The Food Prescription for Cardiovascular Disease

An Old Remedy for the Future of Medicine

MONTGOMERY HEART & WELLNESS

beyond the script

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Overview

- General Patient Profile
- Standard Cardiovascular Evaluation and Intervention
  - Basic Clinical Assessment
  - Optimize Standard Medical Therapies
- Nutritional Integration
  - The Food Prescription Classification System
  - The Clinical Food Prescription Program
  - The Nutritional Boot Camp Class
- Program Specifics
- Clinical Example
- Data Analysis of the Food Rx Effects
  - Food Rx Effects on CV Hemodynamics
  - Food Rx Effects on Cardiac MRI
  - Food Rx Effects on Cardiac Biomarkers
- Concluding Remarks – Proposed Future Outlook
General Patient Profile
Patient Profile Summary

- Married women between 45 – 65 years old
- Head of Households
- Homemakers and professionals
- Average Income between $50 and $75K
- Commercial Insurance and Medicare
- Cardiovascular Disease with at least Two Comorbidities
- Average of 4 – 5 Prescription Medications
Assess the Patient’s Clinical Condition

- General Clinical Evaluation
- History and Physical Examination
- *Detailed Nutritional History*
- Activity Level Assessment
- Biochemical Assessments
- Physiological Assessments
- Assignment to Clinical Category

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Assignment to Clinical Category

**Category 1**  
Optimal Health  
Normal Exam  
Normal Testing  
Physically Fit  
Start Levels 0-6 with at least annual 0-4b or 0-3 Detox Regimes

**Category 2**  
Suboptimal Health  
Abnormal Exam or Abnormal Testing  
No Requirements of Medical or Surgical Therapies  
Start Levels 0-3 for 4 weeks then Levels 0-6 for 2-3 Months

**Category 3**  
Chronic/Stable or Slowly Declining Health  
Chronically Stable or Slowly Declining Health Requiring Medical/Surgical Therapies  
Start Levels 0-3 for 4-8 weeks then Levels 0-6 for 2-3 Months

**Category 4**  
Moderately Declining Health  
Chronic, Progressively Declining Health Requiring Increase Intensity of Medical/Surgical Therapies  
Start Levels 0-3 for 8-12 weeks then Levels 0-6 for 2-3 Months

**Category 5**  
Acute Decompensation of Chronic Illness  
Acutely or Sub-acutely Declining Illness Requiring Urgent or Emergent Medical/Surgical Therapies  
Start Level 0 or Levels 0-3 for 4 weeks then Levels 0-4a for 2-3 Months
Optimized Standard Medical/Surgical Therapies

* Add or Reduce Medications
* Consider and Discuss Possible Needed Surgeries or Procedures
* Attempt to Delay Medical/Surgical Therapies if Possible

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Nutritional Integration
The *Food Prescription* System of Classifying Food

- A system of assigning foods and other nutritional substances to categories based on their ability to facilitate optimal biochemical and physiological function.
- Simple 0 – 10 classification scheme
- Utilizes Five Basic Characteristics of Foods:
  - Fundamental Source of Origin – plant, animal, inorganic mineral, or synthetic (vitamins, etc.)
  - Conditions of Development
  - Level of Processing
  - Basic Chemical Characteristics
  - Potential Effects on the Human Body

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Overview of the Food Classification System

MHW Food Classification System

Level 10: All other foods not included in levels 0-9

Level 9: Inclines meats and animal products

Level 8: Steamed/baked foods

Level 7: Glycerine index > 70

Level 6: Glycerine index > 55

Level 5: Glycerine index > 45

Level 4: Glycemic index > 65

Level 3: Glycemic index > 55

Level 2: Raw foods

Level 1: Raw foods & water

Level 0: 100% Plant-Based

Diet: Level 0-4; Maintenance: Level 0-6; Danger Zone: Level 7+

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# Overview of the Food Classification System

<table>
<thead>
<tr>
<th>Zones</th>
<th>Detoxification Zone</th>
<th>Slow Healing or Maintenance Zone</th>
<th>Disease Development or Progression Zone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Food Levels</td>
<td>Food Level 0</td>
<td>Food Level 4</td>
<td>Food Level 7</td>
</tr>
<tr>
<td></td>
<td>Food Level 1</td>
<td>Food Level 5</td>
<td>Food Level 8</td>
</tr>
<tr>
<td></td>
<td>Food Level 2</td>
<td>Food Level 6</td>
<td>Food Level 9</td>
</tr>
<tr>
<td></td>
<td>Food Level 3</td>
<td></td>
<td>Food Level 10</td>
</tr>
</tbody>
</table>

Source: montgomeryheart.com
The Essence of The Food Rx System:

- Provides a structured nutritional plan
- Goes beyond calorie counting and portion measuring
- Allows for measuring compliance
- Allows for evaluating efficacy
- Enables therapeutic precision
Program Specifics
The Facility

- Independent Location
- Free Parking
- Six Private Patient Rooms
- Onsite Phlebotomy
- Diagnostic Suite
- Onsite Restaurant, Nutrition Center and Food Laboratory
- Fitness Room
- Private ECP Therapy Rooms

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Two Main Structured Programs

The Food Prescription Plan

The Nutritional Boot Camp

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The Food Prescription Plan

* Three Month Clinical Intervention (Covered by Insurance)
  * The Food Prescription is the Foundation of Treatment
  * Medications and Procedures are Adjuncts to the Treatment Plan
  * Baseline and Follow-up Medical Testing Done to Evaluate Progress
  * Progressive Medication Weaning is Done

* Clinical Evaluation by Health and Wellness Team
  * Wellness Coordinators
    * Nutritionist
    * Fitness Specialist
  * Nurse Practitioners
  * Nutritional Chefs
  * Cardiac Technicians
  * Oversight by Cardiologist

* Phase 1 – First Month Nutritional Detox Regimen
  * Food Levels 0 – 4b
  * Prescheduled Weekly Visits and Evaluations

* Phase 2 – Two Month Nutritional Maintenance Regimen
  * Food Levels 0 – 6
  * Monthly Visits and Evaluations
  * Transition to Nutritional Boot Camp Class

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Nutritional Boot Camp Class

* One Month Educational Program
  * Group Setting
  * Food Demonstrations
  * Group Lectures
  * Shopping Rounds
  * Food Preparation/Cooking Classes
* Nonclinical
* Private Pay
* Open to the General Public (not only patients)
* Initiate Other Healthy Lifestyle Interventions
  * Exercise
  * Massage Therapy
  * Etc.

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Clinical Example
Clinical Example

- Patient SC is a 59 year-old man who presents with a desire to undergo our wellness program:
  - Reported Symptoms
    - Fatigue
    - Eye Pain (chronic without dx after complex evaluation)
    - Headaches
  - No Symptoms of Chest Pain, Shortness of Breath, or Palpitations
  - Exam/ Labs:
    - PE – normal BP-136/81
    - TC- 317; LDL-227; HDL-70; Trigs- 286
    - Hs-CRP- 1.4; HgbA1C- 6.3
  - Diagnoses
    - Type 2 diabetes (recent diagnosis)
    - Elevated cholesterol levels (for a few years)
    - Hypertension
Patient SC (continued):

- **Dietary History**
  - Fruits and vegetables
  - Fish and chicken
  - Dairy and eggs
- **Activity Level** – exercise 2-3 times per week
- **Medications** – Excedrin (for eye pain)
- **Clinical Category** – Three
- **Plan:**
  - Food levels 0-4b for 4 weeks
  - Continue current meds for eye pain
  - Obtain baseline cardiac studies and biomarkers
Clinical Example –
Compliance

Overall compliance:

<table>
<thead>
<tr>
<th>Eating at Food Level</th>
<th>Week 1</th>
<th>Week 2</th>
<th>Week 3</th>
<th>Week 4</th>
<th>Total Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0.70</td>
<td></td>
<td></td>
<td></td>
<td>17.9%</td>
</tr>
<tr>
<td>0-3</td>
<td>0.30</td>
<td>1.00</td>
<td>0.86</td>
<td>1.00</td>
<td>78.6%</td>
</tr>
<tr>
<td>0-4a</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0%</td>
</tr>
<tr>
<td>0-6</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0%</td>
</tr>
<tr>
<td>0-7+</td>
<td></td>
<td></td>
<td></td>
<td>0.14</td>
<td>3.5%</td>
</tr>
<tr>
<td></td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>

- **Subjective Findings:**
  - Increased energy after initial week
  - Eye pain subsided after 10 days on Food Prescription
  - Eye pain recurred after eating beyond level 7 on 4/16
  - Pain again subsided after resuming plan
Clinical Example – Results

Systolic Blood Pressures

Diastolic Blood Pressures

Weights

30-Day Changes in Biomarkers

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30-Day Overall Clinical Changes (%)

- SBp
- DBp
- Wt
- Total Cholesterol (mg/dL)
- LDL-C (mg/dL)
- HDL-C (mg/dL)
- Triglycerides (mg/dL)
- hs-CRP (mg/dL)
- HgbA1C (%)

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Data Analysis on the Effects of *Food Rx*
Food Rx Effects on CV Hemodynamics
Overview

• **Background**
  - Plant-based nutrition has been shown to have beneficial effects on cardiovascular disease.
  - *Can a plant-based nutritional regimen be used effectively in a clinical setting to show immediate positive changes in cardiovascular parameters?*

• **Program Description**
  - Fifteen (15) individuals ages ≥ 18 years of age participated in a 4-week nutritional boot camp program
  - Instructed not to change their exercise routine
  - They were assisted with medication changes as needed
  - Assessments of CV hemodynamics and weights were made
    - BP’s, Weights, Waist Circumference, BMI’s weekly
    - Cardiac Output, SVR, Stroke Volume, Thoracic Fluid Content, Pulse Rate using the BioZ ICG device at baseline and completion
  - Group Educational Sessions were held weekly
    - Lectures
    - Food Demonstrations
    - Shopping Rounds
Results

- Trend towards ↑ Cardiac Output
- ↑ Stroke Volume (Significant)
- ↓ SVR (Significant)
- ↑ Thoracic Fluid Content (preload) (Significant)
- ↓ Pulse Rate (Significant)
- ↓ Systolic and Diastolic Blood Pressures (Significant)
- ↓ In Weight, Waist Circumference and BMI (Significant)
<table>
<thead>
<tr>
<th>Measure</th>
<th>Effect for time</th>
<th>Linear trend</th>
<th>Quadratic trend</th>
<th>Cubic trend</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Systolic Blood Pressure</strong></td>
<td>F(4,56)=7.99, p=&lt;.0001</td>
<td>F(1,56)=14.87, p=0.0003</td>
<td>F(1,56)=2.75, p=0.1032</td>
<td>F(1,56)=7.33, p=0.009</td>
</tr>
<tr>
<td><strong>Diastolic Blood Pressure</strong></td>
<td>F(4,56)=5.81, p=0.0006</td>
<td>F(1,56)=7.86, p=0.0069</td>
<td>F(1,56)=1.59, p=0.2126</td>
<td>F(1,56)=7.61, p=0.0078</td>
</tr>
<tr>
<td><strong>Weight (lbs.)</strong></td>
<td>F(4,56)=12.96, p=&lt;.0001</td>
<td>F(1,56)=35.6, p=&lt;.0001</td>
<td>F(1,56)=6.47, p=0.0138</td>
<td>F(1,56)=2.46, p=0.1224</td>
</tr>
<tr>
<td><strong>Waist Circumference (in)</strong></td>
<td>F(4,52)=8.55, p=&lt;.0001</td>
<td>F(1,52)=25.81, p=&lt;.0001</td>
<td>F(1,52)=3.57, p=0.0643</td>
<td>F(1,52)=0.31, p=0.5776</td>
</tr>
<tr>
<td><strong>BMI (kg/m²)</strong></td>
<td>F(4,56)=12.92, p=&lt;.0001</td>
<td>F(1,56)=37.26, p=&lt;.0001</td>
<td>F(1,56)=5.56, p=0.0219</td>
<td>F(1,56)=2.05, p=0.1575</td>
</tr>
</tbody>
</table>

**Mixed Model Measures Design**
- Examines Changes Over Time
- Linear Trend – straight incr./decr.
- Quadratic Trend – one bend in the line
- Cubic Trend – two bends in the line

**SBP and DBP Trends**
- Linear
- Cubic

**Weight and BMI Trends**
- Linear
- Quadratic

**Waist Circumference Trends**
- Linear
- Trended toward Quadratic

**Significance of Difference**
- Suggests BP and Wt. Changes to be Independent of each other
- Suggests Independent Mechanisms
- Suggests BP Reduction not Secondary to Weight Reduction

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Anthropometric and BP Trends

SBP Changes

Baseline Week-1 Week-2 Week-3 Week-4

Baseline 110.00 115.00 120.00 125.00 130.00 135.00 140.00 145.00 150.00

Cubic Trend with two bends in the curve

Bend 1

Bend 2

DBP Changes

Baseline Week-1 Week-2 Week-3 Week-4

Baseline 72.00 74.00 76.00 78.00 80.00 82.00 84.00 86.00 88.00

Bend 1

Bend 2

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Anthropometric and BP Trends

Weight Changes

Baseline Week-1 Week-2 Week-3 Week-4

BMI

Quadratic Trends Showing Single Bends in Curves

Waist Circumference
Advanced Hemodynamic Changes

**Cardiac Output (L/min) (NS)**

- Baseline: 5.19
- Week-4: 5.67

**Stroke Volume (cc)**

- Baseline: 66.6
- Week-4: 77.53

**System Vascular Resistance (Dyn*Sec/cm5)**

- Baseline: 1648.67
- Week-4: 1213.6

**Pulse Rate (beats/min)**

- Baseline: 79.19
- Week-4: 72.81

**Thoracic Fluid Content (cc)**

- Baseline: 21.52
- Week-4: 23.31

Source: montgomeryheart.com
Advanced Hemodynamic Changes in One Month

- Cardiac Output (L/min): -9.3%
- Stroke Volume (cc): 16.4%
- System Vascular Resistance (Dyn*Sec/cm5): -26.4%
- Thoracic Fluid Content (cc): 8.3%
- Pulse Rate (beats/min): -8.1%

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Advanced Hemodynamic Changes

Complete Anthropometric and Hemodynamic Changes in 30-Day Period

-30.0%
-25.0%
-20.0%
-15.0%
-10.0%
-5.0%
0.0%
5.0%
10.0%
15.0%
20.0%

-20.0%
-15.0%
-10.0%
-5.0%
0.0%
5.0%
10.0%
15.0%
20.0%

-30.0%
Food Rx Effects on Cardiac MRI
Overview

• **Background**
  - Plant-based nutrition has been shown to have beneficial effects on cardiovascular disease.
  - *Can a plant-based nutritional regimen be used effectively in a clinical setting to show increased EF, LVH regression, and improved cardiac performance with cardiac MRI?*

• **Program Description**
  - Case Series of three patients with chronic symptomatic CHF
    - EF 22% > 1 year on average
    - NYHA II-III
    - Ischemic CHF
  - Patients treated with standard heart failure management with addition of Food Prescription plan
    - Food Levels 0-4a for approximately 6 weeks then Levels 0-6 thereafter
    - Patients were monitored clinically with medication changes made as needed
  - Cardiac MRI’s done at baseline and on follow up (average of 78 days later)
Overview

• **Results**
  - ↑ LV Ejection Fraction
  - ↑ Cardiac Output
  - ↑ Stroke Volume
  - ↓ LV Mass
  - ↓ End-diastolic Volume
  - ↓ End-systolic Volume

• **Comments**
  - Promising Results
  - More Work Needed
Improved Cardiac MRI Function

**Average LVEF**

- Baseline: 22.1%
- Follow-up (Avg. 79 days): 42.3%

**Cardiac Output (L/min)**

- Baseline: 3.6
- Follow-up (Avg. 79 days): 4.2

**LV Stroke Volume (cc)**

- Baseline: 55.9
- Follow-up (Avg. 79 days): 90.4

**Average Percentage Change in LV Function**

- LV Ejection Fraction: 85.1%
- Stroke Volume: 61.7%
- Cardiac Output: 16.7%
Average Change in LV Mass and Size

Change in LV Mass and Size

- LV Mass (gms): Baseline 214.0, Follow-up 170.0
- End-diastolic Volume (cc): Baseline 252.7, Follow-up 220.7
- End-systolic Volume (cc): Baseline 197.0, Follow-up 133.3

Average Change in LV Mass and Size

- LV Mass: -20.6%
- End-diastolic Volume: -12.7%
- End-systolic Volume: -32.3%
Overall CMRI Changes

Total CMRI Changes with Food Rx Intervention

LV Ejection Fraction: 85.1%
Stroke Volume: 61.7%
Cardiac Output: 16.7%
LV Mass:
End-diastolic Volume: -20.6%
End-systolic Volume: -32.3%
Additional Problem in One Patient

* 46-years-old
* Medical History
  * Obesity
  * Pre-diabetes
  * High Blood Pressure
* Symptoms
  * Chest Pain that woke her from sleep
  * Shortness of Breath with exertion
  * Fatigue
* Initial Heart Test Findings
  * Abnormal EKG
  * EF of 20% to 25% on Echo and 24% on MRI

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After 95 Days of Level 0-4b

BEFORE

CRITICAL NARROWING

AFTER
Food Rx Effects on Cardiac Biomarkers
Overview

• **Background**
  - Plant-based nutrition has been shown to have beneficial effects on cardiovascular disease.
  - *Can a plant-based nutritional regimen be used effectively in a clinical setting to show immediate positive changes in cardiovascular biomarkers?*

• **Program Description**
  - Approximately 200 individuals (95 for CRP and SED rate) ages ≥ 18 years of age participated in a 4-week nutritional boot camp program
  - Instructed not to change their exercise routine
  - They were assisted with medication changes as needed
  - Assessments of CV and metabolic biomarkers were made at baseline and at four week follow-up
    - Cholesterol Panel
    - Blood Glucose
    - HgbA1C
    - CRP
    - SED Rate
    - Blood Pressures
    - Basic Anthropometrics
  - Group Educational Sessions were held weekly
    - Lectures
    - Food Demonstrations
    - Shopping Rounds
Biomarker Results

Change in Four Weeks (%)

-35.0%
-30.0%
-25.0%
-20.0%
-15.0%
-10.0%
-5.0%
0.0%

Change in Four Weeks (%)
Concluding Remarks
Proposed Future Outlook

- **State-of-the-Art Medical and Research Center**
  - Comprehensive Onsite Diagnostics and Therapeutics
  - Continual Data Capture and Mining
    - Optimize Clinical Management
    - Enhance Patient Feedback on Clinical Progress
    - Continued Research
- **Integrated Health and Wellness Center**
  - Onsite Restaurant and Nutrition Center
  - Onsite Fitness Center
- **Future Investigational Goals for Nutritional Interventions**
  - Advanced Heart Failure
  - Atrial Fibrillation
  - Ventricular Arrhythmias
  - LVH

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Thank You!

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