Diabetes Specific Nutrition Formula (DSNF) For Diabetes Management & Cost Reduction

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“Let thy food be thy medicine, and let thy medicine be thy food.”

Hippocrates, father of medicine
Diabetes 1

Prevention and management of type 2 diabetes: dietary components and nutritional strategies

Sylvia H Ley, Osama Hamdy, Viswanathan Mohan, Frank B Hu

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Summary of Meta-analysis of Prospective Studies of Nutrient Intake and Glycemic Variables and Type 2 Diabetes

DHA=docosahexaenoic acid EPA-eicosapentaenoic acid. Relative risks are comparison of extreme categories, except DHA/EPA (per 250 mg per day increase) and alpha-linolenic acid (per 0.5 g per day).

All nutrients and glycemic variables were assessed from dietary intake, except vitamin D for which blood 25hydroxyvitamin D was used.
Summary of Meta-analysis of Prospective Cohort Studies on Food and Beverage Intake and Type 2 Diabetes

Relative risks are comparison of extreme categories, except for processed meat (per 50 g per day increase), unprocessed red meat and fish or seafood (per 100 g per day), white rice (per each serving per day), whole grains (per three servings per day), sugar-sweetened beverages in European cohorts (per 336 g per day), and alcohol (22 g per day for men and 24 g per day for women with abstainers)

Dietary intervention for Patients with Type 2 Diabetes

- Carbs to 40-45%
- Glycemic index
- Protein intake 1.0-1.5 gm/kg
- Fiber
- MUFA
- Saturated fat from meat
- Sodium

Natural food (dinner menus and snacks) and Calorie Replacement

Joslin Diabetes Center
Diabetes-Specific Formulas (DSFs) are designed to improve glucose control

<table>
<thead>
<tr>
<th>Diabetes-Specific</th>
<th>Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Defined nutrient composition to enable better glycemic control</td>
<td>May compromise glycemic control in patients with diabetes</td>
</tr>
<tr>
<td>Modified carbohydrate (low glycemic)</td>
<td>High in rapidly digested carbohydrate (high glycemic)</td>
</tr>
<tr>
<td>Modified fat: favors monounsaturated (MUFA) fats</td>
<td>Lower fat</td>
</tr>
<tr>
<td>May reduce need for additional insulin to maintain good glycemic control¹,²</td>
<td>May require more attention to maintain glucose control</td>
</tr>
<tr>
<td>Clinically demonstrated efficacy in people with diabetes</td>
<td>Limited efficacy demonstrated in people with diabetes</td>
</tr>
</tbody>
</table>

Total estimated cost of diabetes in 2012 was $245 billion (41% up from 2007), with $176 billion direct cost and 69 billion reduced productivity.

Largest component of medical expenditures attributed to diabetes was hospital inpatient care (~43% of costs).
Differences in Resource Utilization Between Diabetic Patients Receiving Diabetes-Specific Nutrition Formula Versus Standard Nutrition Formula In US Hospitals
Objective and Methods

■ Design

– Retrospective review of all inpatients within Premier Research Database
– N=>500 geographically diverse hospitals
– Comparisons made between:
  ● Diabetic patients fed diabetes specific formula (DSNF)
  ● Diabetic patients fed standard nutrition (STD)

Population Flow

Diabetic Population
8.8 million discharges (2000-2009)

Fed either STD or DSF
193,473 discharges

Tube Fed
85,481 discharges

DSNF
37,171 discharges

Standard Formula
48,310 discharges

Results

- Feeding DSF to patients with diabetes results in significant* improvement in patient efficiency and cost of care

<table>
<thead>
<tr>
<th>Per patient</th>
<th>Tube Fed DSNFs</th>
<th>Oral Fed DSNFs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average Length of Hospital Stay</td>
<td>-0.9 days</td>
<td>-0.17 days</td>
</tr>
<tr>
<td>Total Hospital Costs</td>
<td>-$2,586</td>
<td>-$1,356</td>
</tr>
</tbody>
</table>

* Average LOS and hospital cost statistically significant at P < 0.001
Using DSNF drives reduction in room & board, pharmacy, and labor costs for tube fed patients

Tube Fed PWD - $2,586 total savings per patient

Note: Analysis adjusted the Other cost consistent with total cost savings since all costs independently modeled. Other costs include Surgery, Lab, Diagnostic Imaging, and Cardiology. All cost values statistically significant at $P < 0.0001$ except TF Central Supply Costs ($P < 0.003$). N for each sample population > 30k
“Regarding enteral nutritional therapy, diabetes-specific formulas appear to be superior to standard formulas in controlling postprandial glucose, A1C and the insulin response.”

“Based on this available evidence, the ESPEN expert group endorses the utilization of DSFs for nutritional support of people with obesity and diabetes.”
Significant Reduction in Weight By DSF in Patients With Diabetes in Association With Reduction in Glycemic Variability

Changes in Weight

<table>
<thead>
<tr>
<th>Weight (kg)</th>
<th>Baseline</th>
<th>3 Months</th>
<th>6 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;5% wt loss DSN- (n=38)</td>
<td>90</td>
<td>85</td>
<td>80</td>
</tr>
<tr>
<td>&gt;5% wt loss DSN+ (n=40)</td>
<td>92</td>
<td>88</td>
<td>83</td>
</tr>
<tr>
<td>DSN (n=29)</td>
<td>91</td>
<td>87</td>
<td>82</td>
</tr>
</tbody>
</table>

DSN = diabetes-specific nutrition.

*Data logarithmically transformed for analysis.
Significant Reduction in HbA1c By DSF in Patients With Diabetes in Association With Reduction in Glycemic Variability

Changes in HbA1c

*Data logarithmically transformed for analysis.
Strong Correlation Between Meal Replacements and Weight Loss (Look AHEAD Study)

Number in the bar is mean number of MRs used in that quartile

<table>
<thead>
<tr>
<th>Quartile</th>
<th>Percentage Weight Loss (%)</th>
<th>MRs</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st</td>
<td>-5.9%</td>
<td>117</td>
</tr>
<tr>
<td>2nd</td>
<td>-7.2%</td>
<td>277</td>
</tr>
<tr>
<td>3rd</td>
<td>-9.4%</td>
<td>406</td>
</tr>
<tr>
<td>4th</td>
<td>-11.2%</td>
<td>608</td>
</tr>
</tbody>
</table>

MRs = meal replacements

Reproduced with permission from Wadden TA et al. Obesity 2009; 17:713-722
Estimated Cost-Saving After Why WAIT Program for 1 Year

Cost Saving
[1% wt loss]

Cost saving per year:
- $256 (-3.6%)
- $131 (-5.8%)

Estimated Saving in WW
[7.6% wt loss]

Cost saving per year:
- $1,946 (-27%)
- $996 (-44%)

Health Care Cost
Diabetes Related Cost

YU AP et al. Curr Med Res Opin. 2007;23(9):2157-69
Effect of Different Diabetes-specific Formulas Versus Oatmeal on Plasma Glucose Area Under the Curve (AUC)

Each meal is 200 Kcal

*\( p<0.05 \), **\( p<0.01 \), ***\( p<0.001 \) Versus Oatmeal

\( \dagger \)\( P<0.05 \), \( \ddagger \)\( P<0.01 \), \( \ddagger\ddagger \)\( P<0.001 \) Between Glucerna & Ultra-Glucose control

N=22

AUC 0-240 (Area Under the Curve)

Oatmeal = 5933.3
Glucerna = 1684.2***
Ultra-Glucose Control = 3351.1***
Positive AUC0-120 was significantly higher Formula 2 than after OM (p=0.02)
positive AUC$_{0-240}$ was significantly higher after both formulas than after OM (p<0.001 for both)
Positive AUC0-240 was significantly higher after both formulas than after OM (p<0.001 for both)
Amylin (active)

Nutrition Path Study
Structured Meal Plan

Calorie Distribution
• 40-45% from carbohydrates
• 30-35% from fat with <10% from saturated fat
• 1-1.5 gm/kg of body weight from protein
• 14g fiber/1000 Kcal

Diabetes-Specific Nutrition Formula
1-3 times/day to replace equivalent calories

Dinner Menus
17 choices with detailed ingredients, cooking instructions and nutrition facts

Snack Lists
Includes 100 and 200 calorie snacks

Mottalib A et al. Nutr J. 2018;17(1):42. doi:10
A1C is significantly different between groups over time ($p=0.0006$)* $p<0.01$ and ** $p<0.001$ compared to baseline.
Weight loss

-0.95
-3.5
-2.7
-5
-4
-3
-2
-1
0

Group A
Group B
Group C

* p<0.001 compared to baseline

Mottalib A et al. Nutr J. 2018;17(1):42. doi:10
Abdominal Adiposity

Waist Circumference

Visceral Fat

% Change from baseline

* $p<0.05$ and ** $p<0.01$ compared to baseline

Mottalib A et al. Nutr J. 2018;17(1):42. doi:10
## Incretin Therapies: Major Differences

<table>
<thead>
<tr>
<th>Properties/Effect</th>
<th>GLP-1 Receptor Agonists(^1,2)</th>
<th>DPP-4 Inhibitors(^1,2)</th>
<th>MNT with DSF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin production</td>
<td>+++</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td>Amylin</td>
<td>NO</td>
<td>NO</td>
<td>+</td>
</tr>
<tr>
<td>GLP-1</td>
<td>-</td>
<td>+</td>
<td>++</td>
</tr>
<tr>
<td>PYY</td>
<td>NO</td>
<td>NO</td>
<td>++</td>
</tr>
<tr>
<td>Gastric emptying</td>
<td>Delayed</td>
<td>No effect</td>
<td>NO</td>
</tr>
<tr>
<td>Food intake</td>
<td>down</td>
<td>No effect</td>
<td>down</td>
</tr>
<tr>
<td>Body weight</td>
<td>down</td>
<td>No effect</td>
<td>down</td>
</tr>
<tr>
<td>Visceral Fat</td>
<td>NO</td>
<td>NO</td>
<td>down</td>
</tr>
<tr>
<td>Side effects</td>
<td>Nausea, vomiting</td>
<td>Minimal</td>
<td>NO</td>
</tr>
</tbody>
</table>

“Medical Nutrition Therapy (MNT) throughout the course of a structured weight loss plan, is strongly recommended”

“Studies have demonstrated that a variety of eating plans, varying in macronutrient composition, can be used effectively and safely in short term (1-2 years) to achieve weight loss in people with diabetes. This includes structured low-calorie meal plans that include meal replacements”
Clinical evidence from RCTs indicate that DSNF, as suggested medical food, improves outcomes in patients with diabetes


- Better postprandial glucose control
- Increase GLP-1 and satiety hormones
- Lower A1C
- Reduce glycemic variability
- Reduce body weight
- Reduced insulin requirements
- Reduce LOS and hospital cost

GLP-1=glucagon-like peptide; HbA1c=glycated hemoglobin.
Thank You