

THE SCIENCE BEHIND CHANGING LIVES: EVIDENCE-BASED NUTRITION WHITE PAPER

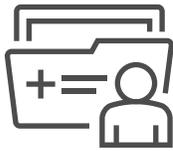
The Dietary Guidelines for Americans (2015-2020) recommend adults eat 1.5-2 cups of fruits and 2-3 cups of vegetables per day.¹ However, recent estimates indicate 88% of adults do not meet the daily fruit intake recommendation and 90.7% do not meet the daily vegetable intake recommendation in the United States.² Poor diet quality is associated with death and disability, and eating a diet rich in fruits and vegetables can protect against several chronic conditions including cardiovascular disease, obesity, type 2 diabetes, and certain cancers.^{3,4} Public health efforts to improve dietary quality and physical activity have been largely ineffective.

Tailored nutrition education has been touted as a promising strategy for improving dietary quality of adults long-term.⁵ Even brief interventions that provided education and feedback were more effective in improving short-term dietary behaviors than education alone or non-tailored advice.⁶ **Profile by Sanford is an evidenced-based, comprehensive behavioral weight management program delivered by health coaches designed to improve nutrition, activity, and lifestyle behaviors. Profile was created by physicians, researchers, and dietitians at Sanford Health, one of the world's largest, not-for-profit, fully integrated health systems.**

ADULTS IN THE U.S. THAT DON'T EAT RECOMMENDED AMOUNT OF FRUITS AND VEGETABLES



PROFILE AIMS TO MEET THESE NUTRITION-FOCUSED GOALS THROUGH A COMBINATION OF PROVIDING:



1

**ESTABLISHED, STRUCTURED
NUTRITION PROTOCOLS**



2

TAILORED EDUCATION



3

**FOCUS ON EATING
BEHAVIORS**

NUTRITIONAL PROGRAM OVERVIEW

Profile's nutritional program is geared toward improving dietary quality with the following goals developed from USDA dietary guidelines for adults¹ and adapted from the Academy of Nutrition and Dietetics⁷: increasing fruit and vegetable consumption, providing adequate micronutrients through a combination of grocery foods and meal replacements (MRs), increasing consumption of heart-healthy fats, and ensuring protein and carbohydrate needs are met. Additionally, Profile nutrition protocols minimize sodium, added sugars, and encourage caffeine intake aligned with dietary recommendations.⁴

Profile aims to meet these nutrition-focused goals through a combination of providing 1) established, structured nutrition protocols paired with

2) tailored education and 3) a focus on eating behaviors. This is accomplished, most effectively, within a health coaching model involving 1-on-1 meetings that go beyond nutrition education alone, and further, focus on identifying personal motivations for behavior change in conjunction with tailored education. Health coaches work with individuals on skills such as meal preparation and grocery shopping to improve self-efficacy, a key component to self-regulatory behavior in adult selection of healthy food choices.⁸ Finally, eating behaviors such as mindful eating, self-compassion, and understanding the connection between food and emotions is addressed through health coaching.

KEY TAKEAWAYS

ESTABLISHED AND TRUSTED PROTOCOLS



Profile’s nutritional program is geared toward improving dietary quality with the following goals developed from USDA dietary guidelines and adapted from the Academy of Nutrition and Dietetics for adults: increasing fruit and vegetable consumption, providing adequate micronutrients through a combination of grocery foods and meal replacements (MRs), increasing consumption of heart-healthy fats, and ensuring protein and carbohydrate needs are met. Additionally, nutrition protocols minimize sodium, added sugars, and encourage caffeine intake aligned with dietary recommendations.

THE EVIDENCE ON MRS



For over 20 years, evidence supports use of Meal Replacements (MRs) to improve dietary quality and improve portion control practices. MRs are endorsed by the Academy of Nutrition and Dietetics as an evidence-based practice to improve dietary quality amongst individuals who struggle with portion control and lack nutrient dense foods in their diet. MRs are used in early phases of Profile protocols and exchanged with grocery food items in later phases of the nutrition plan to improve attrition and compliance.

NUTRITION SKILL BUILDING



Health coaches aim to increase member’s self-efficacy by coaching and educating on food preparation, grocery shopping, and label reading. Existing evidence suggests these skills are associated with improved dietary quality and produce consumption.

EATING BEHAVIORS



Health coaches work with members in 1-on-1 settings to improve mindful eating behaviors (nonjudgmental awareness of physical and emotional sensations related to eating). Mindful eating is associated with improved eating behaviors, psychological distress, and binge eating behaviors. Self-compassion is a promising new approach toward improving physical and mental health and has implications for impulsive eating behaviors. Coaches address emotional eating with members by helping them implement evidence-based stress management techniques into their daily life to cope with negative emotions and anxiety.

1. NUTRITION TARGETS AND MEAL PLANS



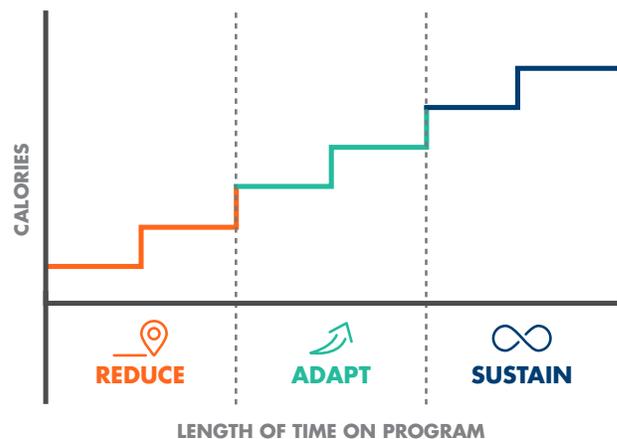
Profile by Sanford relies on an evidenced-based approach to create nutrition protocols and meal plans that guide members toward meeting the nutrition goals outlined previously. Individuals provide their health and medical history upon enrolling in the Profile program. Depending on health and medical history, individuals are placed on one of two primary weight loss nutrition protocols or a specialty protocol created by Profile’s Registered Dietitians and Clinical and Scientific Advisory board. Profile nutrition protocols include a phased approach to managing weight and improving health behaviors by providing structure and simplicity using FDA-approved MRs and grocery foods in the initial phases. All plans are designed to be nutritionally complete and include a combination of grocery foods and Profile MRs.

PROFILE PHASED APPROACH

Profile uses a three-phased approach in nutrition protocols designed to support effective weight loss and weight loss maintenance (Reduce, Adapt, Sustain). The Reduce phase is designed to provide enhanced nutritional structure and focus on foundational skills, such as increasing vegetable intake to 4+ cups per day and increasing physical activity to health enhancing levels. In addition, a variety of educational topics are introduced related to knowledge, skills, and behaviors to support effective long-term weight management in areas of nutrition, activity, and health behavior change. The Adapt phase is intended to be a transitional phase when members are nearing their goal. In this phase, the nutritional structure is reduced as members are able to apply skills and behaviors (such as meal preparation and grocery shopping) more frequently. Knowledge and skills are reviewed during this phase to promote competency to support sustainable behavior change. The Sustain phase provides members with a nutrition and activity plan designed to support energy balance (i.e., weight maintenance). Members continue working with coaches in a 1-on-1 setting as they move through each phase to refine and reinforce skills and behaviors.



— PROFILE PHASED APPROACH —



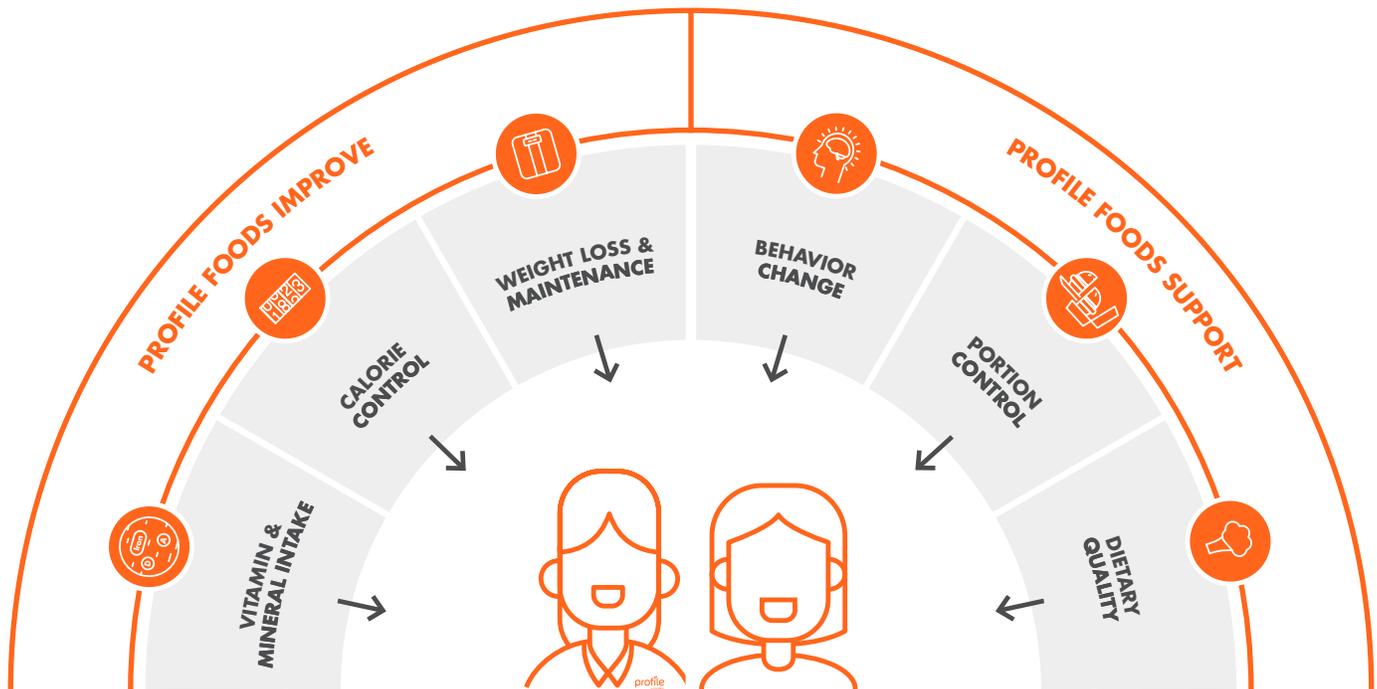
RATIONALE FOR MEAL REPLACEMENTS (MRS)

Early phases include more nutritional structure using MRs allowing coaches and members to focus on behaviors and skill building, such as portion control, meal preparation, label reading, and stress management skills. Over time, MRs are phased out of the meal plan to add for more dietary flexibility needed for long-term adherence.

Profile protocols incorporate FDA-approved MRs that include regulated nutrition facts labels as an evidenced-based tool to manage weight and improve health outcomes. MRs are endorsed by the Academy of Nutrition and Dietetics as an evidence-based practice to improve dietary quality amongst individuals who struggle with portion control and lack nutrient dense foods in

their diet.⁷ For over 20 years, evidence has supported the use of MRs to improve dietary quality and improve portion control practices. Previous work indicates that the consumption of MRs is beneficial to body composition and clinically significant metabolic parameters in males and females with overweight and obesity.⁹ One meta-analysis found that liquid MRs in weight loss produced modest reductions in body weight, BMI, systolic blood pressure, and clinically significant reductions in body fat, waist circumference, HBA1C, fasting glucose, fasting insulin, and diastolic blood pressure in individuals with overweight and obesity who were also diagnosed with type 2 diabetes.¹⁰ A systematic review examined 23 studies and found that programs incorporating

PROFILE FOODS SUPPORT MEMBERS IN A VARIETY OF WAYS





MRs yielded greater average weight loss at 1 year than studies that did not incorporate MRs. Programs that incorporated both MRs and support (such as the support offered from a health coach) resulted in greater weight loss than programs that only included support or did not include MRs or support.¹¹ Taken together, these findings emphasize the importance of pairing health coaching support with MRs that provide nutritionally dense and pre-portioned food options to reduce risk of chronic conditions.

One criticism of MRs is that energy-restricted MRs may not be sustainable for individuals to continue to utilize over time because of the perceived difficulty of maintaining this behavior in real-world settings.⁹ Alternatively, previous work indicates continued use of MRs as a viable strategy to maintaining weight loss long-term. The Look AHEAD Trail found that participants with the highest adherence to consumption of 2 MRs per day had the highest rate of weight loss or maintenance through 8 years of follow up.¹² Weight regain is common in studies utilizing MRs due, in large part, to high attrition rates spanning from 16% to 47%.^{13,14} Profile by Sanford addresses the sustainability of long-term MR use by incorporating fewer MRs in later protocols and relying on grocery foods to be the primary source of nutrients and calories. MR use in Sustain is optional, given the efficacy on long-term use and weight maintenance outcomes, though not required. Individuals who elect not to use MRs are instructed to use other portion-controlled meal strategies.



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MACRONUTRIENTS

The macronutrient composition of the diet varies based on the assigned protocol. For individuals joining to lose weight, managing carbohydrates has proven to be effective.²⁰ These individuals are assigned a ketogenic meal protocol, unless they have certain medical conditions. Ketogenic diets have resulted in greater weight loss, improvements in fasting triglycerides, enhanced appetite control, HDL cholesterol, and diastolic blood pressure when compared to a traditional low-fat, high protein diet.²¹ Older adults may benefit from increasing protein in their diet to reduce the risk of sarcopenia and stimulate muscle protein synthesis.²²

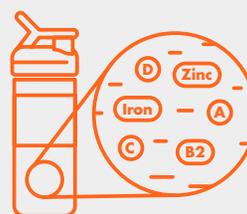


CALORIES

Calories vary based on the protocol assigned to each member. For individuals seeking weight management, calories are restricted in early phases to initiate weight loss. Long-term caloric restriction is associated with reduced food cravings,^{15,16} improved markers of aging,¹⁷ and increased metabolic and molecular health.¹⁸ Low calorie diets (LCDs) have shown improvements in liver and kidney function and reduction in the severity of several disorders aggravated by obesity, such as atherosclerotic disease, colorectal cancer, psoriasis, chronic obstructive pulmonary disease, and obstructive sleep apnea. The health promoting effects of LCDs in individuals with overweight or obesity depend on the extent of weight loss and, more specifically, fat mass reduction.¹⁹

MICRONUTRIENTS

Limited evidence suggests that micronutrient content and adequacy may be compromised when individuals restrict carbohydrates, namely: whole grains, cereals, and fruits.^{23,24} To minimize this risk, Profile MRs are fortified with vitamins and minerals. MRs are well complemented in later phases of protocols through inclusion of a variety of grocery foods, including whole grains, lean proteins, heart-healthy fat sources, fruits, low-fat dairy, and vegetables.



FDA REGULATED

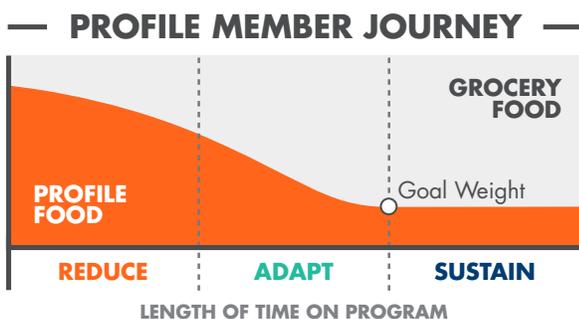
Profile MRs are fortified with vitamins and minerals and regulated by the FDA.

NUTRITION PROTOCOLS

Profile coaches are trained to deliver several nutrition protocols that have been designed by Registered Dietitians to provide a nutritionally complete meal plan while aligning with member goals. Weight loss nutrition protocols include Reboot and Balance, described below. Other nutrition protocols have been developed to support other populations with varied health goals from pre-pregnancy, pregnancy, and breastfeeding, to supporting individuals with high levels of exercise focused on performance.

THE REBOOT PROTOCOL

Profile’s Reboot 3-Phased (Reduce, Adapt, Sustain) Protocol is a safe, effective, and structured plan to help members reach a healthy weight while developing the skills and behaviors to improve health long-term. The plan focuses on foundational skills of increasing vegetable intake to 4+ cups per day and cooking a lean and green grocery meal. The weight loss phase (Reduce) provides a ketogenic meal plan that incorporates moderate protein (1.2-1.6g/kg Ideal Body Weight), low-carbohydrate (40-70g net carbohydrate), low-fat (25-35%), nutritionally complete plan with simple, easy-to-follow structure while members work with a Certified Profile Coach to increase physical activity and make healthy lifestyle changes. The Reboot Reduce meal plan consists of 950-1200 calories. During phase 2 (Adapt) and phase 3 (Sustain), members transition to more grocery foods and fewer to no Profile foods (including MRs) as they gain the behavioral tools to maintain their weight.



THE BALANCE PROTOCOL

Profile’s Balance 3-Phased (Reduce, Adapt, Sustain) Protocol is a weight loss and maintenance plan designed for individuals with certain medical histories, such as use of insulin where a lower carbohydrate meal plan would be contraindicated. In some medical cases, consent from an endocrinologist or physician may be required to begin a member’s Profile journey to lasting lifestyle change. The 3-phased approach begins with a balanced macronutrient distribution and lesser calorie deficit providing moderate protein (1.2-1.6g/kg Ideal Body Weight), moderate carbohydrate (40-45%), and low-fat (25-35%) to ensure a nutritionally complete plan.

THE MOM PROTOCOL

Developed by OB/GYNs and Registered Dietitians at Sanford Health and Profile, the Profile MOM Protocol is designed for women to optimize nutritional status and support health behaviors during the lifecycle stages of pre-conception, pregnancy, and breastfeeding. Nutrition plans encourage positive pregnancy outcomes through unique caloric targets supporting appropriate weight gain and rate of weight gain for each stage of pregnancy. Dietary recommendations are met through nutritionally complete meal plans, using a combination of grocery foods complimented with prenatal MRs designed to meet the nutritional needs of women before, during, and after pregnancy. More detail available upon request.



2. NUTRITION SKILL BUILDING

Due to the structure and simplicity of the meal plan in early phases, skill building of dietary and lifestyle behaviors is the primary focus in health coaching appointments. Education by itself is a small component of a comprehensive program. At Profile, it is believed that education is a powerful tool to change behavior when paired with a skillful health coach. Profile education resources are regularly presented in a “read, do, reflect” format in order to 1) introduce a skill/concept, 2) have the learner apply the skill/concept, and 3) have the learner reflect on the experience of applying a new skill/concept. Following this format increases the self-awareness and self-efficacy of the learner.²⁵ For example, effective meal planning requires knowledge of different meal planning options, the skill of executing meal planning, and reflecting on that experience to explore ways to continue with the behavior or make any necessary adjustments. Nutrition skills addressed through health coaching include, but are not limited to, food preparation, grocery shopping, and label reading. Health coaches work with individuals to increase confidence of cooking skills and provide resources for

food preparation. Findings support the idea that food preparation is associated with better diet quality and away-from-home food expenditures associated with lower dietary quality.^{26,27} Grocery shopping skills are accomplished through reviewing grocery lists and assisting individuals in preparing a list of nutrient-dense foods. Research indicates that use of a grocery list is associated with improved diet quality²⁸ and recognized as a cost-effective means for reducing obesity and related chronic conditions.²⁹ Finally, label reading is practiced and reviewed with a Certified Profile Coach. Label reading is associated with healthier diets and should be included in health policies and education programs.³⁰

Knowledge and skills are reinforced through SMART goal setting with a health coach. Health coaches are trained in motivational interviewing and work with members to identify reasons for change and help them devise a plan for change. For more information on Profile’s evidence-based health coaching and SMART goal setting, please refer to the white paper: “Health Coaching: The Science Behind Changing Lives.”



HOW PROFILE EDUCATION RESOURCES ARE PRESENTED



3. EATING BEHAVIORS

Mindful eating is non-judgmental awareness of physical and emotional sensations related to eating.³¹ Other eating focused mindfulness-based interventions yielded significant improvements in eating behaviors and psychological distress in adults with obesity.³² Additionally, mindfulness training has been shown to reduce binge eating as well as emotional eating.³³ Mindful eating is associated with positive body image³⁴ and could be a beneficial strategy to reduce impulsive food choices.³⁵ Both positive body image and flexible

eating restraint are important mechanisms for medium and long-term weight control.³⁶ The Profile program encourages individuals through health coaching and education to adopt mindfulness eating behaviors into everyday life.

A newer approach to improving dietary behaviors, body weight, eating disorders, and body image is self-compassion. Preliminary results suggest that self-compassion can be beneficial for weight loss, nutrition behaviors, eating behaviors, and body image.³⁷



Self-compassion interventions have been as effective as other behavior change techniques at improving self-regulation of health behaviors and provides a holistic approach toward improving dietary behaviors.³⁸ Health coaches work with members to implement self-compassion exercises in the member’s daily life to improve both physical and mental health.

Finally, individuals are encouraged to understand and reflect on the connection between emotions and food. Emotional eating is associated with higher levels of

psychological distress and higher BMI.³⁹ Health coaches help members identify healthy coping responses and effective stress management techniques, beyond eating, to address stress and negative emotions. Members are encouraged to identify stressful situations and typical emotions and responses that accompany those situations. From there, members work with coaches to plan new responses to stressful events that are more aligned with the member’s goals and values.



Based on Neff, 2003

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