Program Orientation

Amy Rothberg, MD, PhD ● Andrew Kraftson, MD ● Nevin Ajluni, MD ● Carol Catalano PA-C
Catherine Nay, MEd, RD, CHES ● Megan Brown, MPH, RD ● Nicole Miller, MPH, RD
**What is it?**

- Behavioral lifestyle program.
- 100 week program consisting of Physician/Provider and Dietitian visits.
- Very-low calorie diet followed by transition to balanced, individualized low calorie meal plans.
- Focus on long-term sustainable weight maintenance.

**Who may be eligible?**

- Age between 20 – 70* years old –AND--
- Body Mass Index (BMI) between 35 to 50 (kg/m^2)*
  - **Asian/Asian-Indian with BMI between 27 to 50.
- OR-
- BMI between 32 to 35 AND a weight-related health condition (e.g.: type 2 diabetes)

**Which insurers cover the program?**

- Blue Care Network (BCN)
- Blue Cross Blue Shield of Michigan (BCBSM)
- Health Alliance Plan (HAP)
- Priority Health
- Commercial (other): patient would be provided with billing codes to check with the insurer

*Medicare does NOT cover the program
WEIGHT MANAGEMENT PROGRAM — Brief Overview

Start: Orientation & Paperwork

Scheduling

Provider Visit:
- Medical history
- Exam
- Discussion
- Labs

Dietitian visit: Start the Diet

*Optional

Research*

Dietitian visit: Start the Diet

Research*

Very Low Calorie Diet Phase
- Weekly visits x 1 month
- Monthly visits, thereafter

Research*

Low Calorie Diet Phase

Research*

Maintenance Phase

Program Completion
- 100 weeks, total
Want to know some **STATISTICS** about the **PROBLEM** of **OBESITY**?

Check out **Appendix (A)**
We think it is important to know some of the FACTS about OBESITY.
Energy Intake
Ingestion of:
• Protein
• Fat
• Carbohydrate

Energy Expenditure (EE)
• Physical Activity (exercise)
• Diet-Induced Thermogenesis (energy needed to break down and metabolize food)
• Basal Metabolic Rate (energy burned while at rest and the biggest contributor to EE)

Body weight is determined by the balance between the calories we consume and the calories we expend (aka: “burn”).
What are the consequences of too much weight? Overnutrition leads to a number of metabolic problems that lead to diseases such as diabetes and heart disease.

**OBESITY HEALTH RISKS:**

- Heart disease
- Stroke
- Diabetes
- Kidney disease
- Blood clots
- Breathing problems
- Cancer
- Pregnancy complications
- Fatty liver disease
- Premature death
Want to have a better understanding of the DISEASE of obesity?

Check out Appendix (B)
PROGRAM GOAL: Identify strategies that will result in long-term weight management for individuals with obesity, using the latest research and clinical strategies.

We are committed to educating, motivating, and empowering individuals to make healthy lifestyle choices!
PERSONALIZED PROGRAM:
Multidisciplinary approach to weight loss and weight maintenance

Structured and organized into different phases:
- Initial: very low calorie diet
- Transition: low calorie diet
- Maintenance: individualized diet plan

Services: one-on-one sessions that provide...
- Medical guidance
- Advice regarding activity/exercise/conditioning
- Strategies for prevention of weight regain:
  - Behavioral
  - Nutritional
  - Pharmacological
What happens at the FIRST VISIT to the physician/provider?

- Your health and weight history is obtained.
- A physical exam is performed.
- Your current medication list is reviewed.
- Blood work (aka: labs) are performed.
- The research is discussed and your consent to participate is obtained (if you are interested).
ADJUST medication regimen

- Minimize ‘weight positive’ medications
- Substitute with weight neutral or weight negative medications
Recommendations will be customized based on health status.

- **Standard:** work up to 40-60 minutes of exercise/enhanced activity per day.
- **Initial** phase: low intensity activity
- **Maintenance** phase: moderate intensity activity
INITIATE caloric restriction

- Initial **very-low**-calorie diet (VLCD) (800 cals/day) or **low**-calorie-diet (LCD) (1000-1200 cals/day):
  - Meal substitution/replacement
  - Dietary counseling: One-on-one with registered dietitian (RD)
  - Initial emphasis on calories and caloric density, not fuel

*The meal replacement diet will not start until you meet formally with the program’s dietitian.*
VERY-LOW Calorie Diet (VLCD) Phase

- Duration: 8-12 weeks*
- Caloric intake: typically 800 calories/day*
- Product(s):
  - Optifast® 800 Shakes (or Ready-to-Drink shakes)
  - Optifast® soups
  - Optifast® Bars (*not used, initially*)
- Details: will be explained by the dietitian.
- Average diet: typically 4-5 shakes + 1 soup

*Variable: as determined by your provider

The meal replacement diet will not start until you meet formally with the program’s dietitian.
WHY use a VERY-LOW Calorie Diet (VLCD)?

- Research on diets using VLCD shows that it is an effective tool both for weight loss and maintenance of a reduced weight.
- It is intended to be a tool that is meant to be used on an intentional basis for a limited amount of time.
- It is a tool that can help the participant separate him/herself from unhealthy food habits by making meals “decision-free.”
- While on the VLCD, there is time to learn nutrition information and start practicing lifestyle and behavioral skills
WHEN is a VERY-LOW Calorie Diet (VLCD) used?

• Full meal replacement/ VLCD is appropriate for individuals who have a significant amount of weight to lose
  -AND-

• Past efforts to cut-back on food or follow a reduced calorie meal plan have not resulted in weight loss
  -OR-

• Past diet efforts have resulted in weight LOSS but the reduced weight could not be SUSTAINED.
WHAT amount of weight loss should be expected on the VERY-LOW Calorie Diet (VLCD)?

- Every individual is DIFFERENT!
- In general, the following would be reasonable expectations:
  - After 1-4 weeks: a weight loss of 3-5%
  - After 5-8 weeks: a weight loss of 7-10%
  - After 9-12 weeks: a weight loss of 11-15%
CAN individuals with DIABETES use a VERY-LOW Calorie Diet (VLCD)?

• YES! Optifast® is frequently recommended by physicians for their patients with diabetes because of the foods' nutritional formulation and low calories.

• Your medication(s) will be monitored by our physicians/providers and dosage may change throughout the program.
Optifast® products are generally well tolerated by most people.

Optifast® POWDERED shake mix (chocolate, vanilla, and strawberry) DO contain lactose. All other products are lactose-free.

Some of our products, however, contain common allergens such as DAIRY, EGGS, WHEAT, SOY AND PEANUTS.

Please let us know if you have any allergies prior to beginning the shake regime, or if any GI discomfort occurs.
WHAT is the COST of OPTIFAST®?

• You are responsible for purchasing the product (~$2.50 per shake or ~$12-14/day). Insurance does NOT cover the cost of meal replacements.

• Of note: The average American spends $151/week on food according to the US Bureau of Labor Statistics Consumer Expenditure Survey.
HOW does the COST of OPTIFAST® compare to fast food purchases?

![Comparison chart showing costs of different fast food chains.](chart.png)

Source: Citi Research, NPD Crest, FRSH Investor Presentation, Blaze Investor Presentation
HOW does the COST of OPTIFAST® compare to other weight management programs?

- The costs of our program our comparable to/ competitive with many major commercial weight programs.
• We know that weight loss at **2 weeks** is associated with the amount of weight loss at **4 weeks**.
• Therefore, if the weight loss goal at 2 weeks is not what is expected, we will re-assess any barriers or issues related to diet and help you navigate through any challenges.
• If the weight loss at 4 weeks is again less than expected, we will discuss alternative strategies.

Notice that there is a difference, even early on, between those who complete the program and those who leave the program early (and struggle)
Want to learn more about the RESEARCH DATA surrounding MEAL REPLACEMENT?

Check out Appendix (C)
LOW Calorie Diet (LCD) Phase

- Initiation: following ~15% weight loss, “conventional” food is gradually reintroduced. This is tailored to your needs & preferences.
- Duration: Variable.
- Purpose: transition from full meal replacement back to convention food in a STRUCTURED way.
Weight MAINTENANCE Phase

- Duration: Entire rest of the program
- Purpose: Maintain the REDUCED WEIGHT STATE
- Methods:
  - Dietary counseling/education
  - Behavioral techniques
  - In appropriate situations, the following may be considered:
    - Referral to a therapist
    - Use of weight control medication(s)
What **RESULTS** have been attained by participants?

**Average % MAINTAINED weight LOSS at TWO YEARS**

Baseline weight change

- **14% mean:** 38 lbs
- **11% mean:** 28 lbs

Note: this is sustained weight loss

Adapted from: Rothberg et al., 2014 J Diabetes Complications
What RESULTS have been attained by participants? – here’s another view of the data:

Weight Maintenance by Sex

- Male
- Female

Baseline | Week 2 | Week 4 | Week 8 | Week 12 | Week 18 | Week 24 | Week 32 | Week 36 | Week 40 | Week 44 | Week 52 | Week 56 | Week 60
--- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | ---
129 | 125 | 120 | 114 | 110 | 106 | 104 | 104 | 106 | 103 | 103 | 103 | 103 | 103
111 | 107 | 104 | 100 | 97 | 94 | 92 | 90 | 91 | 93 | 93 | 92 | 92 | 93
85 | 90 | 90 | 91 | 90 | 90 | 90 | 90 | 90 | 90 | 90 | 90 | 90 | 90
Those who complete our 2 year program continue to have markedly reduced weight from baseline weight despite some weight regain (which we expect) and why we have aggressive weight loss goals early in the program. Those who went on to withdraw, lost weight initially, but regained most of their weight lost.
What **RESULTS** have been attained by participants with **DIABETES**?

**Effect on Diabetes** *(study n=58)*

<table>
<thead>
<tr>
<th>A1c UNDER 7%</th>
<th>A1c OVER 7%</th>
</tr>
</thead>
<tbody>
<tr>
<td>40% Baseline</td>
<td>60% Baseline</td>
</tr>
<tr>
<td>76% Follow-up</td>
<td>24% Follow-up</td>
</tr>
</tbody>
</table>

- **Sixty percent** of patients with established diabetes had baseline HbA1c over 7.0%.

- **At follow-up**, 76% of patients had HbA1c **UNDER 7.0**%.

- **At follow-up**, 100% of patients with **newly diagnosed diabetes** and 76% of patients with established diabetes had HbA1c **UNDER 7.0**%

- **At follow-up**, 57% of patients were on ≤ 1 diabetes medication(s)

Adapted from: Rothberg et al., 2014 J Diabetes Complications
Research programs are offered by the UNIVERSITY OF MICHIGAN. Research is separate from the clinical program, but can be helpful to add important information to help you manage your health. Participation is voluntary.
RESEARCH COMPONENT: “PHENOTYPING”

• **WHAT IS IT?** It is an examination of gene-gene interactions and gene-environmental interactions for the purposes of understanding the biology of weight regulation.

• **WHY DO IT?** This better understanding may help us identify the factors that predict success for weight loss and maintenance of weight loss. Furthermore, this may be the key to changing our treatment paradigms so that they become *even more* individualized and *even more* effective.
  
  ▪ We believe that the research is integral to the *understanding of obesity*.
  ▪ It may also lead to finding/examining potential novel therapeutic targets.

• **MUST I DO IT?** NO - Participation is VOLUNTARY.
RESEARCH COMPONENT: “PHENOTYPING”

WHEN DO I GO FOR TESTING?

- **INITIAL TESTING:** after seeing the physician/provider but BEFORE starting the diet.
- **INTERIM:** after you achieve a certain degree of weight loss (typically 10-15%)
- **FINAL:** At the END of the program
RESEARCH COMPONENT: “PHENOTYPING”

*NOTE: ~1/3rd of the participants in the program have Type 2 diabetes mellitus and many were undiagnosed prior to OGTT.
WHAT will be done with the RESEARCH information?

- If you participate in research, information and data that is relevant to your care will be shared with you and your primary physician/provider. This information includes your resting energy expenditure, your VO2 max (aka: exercise capacity/level of fitness), your body composition data from DEXA, and your oral glucose tolerance test results.

- This information is NOT shared with your insurance company.
Want to learn more about the different RESEARCH COMPONENTS?

Check out Appendix (D)
Please fill out "INITIAL EVALUATION FORM" and all the QUESTIONNAIRES BEFORE your first physician visit. Remember to BRING these with you to your first appointment. You may also email them to wmpconnection@med.umich.edu.

You will complete the questionnaires again following ~15% weight loss and at the end of the 2 year program.
QUESTIONS CONCERNS?

Please contact:

➤ Nicole Miller, MPH, RD: npiazza@med.umich.edu

Need to set up your first visit? Please call: 734-647-5871

Other contact information:

• Catherine Nay, MEd, RD, CHES: catkraus@med.umich.edu
• Megan Brown, MPH, RD: schleifm@med.umich.edu

• Carol Catalano, PA-C: cacatala@med.umich.edu
• Andrew Kraftson, MD: andrewkr@med.umich.edu
• Nevin Ajluni, MD: noksuz@med.umich.edu
• Amy Rothberg, MD, PhD: arothber@med.umich.edu
The Impact of weight loss on health-related quality of life
www.ncbi.nlm.nih.gov/pubmed/24129672

The impact of a managed care obesity intervention on clinical outcomes and costs: A prospective observational study

Very-low-energy diet for type 2 diabetes: An underutilized therapy?
www.ncbi.nlm.nih.gov/pubmed/24849710
APPENDIX A: The Scope of Obesity
Where is obesity most common in the US?
Obesity is especially common in the South. It has 10 out of the 12 states with the highest obesity rates, including Mississippi along with Alabama and Tennessee, which tied for second place.
Obesity Rates: United States

MICHIGAN is one of 12 states with a prevalence of obesity greater than 30%.
Other Sources of Information:

- **Documentary:** [https://www.hbo.com/documentaries.the-weight-of-the-nation](https://www.hbo.com/documentaries.the-weight-of-the-nation)

- **CDC website:** [https://www.cdc.gov/obesity/data/adult.html](https://www.cdc.gov/obesity/data/adult.html)
APPENDIX B:
A Scientific Understanding of Obesity
The conditions of OVERWEIGHT and OBESITY are a response to an environment of too many calories and/or sedentary lifestyle in genetically susceptible individuals. At the moment, we cannot change our genes. We can influence EPIGENETICS (aka: early life events) of our children by maintaining a healthy weight or reducing weight in women and men before pregnancy.
In addition, lifestyle habits adopted in childhood can result in excess weight and poorer health in adulthood perpetuating the vicious cycle.
What are some of the EXTERNAL FACTORS contributing to the rise in obesity?
ECONOMIC & ENVIRONMENTAL FACTORS

• Reduction in job strenuousness (physically)

• Hours spent in our cars commuting

• Reduction in food prices introduced by technological change
ECONOMIC & ENVIRONMENTAL FACTORS

• Increased demand for inexpensive convenience food and one-stop shopping

• Habit/pattern of food consumption

• “Addiction” to macronutrients

• Increased food-away-from home

• Domestic Appliances

• Increase in tobacco prices leading to smoking cessation (yay!), but leading to increase in food intake (boo!)
Food intake is a complex process. The AMOUNT AND TYPE of food ingested is determined by:

- Genes
- Environmental setting
- Experience
REGULATION OF EATING

Why we eat, what we eat and the amount we eat is governed by:

- Taste perception
- Meal size, calorie density
- Environmental setting
- Signals from our gut system and fat tissue relay information to our brain and visa versa to tell us we are hungry or full.
CALORIC DENSITY as a concept

Think of foods in terms of CALORIES PER POUND

- Fresh corn: 490
- Tortillas: 980
- Tortilla chips: 2450
CALORIC DENSITY as a concept

Think of foods in terms of CALORIES PER POUND

The lower in caloric density, the greater the volume and the fewer the number of calories. Fresh corn has far fewer calories than a similar serving size of tortillas (made from corn) and Tostito’s® (a product of corn).
Our sense of hunger and fullness are determined by complex interactions between a number of peptides (proteins) and hormones (such as leptin, PYY, CCK, ghrelin, and insulin) that relay signals from our gut to our brain. We are studying these signals and processes.
As you may know, our eating patterns are affected by more than the caloric and nutritional value of food. The emotional and pleasurable aspects of feeding affect food intake.

It will come as no surprise, then, that the brain (particularly parts of the brain called the hypothalamus and the brainstem) has a central role in coordinating the many nutrient, hormonal, and behavioral signals to regulate food intake, metabolism, and ultimately body weight.
There are other parts of the brain involved in mediating the motivational (drive to eat), cognitive, and emotional components of food intake. Gaining a better understanding of the brain’s role in weight is one of our goals.
APPENDIX C: Meal replacement DATA
Meal Replacements Enhance Initial and Long-term Weight Loss

- The following slide summarizes data from one scientific study that helps illustrate why we elect to use an aggressive meal replacement strategy.

- The graph shows a comparison of a conventional diet versus a meal replacement diet (with eventual transition to food).

- The results show that at the end of the study period, despite both groups being on similar diets, the group that started with meal replacement lost more weight, overall.
Meal Replacements Enhance Initial and Long-term Weight Loss

*1200–1500 kcal/d diet prescription.
CF=conventional foods.
MR-2=replacements for 2 meals, 2 snacks daily.
MR-1=replacements for 1 meal, 1 snack daily.

Fletchner-Mors et al. Obes Res 2000;8:399
APPENDIX D: Research Element DETAILS
PROCEDURES

*Note: this is not a complete list of the procedures. For full details, an appointment with the research coordinator will be arranged.
Metabolomics is the analysis of small molecules that generate a specific fingerprint of your current metabolic state at any given time point. It allows us to characterize some of the dynamic changes that occur in response to nutrients.

- Metabolomics is the analysis of small molecules that generate a specific fingerprint of your current metabolic state at any given time point. It allows us to characterize some of the dynamic changes that occur in response to nutrients.
- DNA looking at obesity-related genes

MIXED MEAL TOLERANCE TESTING:
3 hour test examining hormones (insulin, glucose, and fat hormones) in response to nutrients.
DXA
Measures body composition including fat free mass, fat mass and bone density
BOD POD
Alternative method to measure fat free mass and fat mass
RESTING ENERGY EXPENDITURE
Measures the fuel the body burns at rest (the number of calories burned at rest)
V02 MAX

Exercise capacity is highly predictive of disease risk, longevity and may predict the ability to lose weight. Graded exercise test done on a treadmill.