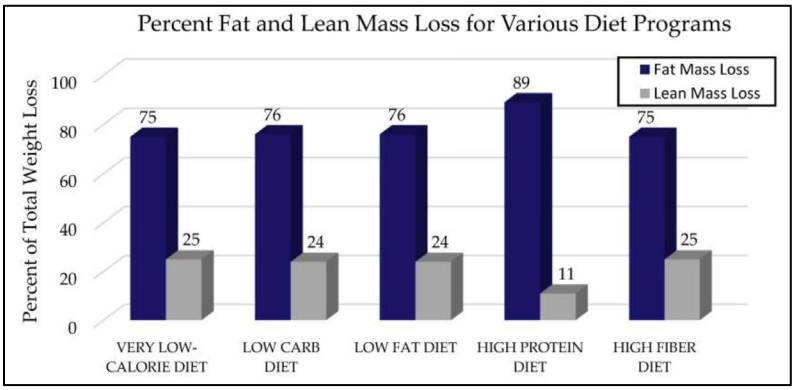
Protein Intake in Weight/Body Fat Loss

Loss of lean body mass (LBM) is an undesirable and mostly unavoidable consequence of conventional weight loss practices. Not solely because of the misery incurred as the human body mounts its natural defenses (e.g., increase in appetite, decrease in energy and metabolism, etc.) to continuous losses of evolutionary driven perceived hard earned body mass, which most often eventually lead to surrender and weight regain, but diet induced loss of LBM is strongly associated with the weight regain phenomenon. Higher protein diets in a dose-dependent manner (25-50% of total calorie intake) have been shown to ameliorate the body's weight loss defense actions including supporting LBM and forcing greater losses of body fat during weight reduction attempts.

Higher protein diets (25-50% of total calories or significantly greater than the RDA) which include low/moderate fat and/or low carbohydrate are generally more successful for weight loss than lower protein diets, at least in

the short term, especially in terms of protecting LBM (see Figure 1 below from Willoughby et al.[64]).[65,66,67,68,69,70] The basic mechanisms of action include greater satiety, increased daily energy expenditure (including thermic effect of food [TEF]), fat oxidation,[71,72,73,74,75,76,77,78] and preservation of LBM.[66,78,79,80,81,82,83,84] The latter arguably being protein's most important action since loss of LBM not only compromises the body's structure, functions, and total energy expenditure, but greater losses of fat free mass (e.g. muscle, bone, other organs[68,85,86,87,88,89]) are strongly associated with weight regain and increased appetite.[90] Of all these actions of protein, whey proteins compared to other sources appear to deliver superior outcomes when integrated into daily meal planning.[71,81,91, 92,93,94,95,96]

Figure 1 – Fat Mass vs. Lean Mass Loss in Various Diets (Source: Willoughby et al.[64])



Protein and Satiety

Of the three macronutrients, it is well known that protein is the most satiating, followed by carbohydrates, (CHO) and fats.[97,98,99] Increased satiety has been demonstrated after meals with a protein content in the range of 25-81% of total calories and up to a point, at least in the short term, is relatively dose dependent.[100,101] High protein diets decrease postprandial hunger and increase postprandial satiety.[71] One reason for protein's superior effect on satisfying hunger may be protein's (amino acid content[102]) modulation activity of MU-opioid receptors (MORs) which is similar to morphine. This signal goes to the brain to tell the intestines to release glucose and glucose suppresses appetite.[71,103] Other protein satiety mechanisms include the following: 1) the direct effect of high amino acid circulation induces a vagal feedback to the satiety center of the nucleus tractus solitarius in the brainstem and the hypothalamus to suppress hunger;[104] 2) stimulation of cholecystokinin (CCK) release into the gut to slow gastric emptying;[105,106] 3) postprandial thermogenesis described below (increased oxygen demand);[107] 4) alterations in gluconeogenesis including hepatic and intestinal gluconeogenesis to better maintain glucose homeostasis.[108,109] Clinical trials comparing protein sources suggest that whey protein has a greater effect in suppressing appetite through the aforementioned mechanisms.[71,91,96]

Protein, Energy Expenditure and Lean Body/Fat Free Mass

The thermic effect of food, also called diet-induced thermogenesis (DIT), is a metabolic response to food. Food intake transiently increases energy expenditure (EE) because of the work involved in nutrient digestion, absorption, transport, metabolism, and storage. DIT is generally expressed as a percentage increase in EE over the resting energy expenditure (REE) or basic metabolic rate (BMR). DIT values are greatest for protein (~15-30%), followed by carbohydrates, (~5-10%) and fat (~0-3%).[110,111] DIT for alcohol is ~10 to 30%.[107] Shown in a meta-analysis, the thermic effect of food (or DIT) increases ~7 calories of every 1,000 calories of ingested food for each 10% increase in the percentage of energy from protein.[112] Example: someone consumes a 2,000-calorie diet with 30% protein; the thermic effect of food would be ~14 calories higher than if protein was 20% of the dietary energy. Together (higher DIT protein values and higher protein percentage of energy in the diet) it's

been shown that subjects consuming diets consisting of 30-36% protein vs. 11-15% protein increased 24 hour EE by 213 calories/day (increase in REE against an equal calorie 11% protein diet) and 71 calories/day, respectively.[113,114] Protein's DIT increase in EE is also related to its greater satiating properties because of the increase in oxygen demand to metabolize protein (particularly the high postprandial amino acid oxidation rate) which may also suppress appetite.[101,107,115,116] And finally, Bray et al. compared overfeeding calories (all subjects consumed 40% excess energy) from fat in a low protein diet to overfeeding calories from protein in a high protein diet. Protein overfeeding resulted in significant increases in 24-hour EE, sleep EE and fat oxidation whereas the low protein diet did not, suggesting not only an increase in calories burned but also repartitioning of energy usage shifting to fat.[117] Overfeeding low protein versus equal-caloric high protein diets may lead to less weight gain, presumably because of the documented loss (or no gain) in FFM during the weight gain, whereas the equal high protein diet gained both FM and significant FFM. In fact, in an earlier Bray et al. overfeeding study, the low-protein group lost a non-significant amount of FFM to the extent that the increase in FM represented 119% of the gain in body weight. By contrast, the normal- and high-protein groups had a FM gain of 58 and 52% gain in body weight, respectively.[118] Other overfeeding studies comparing macronutrient differences have found similar results.[119]

The muscle sparing action of high protein diets, especially during energy restriction helps to maintain EE during weight reduction.[32,79,80,120] Gordon et al. demonstrated that protein intake at twice the RDA reduced muscle loss by 300% during 20 weeks of an energy restricted diet (3.0 vs 9.5 lb loss in the low protein diet).[121] Regardless if the energy deficit is created by exercise or food, high protein diets defend the obligatory muscle loss, thus total daily energy expenditure.[122,123] For more information on high protein/amino acids mechanisms in defending LBM during energy restriction the reader is referred to *The Assessment of Skeletal Muscle Proteolysis and the Regulatory Response to Nutrition and Exercise by* Stefan M. Pasiakos and John W. Carbone et al.,[124] and Moon J, Koh G. et al. *Clinical Evidence and Mechanisms of High-Protein Diet-Induced Weight Loss*.[99]

When considering skeletal muscle at rest burns ~6 calories/lb/day and adipose tissue ~2.2 calories/lb/day, the loss of both significantly lowers REE during prolonged weight reduction,[125] contributing (along with enhanced movement efficiencies) to common weight loss plateaus.[126] Therefore the ability to preserve LBM during weight loss is paramount to not just maintaining energy expenditure but also physical performance, including injury prevention.[32,123,126,127] Further shown in the next section, similar to whey protein's "better effect" on satiety compared to other proteins, whey protein has also been shown to be superior in enhancing muscle protein synthesis (MPS) during energy restriction, suggesting greater preservation in LBM during dieting.[128,129]

Whey Protein in Weight Loss

While the previous section described protein's favorable and potential mechanisms of action in supporting healthy bodyfat reduction and weight control, research has also demonstrated whey protein may deliver superior outcomes when compared to other protein sources.

Whey protein appears to have greater influence on satiety,[71,90,91,92,93,130,131] MPS, LBM preservation,[92,128,131,132,133,134,135,136] fat oxidation, body composition,[71,92,131,135,137,138,139,140] and health when compared to other protein sources.[94,96,141] Much of whey protein's added value may be due to its EAA structure including high leucine content and rapid amino acid absorption rate.[92,94,129,132,142] Whey protein compared to other protein sources such as soy, red meat/steak, chicken, etc., has a relative significant greater amount of leucine per gram of protein.[92,143,144,145,146] 25 grams of whey protein contains three (3) grams of leucine whereas soy has 1.4 grams, casein contains 2.3 grams and most meats contain even less.[147] Scientific data suggests that at least 2.5 grams of leucine may be the turning point for benefits when it comes to protein synthesis.[92,148,149,150] Xu ZR et al. found that leucine supplementation alone is useful to address the age-related decline in muscle mass in elderly individuals because it increases the muscle protein fractional synthetic rate,[151] but it appears that a leucine fortified whey protein is even more effective in supporting MPS, suggesting that leucine supplementation alone has a MPS trigger threshold based on the need for the supporting factors of the other

AAs.[103,152,153,154] In other words, the available remaining complimentary EAAs and/or NEAAs would be the limiting factor in leucine's potent MPS actions.[105,106,107,155,156]
For more details on whey protein mechanisms of actions the practitioner is referred to the PDSRG WheySmooth document **here**.

Milk Proteins and Whey Isolate

The main constituents of milk are considered functional foods, with direct impact on human health.[132,157] Milk has two primary fractions of protein, casein and whey. These fractions are further sub-divided as: four caseins (CN), α_{S1}-, α_{S2}-, β- and κ-CN, and two primary whey proteins, α-lactalbumin (α-LA) and β-lactoglobulin (β-LG), that collectively account for approximately 90% of all milk protein fractions.[158,159] Whey is the liquid portion making up approximately 20% of the total protein content of bovine milk with casein being 80% (human milk is 60/40, respectively).[160,161] Bovine whey is composed of β-lactoglobulin (50%–60%), α-lactalbumin (15–25%) and minor contributions of bovine serum albumin (BSA, 6%), lactoferrin (<3%) and immunoglobulins (<10%).[161]

Processing to Produce Whey

Processing, such as ultra-filtration (UF) and microfiltration create different whey protein products. The most utilized whey proteins include concentrate (35-90% protein, with or without lactose), isolate (~90-95% of protein, normally without carbohydrates, cholesterol and other whey fractions), hydrolyzed (smaller peptide fractions that are considered less allergenic but costly), and non-denatured (native protein structures).[162,163] Whey isolate (WI) extracts with protein contents as high as 95%, such as the source used in LeanMR, are produced by direct ultrafiltration to remove components such as the natural lactose, cholesterol, and non-protein nitrogen, and diafiltration to wash out the final unneeded lower molecular components – i.e. virtually all lactose, cholesterol and unwanted minerals, which now pass through the membranes.[163,164]

Whey Isolate in LeanMR

For all the aforementioned reasons, whey protein isolate is the primary ingredient in the LeanMR formula, and using the isolate form eliminates the normal cholesterol content found in whey fractions of milk proteins, which may be important to some weight loss participants.[162] The whey isolate protein makes up 42% of the calories in one serving of LeanMR in order to meet the protein to calorie ratio requirements demonstrated in successful weight loss through mechanisms described above such as, but not limited to: 1) increasing daily energy expenditure; 2) delivering greater satiety following each daily usage as opposed to other protein sources and/or equal calories in different macronutrient percentages; and 3) preserving LBM during energy restriction. Additionally, because of the powdered form, users can adjust the macronutrient percentages to meet their overall daily needs.

Carbohydrates in Bodyfat/Weight Loss and Maintenance

Introduction

Carbohydrates (CHO) are the preferred energy source for the body and along with their fiber content, CHO make its own contributions to satiety.[97,100,165] Government health guidelines for CHO is generally 45-65% of total energy intake,[166] which is also supported by other researchers, with the added recommendation of <10% from free (e.g. generally added) sugars.[167,168,169] Meaning, the majority of CHO in the diet should be from lower glycemic foods, such as whole/fibrous grains, fruits, vegetables, potatoes, etc.[169,170] Moreover, refined carbohydrates including added sugars are now targets for overweight/obesity therapies because of the impact their consumption has on the regulation/cravings by our hedonic and homeostatic systems established throughout human evolution.[171,172,173] While this appetite regulation, including carbohydrate cravings (e.g. sweet tastes) were important to early human survival, this leftover genetic trait now wreaks havoc in modern societies where food is not only plentiful with easy access, but extremely palatable, which often leads to

consumption of excess calories and subsequent unhealthy weight gain and related disease.[2,4,6,54,56,174,175,176] The rapid decline in blood glucose after a high glycemic index* (GI) meal (high in fast digesting/refined carbohydrates) causes both homeostatic and hedonic exaggerated hunger signals,[177,178] leading to cravings for more fast acting carbohydrates.[179,180] In addition, the more this eating cycle continues, the less sensitive (down regulation in dopamine/opioid receptors) the brain's reward system becomes to the food signals, thus causing greater cravings and additional food to become fully satiated or satisfied.[181,182,183] This latter problem describes the typical "sweet tooth" feelings even after a full meal despite not being truly hungry.[177,182,184] For many people who find themselves in this eating conundrum, allowing reasonable carbohydrate intake to help satisfy cravings while within a caloric allotment that allows proper weight control may be very important to proper weight maintenance.[185] In other words, humans evolved to crave CHO as it signals immediate energy, which was important to early hominids forging for food. This appetite trait is no longer necessary but still a part of our genome, and therefore consuming some CHO daily can help hold our natural cravings at bay.

Carbohydrates in Weight Loss

Carbohydrates are important for energy production, especially for exercisers and athletes who desire to perform at their highest level.[64,120,127,186,187,188,189,190,191] Efficient or rapid weight reduction can run counter to performance and therefore athletes/exercisers who desire weight loss must proceed judiciously in order to successfully accomplish both goals.[32,64,127,192,193,194] Generally speaking, daily carbohydrate intake for athletes and exercisers should not be less than 40% of total daily caloric intake (TDCI)[195] unless weight/fat reduction becomes the primary focus in order to make a weight class or compete in physique competitions where body fat level requirements are extremely low.[194,196] For these competitors, as calories continue to lower and fat intake is minimal, carbohydrates are the only dispensable food because the protein is needed to help preserve LBM and it can be converted to energy whereas carbohydrate only performs the later.[32,80,194,196,197] During prolonged calorie restriction the body will decide its immediate needs and only protein's components (amino acids) can be used for both energy and building/maintaining tissues. The lower the calories and body fat, the higher the protein requirement as a percentage to total calories in order to preserve LBM.[27,28,29,30,31,32,33,80,66,78,79,80,81,82,83,84,194,196]

For most non-competitive adult exercisers (e.g. walkers, gym members exercising one (1) hour, 3-5 times per week, recreational biking, etc.) carbohydrate intake is not nearly as important as it is for performance athletes, unless individual exercise sessions last longer than an hour.[64,120,127, 187,188,195] However, exercisers attempting to lose body fat may benefit from keeping carbohydrates to no less than 40% of TDCI unless unusual circumstances come into play such as those described above or for medical reasons. For weight reduction, the determining factor is calories in against calories out, (calorie balance)[198,199,200,201,202,203] but the daily calorie intake that allows the desired weight loss rate should be made up of what makes one feel better throughout the day, which can lead to more voluntary activity, thus more calories burned and potentially greater weight loss and maintenance.[8,9,12,13,64,185,204,205] In other words, up to a point, it sometimes takes calories from carbohydrates to burn more calories because carbohydrates are the body's preferred energy source.[206,207] Our general recommendation for dieters (non-athletes), once the dotFIT program establishes how many daily calories allow the desired rate of weight/fat loss, is 40-50% CHO (primarily minimally processed, low glycemic because they're generally more nutrient dense and often contain fiber that can add to satiety*[207]), 25-35% protein, (low/non-fat dairy, lean meats/poultry, appropriate vegetable proteins, etc.) and 20-35% fat (primarily unsaturated). Most of the carbohydrates would be consumed throughout the day before the last evening meal so that energy levels would be at their highest for exercise and/or daily activities.[32,196,208,209,210,211,212,213]

Compared to other daily calorie ratios of macronutrients, this recommendation including meal frequency[214,215,216] would allow the majority of dieters to improve overall daily performance and avoid many unpleasant factors (referenced above) commonly associated with dieting such as hunger, loss of LBM, stress and

low energy levels, all while potentially performing better workouts.[32,62,207,213,217] Properly formulated meal replacements can be a big part of this overall equation.

** High glycemic carbohydrates (refined grains/sugars, etc.) break down and enter the body faster than lower glycemic foods (fibrous, whole grains, etc.) and depending on which foods accompany the carbohydrate during a meal, high GI CHO consumption can negatively affect hunger/cravings, satiety, blood sugar and ultimately heath.[218,219] The glycemic index (GI) is defined as the incremental area under the blood glucose curve after ingestion of a test food, expressed as a percentage of the corresponding area following an equivalent load of a reference carbohydrate, either glucose or white (wheat) bread.[220] Low glycemic diets have been associated with healthier outcomes[218,219,221] including improved blood sugar control and insulin sensitivity[222] and a longer feeling of fullness.[223]*

Sustained-Release Carbohydrate Blend, with Beta Glucan, in LeanMR

Rice Oligodextrins, Digestion Resistant Maltodextrin (Fibersol® & Beta Glucan), Isomaltulose (Palatinose™) Glucomannan

Based on all factors established above, the CHO, including a patented blend of fiber and beta-glucan, is provided in a strategic ratio and form in the LeanMR formula to best assist in weight control. The 21 grams of whey protein is balanced with 23 grams of a low glycemic customized CHO blend that includes 7 grams of a patented fiber source (and 1.5 grams of a specialized blend of healthy fats). These are all contained in 170 calories per serving, resulting in the desired macronutrient ratio (50% CHO, 42% protein, 8% fats) that best allows a meal replacement to help support daily meal planning for weight reduction and maintenance as described above.

The combination of rice oligodextrins (low glycemic carbohydrate source containing 4-10 units),[224] Palatinose™ (generic name Isomaltulose), Glucomannan (a soluble fiber), Fibersol-2™ (functional soluble fiber/digestive resistant dextrin) and β-glucan, may allow users of the LeanMR mix to experience even and prolonged energy levels and greater satiety when compared to an equal caloric load of higher glycemic carbohydrates,[225,226] and especially when combined with whey protein.[227]

Rice Oligodextrins (6.47 grams)

Dextrins are a group of low-molecular-weight carbohydrates produced by the hydrolysis of starch and glycogen leaving mixtures of polymers of D-glucose (the naturally occurring form of glucose) units linked by α-(1→4) or α-(1→6) glycosidic bonds (covalent bond that joins a CHO/sugar molecule to another group, which may or may not be another CHO).[224,228] Oligo means few or little, so as it relates to dextrin, it describes the molecular length/weight of the CHO/dextrin and its natural unique food additive properties. Therefore, **rice oligodextrin** is a hydrolyzed (dried) rice starch that may be used as a source of low-glycemic carbohydrates often found in meal replacements. Moreover, oligodextrins provide a pleasing texture with less sweetness than other equivalent sources of CHO/dextrins.[229]

Digestive Resistant Maltodextrin: Fibersol-2 (6.72 g) and Beta-Glucan (3 g)

Resistant starches/dextrins are potential prebiotics defined as any starch which resists digestion in the small intestine and is fermented by bacteria upon reaching the large intestine and shown to confer benefits related to satiety, insulin sensitivity, blood glucose, lipid profiles and potentially weight control.[230,231,232,233]

Maltodextrin consists of D-glucose units connected in chains of variable length ranging from three to seventeen glucose units in length and linked like the linear derivative of glycogen (following removal of α1,6- branching). Resistant dextrins (RD) are short chain glucose polymers, strongly resistant to human digestive enzymes and do not yield a sweet taste.[234] Resistance of RD toward digestive enzymes are due to presence of (1→2)-, (1→3)-, (1→6)-α-, and β-glycoside bonds which are not present in native starch.[235]

Digestion Resistant Maltodextrin (DRM) is a dietary fiber made from corn starch by a controlled conversion of the digestible glucose constituents in starch into non digestible ones by changing the bonds that connect the sugar units and been available in the United States since 1999. The resulting product is indigestible as our bodies do not have the enzymes necessary to break down the new bonds.[236] Therefore, as opposed to maltodextrins,

DRM does not contain calories or affect blood sugar levels. However, it still offers many of the benefits of soluble/digestible fiber.[237,238,239] Further, DRM studies have shown that proper daily use may improve blood glucose, insulin sensitivity, lipid profile, and obesity, and because DRM are fermentable in the colon, they help produce short-chain fatty acids (SCFAs) and subsequently confer positive effects on the host's microbiome.[236,240,241]

Fibersol-2 a Soluble Prebiotic Dietary fiber – Prominent Digestive Resistant Maltodextrin at 6.72 g/serving.

Fibersol® is included on the FDA's list of dietary fibers. Readers are referred to the Fibersol-2™ website for complete ingredient facts related to clinical trials, unique patented production process, and use in food products including meal replacements.

Fibersol-2™ is a soluble fiber and is included in this formula to help deliver dietary and/or supplemental fiber's positive impact on health and weight control/appetite.[236,239,242,243,244,245,246] Fibersol-2, digestion resistant maltodextrin (DRM), is a dietary fiber. This classification is consistent with both the American Association of Cereal Chemists' and the Food and Nutrition Board of the National Academy of Sciences' (NAS) definitions of dietary fiber. In both cases, Fibersol-2 DRM, is classified as "resistant maltodextrin," and in both cases, "resistant maltodextrin" is classified as a dietary fiber, therefore consumption contributes to the recommended daily fiber intake. Total dietary fiber intake should be 19 to 38 grams/day (depending on age/gender/calorie intake) preferably from a variety of food sources. Currently, adult dietary fiber intake in the United States averages ~15 grams a day (children are significantly lower in meeting needs).[247,248,249,250] This deficit triggered dietary fiber to be listed in the 2020–2025 Dietary Guidelines for Americans as a nutrient of public health concern.[251,252] Further, fiber is extremely important in a weight control program primarily because it produces the feeling of fullness sooner and longer when added to a meal.[165,231,236,238,243,244,245,253,254,255] Fibersol-2™ is the dominate fiber in LeanMR not only for structural gastrointestinal (GI) transit viability but also because it doesn't affect taste nor does it interfere with mineral or calcium absorption, traits that are common among other food fibers.[256,257,258] Because Fibersol-2™ is fermented slowly, it produces less acid and gas than most soluble fibers. A randomized, double-blind, placebo-controlled crossover study demonstrated in healthy subjects that 10 grams of Fibersol-2 with a meal stimulated production of satiety hormones and enhanced satiety.[259]

All these traits make Fibersol-2™ the ideal fiber to include in a meal replacement formula and is therefore included in the LeanMR mix.[260] The user receives the benefits of a "better fiber" in a convenient delivery system without fiber's sometimes less desirable effects (taste, gas, bloating, etc.).[261] Studies have shown Fibersol-2™ to improve bowel regularity,[262] exert a positive effect on blood glucose,[263] lower cholesterol and serum triglycerides,[263] increase probiotic levels (good bacteria) and help keep the digestive tract clean and healthy.[264,265] Additionally, Fibersol-2™ has been granted GRAS (generally regarded as safe) status by the Food and Drug Administration (FDA).

In summary, **Fibersol® is a digestion resistant maltodextrin** and is included in the FDA's dietary fiber definition. Dietary fiber is defined as having a physiological effect beneficial to human health. Each gram of Fibersol is 90 percent fiber and provides virtually no sugar and only 1.6 Kcal. Studies have confirmed that Fibersol is well tolerated, even when tested at a consumption rate as high as 68 g/day. Fibersol's physiological benefits have been demonstrated with over 20 years of clinical research and more than 100 published studies.

Beta-Glucan

Beta-glucan (BG), a natural polysaccharide (d-glucose monomers linked through β-glycosidic bonds), is another healthful soluble fiber found in plant cell walls such as oats, barley, and wheat. BG also occurs in baker's yeast cells, fungal cell walls, and some microorganisms.[266,267] BG belongs to the family of prebiotics that stimulates the growth and activity of the desired natural intestinal bacteria, while inhibiting the growth of pathogens, therefore favorably effecting the host's microbiome and gastrointestinal (GI) health, which subsequently can confer other health benefits throughout the body.[268,269,270,271] Like other soluble fibers, BG intake is associated with several

beneficial health properties through its unique molecular structure's prebiotic and antioxidant activities including, but not limited to, supporting the health of the digestive,[270] immune[272] and cardiovascular systems.[273,274,275] Besides improving the host microbiome, BG has been shown to reduce cholesterol/lipids, inflammation,[271,276,277,278,279] and blood glucose,[280] and its immunostimulatory actions is a result of its attachment to specific receptors present on the immune cell surface.[272]
In summary, beta-glucan is included as part of LeanMR's fiber blend to deliver its unique health benefits referenced above (3 g/serving), while also supporting appetite control,[281,282,283] actions that collectively support desired bodyfat/weight control.[284,285] Readers interested in validated health claims associated with BG, are referred to the article by Hughes et al. titled "Oat and Barley in the Food Supply and Use of Beta Glucan Health Claims"[286]

Glucomannan

Glucomannan (GM) is a soluble fiber added to LeanMR because it has been clinically shown to beneficially affect total cholesterol, LDL cholesterol, body weight and fasting blood glucose.[287] Glucomannan has been used within fiber mixtures successfully in clinical trials related to improved weight loss, satiety and decreases in LDL-cholesterol.[288,289,290,291,292] While a study using 1.33 grams of GM showed no benefits in body composition or weight loss,[293] there is evidence that GM exerts its beneficial effects at 2-4 grams a day by promoting satiety and fecal energy loss.[291,294] Additionally, GM has been shown to improve lipid and lipoprotein parameters and glycemic status.[294]

Palatinose™

Palatinose™ is a disaccharide carbohydrate comprised of glucose and fructose (chemical name: 6-0-a-D-glucopyranosyl-D-fructose) manufactured by the enzymatic rearrangement of sucrose from cane sugar, commercialized in 1980 as a sweetener. Palatinose™ is a low glycemic functional carbohydrate that delivers prolonged energy due to its unique structure and low insulinemic response.[295,296,297] With its slow but complete absorption, Palatinose™ provides constant and extended streams of energy for muscles and the brain.[298,299] This energy source lasts over a longer period when compared to quickly absorbed carbohydrates.[225,295,299,300,301]

Total Carbohydrate/Fiber blend

- Corn Fiber (Fibersol): 6.72 g
- Rice oligodextrins: 6.47 g
- Palatinose: 3.75 g
- Glucomannan: 1.20 g
- Beta-glucan: 3.0 g
- Remaining co-factors contributes less than 1 g

Healthy Dietary Fat Blend

1.5g Flaxseed Powder, High Oleic Sunflower Oil, Conjugated Linoleic Acid (CLA)

As mentioned above, although fats make the least contribution to satiety, they do make a unique and necessary contribution.[96,97,302] Therefore to complete the desired percentages of total calories with 8% from fats,[62] LeanMR includes a combination of healthy polyunsaturated fats including flaxseed powder,[303,304,305] high oleic sunflower oil and conjugated linoleic acid (CLA).[306,307,308,309] Further, in LeanMR's native form, the lower fat content per serving allows freedom to add dietary fats of choice or necessity to achieve desired levels.

Meal Replacements for Weight Control

Early Research with MR Integration and Traditional Meals

Early studies demonstrated the use of meal replacements (MRs) to be an effective aid to weight reduction[310,311,312] and in almost all cases are more effective than conventional methods of dietary restriction.[313,314,315,316] (Figure 2) Additionally, MRs were shown to be just as effective as dietary restriction combined with pharmacological therapy[317] and an important continuing protocol for maintaining weight loss.[318,319,320] (Figure 3). By 2009, meal replacements had risen to the "evidence-based" category as a weight loss and maintenance treatment,[321,322] and continues to be supported as noted in the Position of the Academy of Nutrition and Dietetics: **Interventions for the Treatment of Overweight and Obesity in Adults**[323] Further, this MR dietary strategy has been officially included as a treatment option for type 2 diabetes as well as overweight and obesity.[324,325]

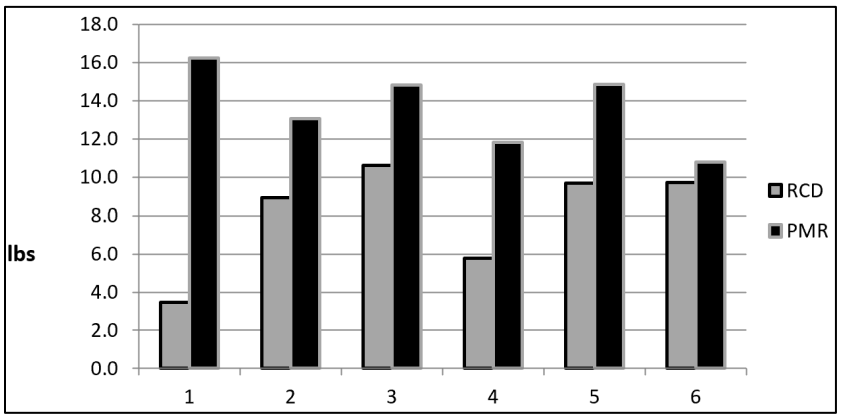


Figure 2: In all six studies the groups that were using meal replacements (PMR) as part of their overall calorie intake lost significantly more weight than the reduced calorie diet (RCD) group.[19]

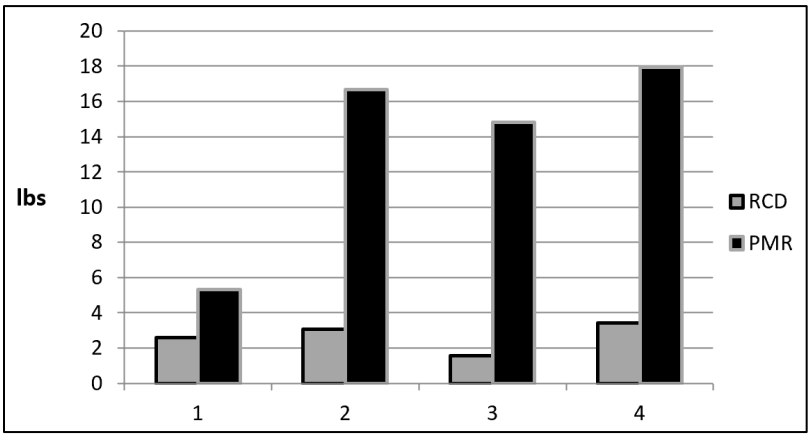


Figure 3: In a 1-year follow-up in the groups that were tracked, the subjects still using meal replacements maintained significantly more weight loss than the RCD group.[19]

As was shown in 2014 by Johansson et al. MRs were the among the most successful diet and maintenance therapies.[61] The researchers compared anti-obesity drugs, high protein diets and MRs in weight loss and maintenance and found a 26 pound loss was maintained for 22 months, 22 lbs lost for 6 months, and 28 lbs lost for 18 months respectively, demonstrating MRs greater efficacy.[61]

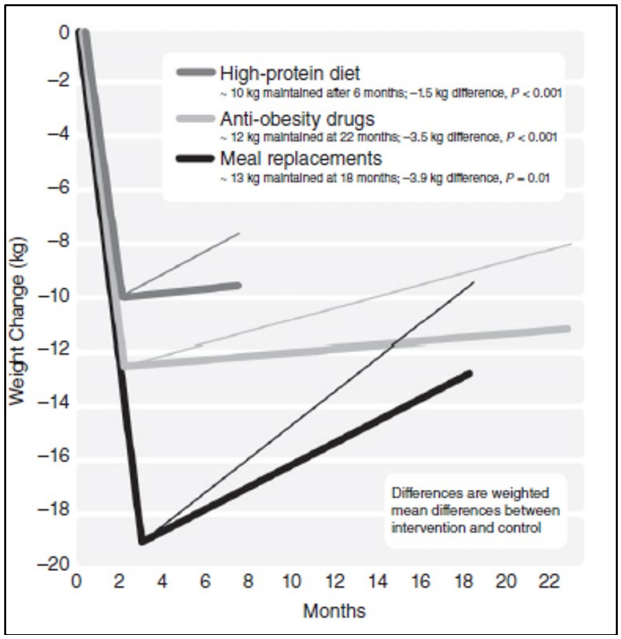


Figure 4 - Bodyweight change during the very low-calorie diet or low-calorie diet period followed by the weight loss maintenance period. The thin lines represent the control subjects in each category while the thick lines represent the active intervention. (Adapted from Johansson et. al. 2014).[61]

Meal replacements were shown to be especially important in maintaining weight loss from low (800-1,200) or very low (400-800) calorie diets,[326] and successful as a weight loss therapy in subjects who eventually returned to traditional foods during a year-long program where most participants maintained the weight lost within guidelines.[327] Similarly, Basciani et al. started subjects on four MRs/day and weaned them to one/day after 60 days. Subjects lost 15% of body weight and improved metabolic parameters; deeming the protocol effective, safe, and well tolerated for weight control.[328]

- Frestedt et al. used a MR mix twice daily within a 500-calorie deficit diet and found the MR aided weight loss by curbing hunger.[329]
- Whitham C et al. found that structured support using MRs for 24 weeks followed by 28 weeks of self-care can result in weight maintenance.[330]
- Ames GE et al. determined that subjects who lost 18% of body weight on a liquid MR program also recorded self-selected maintenance behaviors. The most commonly reported daily behaviors were self-weighing, use of meal replacements and step counting.[331]
- Theim KR et al. found the use of MRs during weight loss improved use of weight control behaviors, increased weight lost, and hedonic (susceptibility to environmental cues) hunger decreased.[332]
- Khoo J et al. had obese men with lower urinary tract symptoms (LUTS) use either restricted diet alone or restricted diet with MRs and found weight loss and relief of LUTS similar, but the MR group produced greater reduction in fat intake, adiposity, and storage of LUTS.[333]

This early work helped establish MRs as a viable weight control solution in everyday life, not only as an initial weight loss and weight maintenance aid, but continued use was also shown to improve overall diet quality.[334] During a one year follow up to weight loss, Raynor et al. found that a greater percentage of participants consuming two or more meal replacements per day than participants consuming less than one meal replacement per day met most fat-related and food group recommendations. They also consumed more servings of fruits and vegetables. The conclusion was that the partial meal replacement plan was related to superior diet quality.[334]

Current and On-going Research with MR Integration and Traditional Meals

Meal replacements (MRs) or what are referring to for our purposes Fitness Foods (FF) have become a modern day viable solution for many of the challenges and barriers to successful weight control especially when properly integrated into daily meal planning - i.e., partial meal replacement or addition to any eating pattern to increase feeding frequency within proper caloric allotment.[13,18,19,20,21,22,61,78,326,335,336,337,338,339,340,341] The Webb et al. meta-analysis found that partial use of MRs is as effective as their sole use in the more restrictive very low-calorie diets (VLCD). And that both dietary interventions are more effective than lifestyle programs to induce significant weight loss and improvements in physical function in overweight/obese subjects with osteoarthritis (OA).[342] Likewise, López-Gómez et al. using similar subjects found the substitution strategies of one or two meal replacements were effective in weight and fat mass decrease without differences between the two groups. Subjects showed improvements in lipid parameters, glycemic control, and systolic blood pressure without differences between strategies.[340] Further, MR programs are used successfully as a therapy for non-alcoholic fatty liver disease (NAFLD), which is a rapidly growing problem often brought on by unhealthy weight gain.[343] Worm et al. determined through clinical studies that an initial very low-calorie diet period of several weeks on a total diet MR program with a nutritionally complete, high protein, and low-energy formula, followed by a structured program of food reintroduction that implements a Mediterranean style low-carbohydrate diet should be "viewed as an optimal nutritional therapy for patients with NAFLD (and type-2 diabetes[344])".[343]

Summary of Mechanisms of Action for High Protein Meal Replacements

MR/FFs success as a modern-day weight control aid can be ascribed to its known primary actions: portion control, satiety, protection of LBM and overall energy expenditure.

- **Portion control:** people generally attempt to consume meals to completion,[11,345,346,347] therefore meal portion size significantly impacts a person's total calorie intake.[11,345,348,349,350,351] Overwhelming evidence validates that the smaller the portions, the fewer daily calories consumed and vice-versa.[11,348,350,351,352] Use of portion-controlled meals has proven to yield greater weight loss than conventional diet therapy alone,[11,18,19,21,22,61,326,327,334,352,353,354,355,356,357,358] and accurate calorie counts of total daily food intake when compared to having to estimate the calories of self-prepared or unmarked meals.[8,11,18,19,21,358,359,360,361,362]
- **Satiety:** use of a properly formulated whey protein-based MR/FFs, such as the LeanMR™ mix allows the user to increase the frequency of daily meals necessary to assist weight reduction while managing calories (while diets that limit eating times such as intermittent fasting [IF] can be effective for short-term weight loss, weight loss maintainers as described above consume 4-6 meals/day, including breakfast[12,57,185,363,364]).[4,64,214,215,216,217,321,334,364,365,366] This along with whey protein, fiber, and low GI carbohydrate content would help satisfy appetite and increase daily energy levels.[71,90,91,92,93,96,130,131,225,226,230,231,232,233,259,260,281,282,283,284,285,329,332] Proper use throughout the day can deliver good nutrition while helping to save calories, allowing the user to partake in larger meals or favorite foods at desired times (e.g. higher calorie lunches and/or dinners).
- **Preserve LBM and energy expenditure:** as described and referenced in the *Protein Intake in Weight/Bodyfat Loss* section above, frequent feedings of higher protein (especially whey) within total daily calories protects

diet induced LBM losses, subsequently helping maintain total daily energy expenditure and performance, which is otherwise compromised when consuming only a restricted conventional lower protein diet (see above named section for complete up to date references).

Successful use of High Protein MR/FFs within the Daily Meal Planning

Healthy, economical, and convenient FFs addition to daily meal planning in support of achieving desired body composition in the modern era.

Overall Diet

Taken in totality for the goal of weight loss and subsequent maintenance, as referenced above, science favors a whey protein mix-type "meal replacement" (or FF substitute) to be integrated and complement a high protein calorie restricted overall diet containing 30-40% carbohydrates, 30-35% protein and the remainder dietary fat (always maintaining a minimum of 1 g of protein per pound of LBM per day). In other words, daily menus containing traditional food meals, with protein at each meal, and the inclusion of controlled calorie high protein-based mixes to complete the allowed caloric allotment, has been validated as a top successful strategy to support weight/fat loss while protecting LBM and reducing the likelihood of weight regain. Further, using the category "meal replacement" for a malleable protein mix in the context of inclusion (or addition) to traditional food meals versus an actual replacement, is often a misnomer depending on formulation and how it's used within daily meal planning, since properly prepared MR/FFs are food products, thus actually a meal offering and potentially more nutritious daily meals within the daily goal calories. That said, LeanMR, in its native macronutrient form, meets the **legal definition of a meal replacement**[367] and is therefore well-suited for integration into total daily meal planning including controlling calories via supplying essential nutrition within caloric efficiently.

Meal Replacement/Fitness Food Integration

Weight Loss Phase:

- Except in the early stage of diets when meal replacements may be used extensively in daily meal planning (often physician monitored and sole/predominant food source),[17,18,338,368] they are generally used to replace two meals a day and allow freedom of choice from traditional foods for the remaining allotted foods/calories.[13,18,19,20,21,22,61,78,317,323,326,334,336,337,338,339,340,341]
- MR/FFs may supply two small meals within any calorie restricted meal plan of four to five meals/snacks (**see sample menus**) since it's been shown that frequent, smaller meals, including breakfast, are generally better for weight loss/maintenance than fewer larger ones, particularly as it relates to satiety, preservation of LBM and energy levels.[18,32,65,120,214,321,322,334,337,338,369,370,371,372,373]

Maintenance Phase

- Consume the required calories for maintenance spread between four to five meals/snacks daily which may include two MR/FFs for convenience and to help ensure overall diet quality while reducing food costs.[334,373]

LeanMR Formulation

Incorporating LeanMR into daily meal planning offers a financial and health benefit*

This formula is based on all the scientific data presented above. The specific macronutrient ratios (incorporated by successful weight maintainers including those listed in the National Weight Control Registry) and ingredients were selected in accordance with best potential weight control outcomes shown in clinical trials, such as but not limited to: 1) protein type (whey isolate) and amount (~45%), 2) CHO source (digestive resistant fiber blend and low GI sustained release) and amounts (~45%), and 3) dietary fat sources (unsaturated) and amounts (~10%, which allows users to add daily fats as necessary). As a palatable, calorically efficient nutrient dense FF addition

to the daily diet, these ingredients, and their ratios along with usage recommendations would give the user best chances of improved satiety, preservation of LBM and total energy expenditure while enhancing overall diet quality and ameliorating the common discomforts of dieting when compared to other MRs formulas, restricted calorie diets alone, or diet-drug therapies.

170 calories per serving supplies:

- 21 grams of the highest-quality whey isolate protein to protect LBM and energy expenditure and improve satiety.
- 23 grams of a Sustained Release Patented Carbohydrate Blend with 7 grams of fiber (including Fibersol-2®, Glucomannan and beta-glucan) and no sugar to deliver immediate and long-lasting energy and fullness while supplying one of the major under-consumed nutrients listed in the 2020–2025 Dietary Guidelines for Americans (DGA) as a nutrient of public health concern [251,252]
- 1.5 grams of a healthy lean fat blend
- 236 mg of calcium and 249 mg of potassium to help add two more under-consumed nutrients also listed as nutrients of public health concern in the current DGA [252]

*Note: Humans of all ages require 1 g/lb/LBM/day from a variety of high-quality protein to help remain active and healthy during a lifetime. Adding LeanMR as another unique protein source (whey protein isolate) to daily protein needs, improves overall diet quality while supporting the goals listed here, with the added benefits of convenience and reducing food costs in meeting daily protein needs.

Summary

A delicious high protein and fiber meal or snack to curb hunger, control calories, feed muscles and starve body fat to help achieve a desired body composition. Fortified with calcium, potassium, and fiber .

Purpose

Designed to address the modern-day obstacles to successful bodyfat/weight control when incorporated into daily meal planning (**see sample menus**), via:

- Allowing portion control and accurate calorie counts
- Improved satiety (sooner and prolonged fullness) through convenient meal frequency, high fiber content, protein to caloric ratio and type (whey isolate) with low glycemic and digestion resistant carbohydrates
- Feeding muscle while starving bodyfat to preserve (or increase) LBM by addition of a superior protein in low calories also supporting lifelong activity – i.e., nutrient dense caloric efficiency
- Increasing daily energy levels and expenditure (calorie burn) because of the aforementioned actions (meal frequency, protein to calorie ratio, protein type (whey) and LBM preservation)

Unique Features

- Contains the highest known biological value (BV) protein source, whey protein isolate (104-BV)
- Unique blend of carbohydrates, including functional fibers, deliver a “better lasting” energy and satiety to support aggressive bodyfat/weight loss goals.
- Contains no sugar and is low in sodium.
- 7 grams of fiber with beta-glucan for satiety (fullness) and health, including helping to maintain the integrity of the digestive track and bowel regularity.
- Healthy blend of essential fats.
- Designed in a synergistic relationship with all dotFIT products and a person’s traditional food intake. LeanMR is not spiked with unnecessary nutrients. Many other products in this space (e.g., bars, shakes, etc.) are heavily spiked with different nutrients, leading to undesirable levels within the body when

combining multiple manufacturers, products and normal food intake. Therefore, users are assured of keeping the body at a safe and optimal nutrient level.

- Formulated and manufactured for great taste and pleasing texture in a regularly inspected NSF certified facility, in compliance with Good Manufacturing Practices (GMPs) exclusively for dotFIT, LLC.

Nutrition Facts Panel

Nutrition Facts

20 servings per container

Serving size 2 Scoops (51g)

Amount per serving

Calories 180

	% Daily Value*
Total Fat 2 g	3%
Cholesterol 15 mg	5%
Total Carbohydrate 23 g	8%
Dietary Fiber 7 g	25%
Total Sugars 3 g	*
Includes 1 g Added Sugars	2%
Protein 21 g	
Calcium 240 mg	18 %
Sodium 160 mg	7%
Potassium 256 mg	5%
Sustained Release Carbohydrates Blend 19.4 g Maltodextrin, Digestion Resistant Maltodextrin (Fibersol & Beta Glucan), Isomaltulose, Glucomannan	*
Lean Fats Blend 2.5 g Flaxseed Powder, Coconut Oil Creamer, Conjugated Linoleic Acid	*

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