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

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HARVARD MEDICAL SCHOOL

"Let thy food be thy medicine, and
let thy medicine be thy food."

Hippocrates, father of medicine

THE LANCET

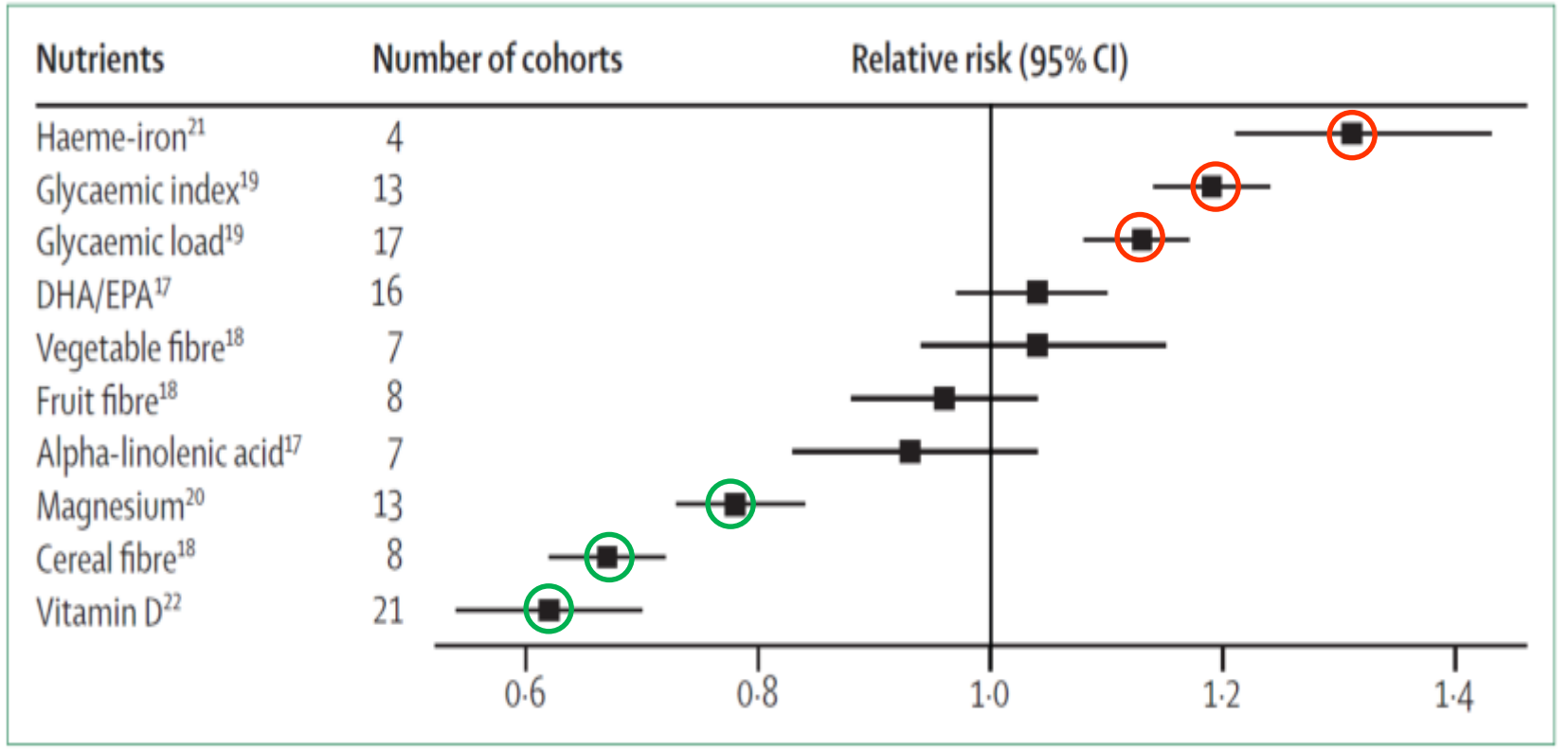
Diabetes 1

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

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

Vol 383 June 7, 2014

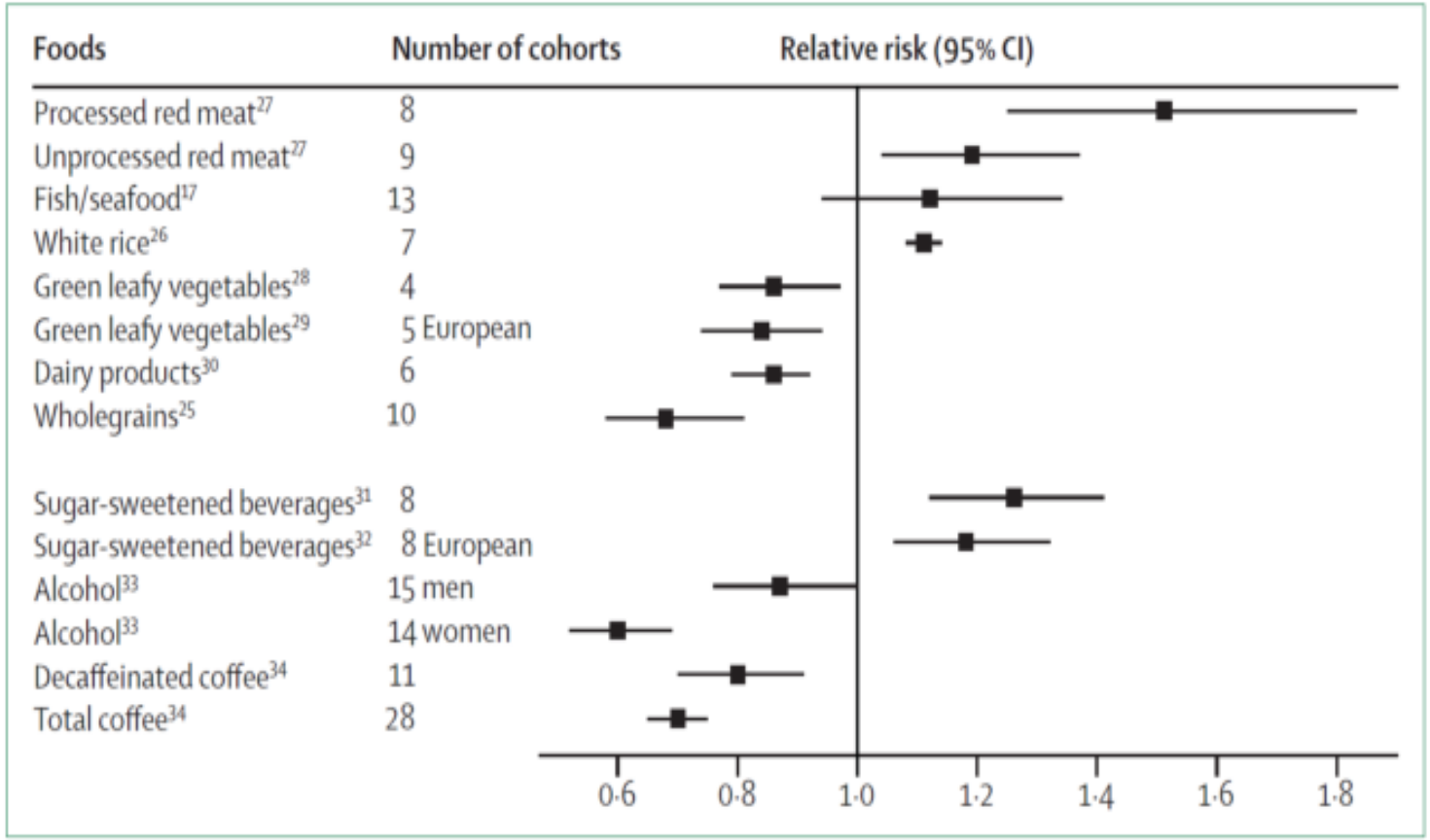
Summary of Meta-analysis of Prospective Studies of Nutrient Intake and Glycemic Variables and Type 2 Diabetes



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.

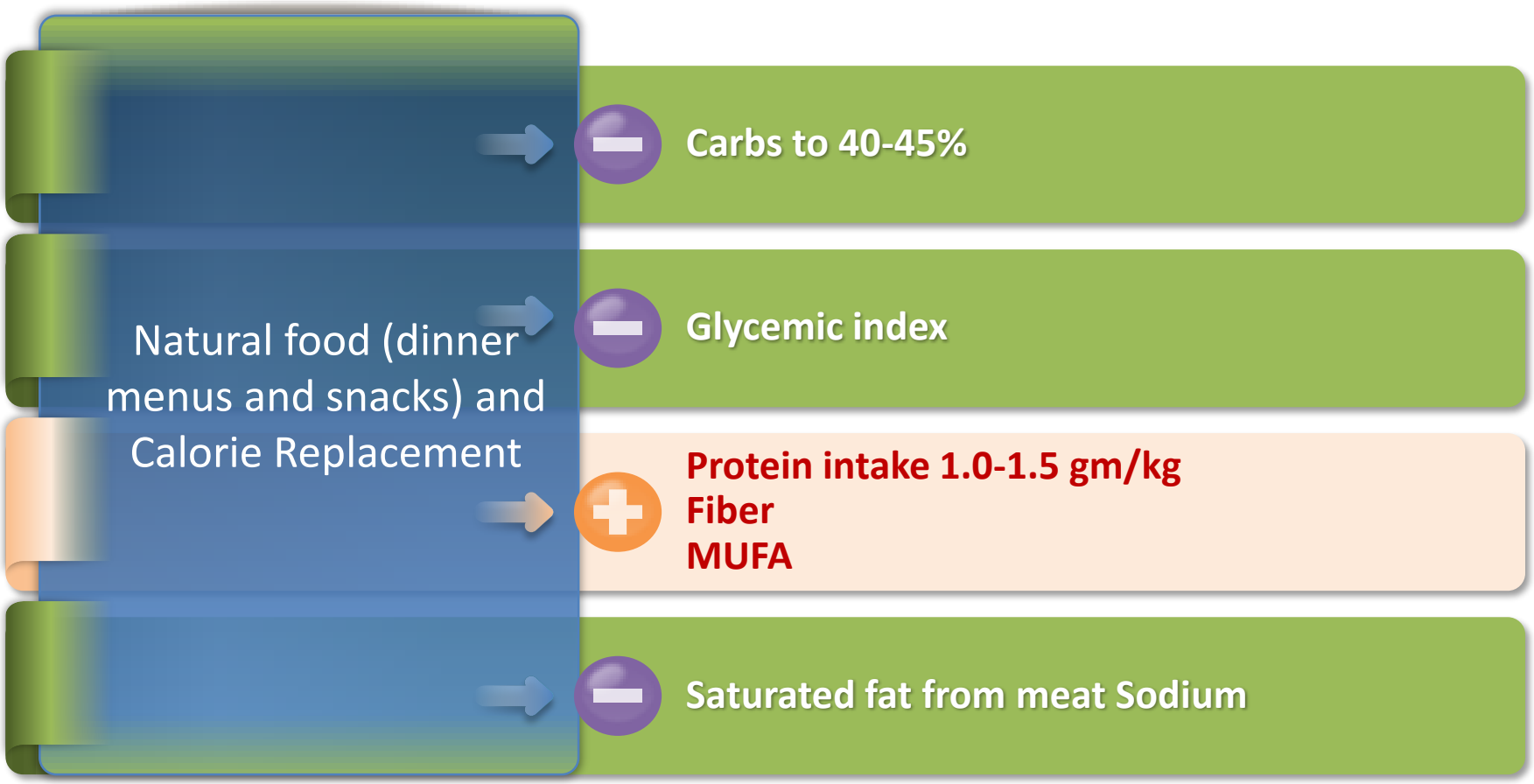
Summary of Meta-analysis of Prospective Cohort Studies on Food and Beverage Intake and Type 2 Diabetes



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)

Ley SH, Hamdy O, Mohan V, Hu FB. *Lancet*. 2014;383(9933):1999-2007.

Dietary intervention for Patients with Type 2 Diabetes



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

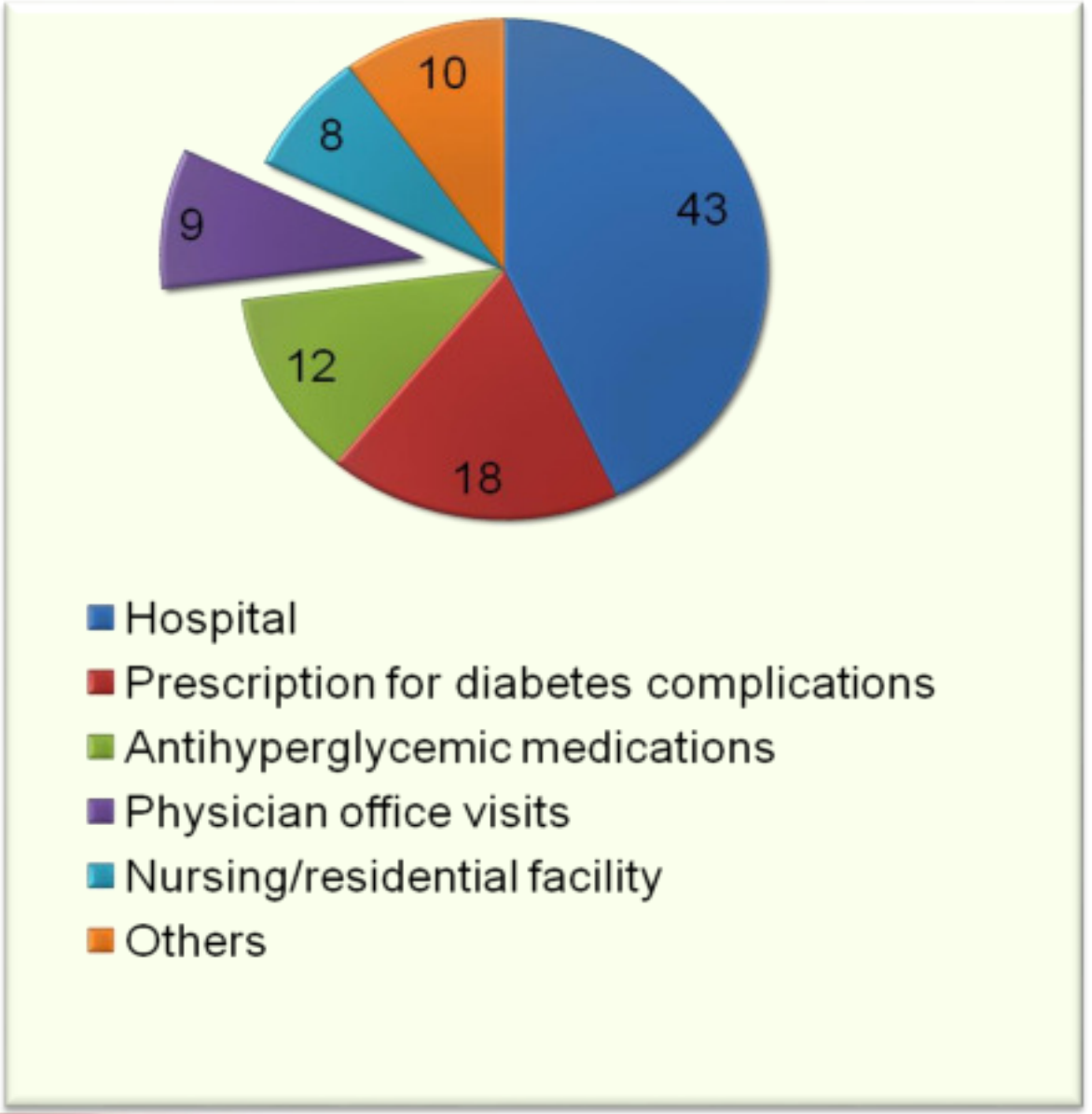
Diabetes-Specific	Standard
Defined nutrient composition to enable better glycemic control	May compromise glycemic control in patients with diabetes
Modified carbohydrate (**low glycemic)**	High in rapidly digested carbohydrate (**high glycemic)**
Modified fat: favors monounsaturated (MUFA) fats	Lower fat
May reduce need for additional insulin to maintain good glycemic control[1,2]	May require more attention to maintain glucose control
Clinically demonstrated efficacy in people with diabetes	Limited efficacy demonstrated in people with diabetes

1. Elia M, et al. *Diabetes Care*. 2005;28(9):2267–2279.
2. Mesejo A, et al. *Crit Care*. 2015;19:390. doi: 10.1186/s13054-015-1108-1.

COSTS OF DIABETES

- 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)

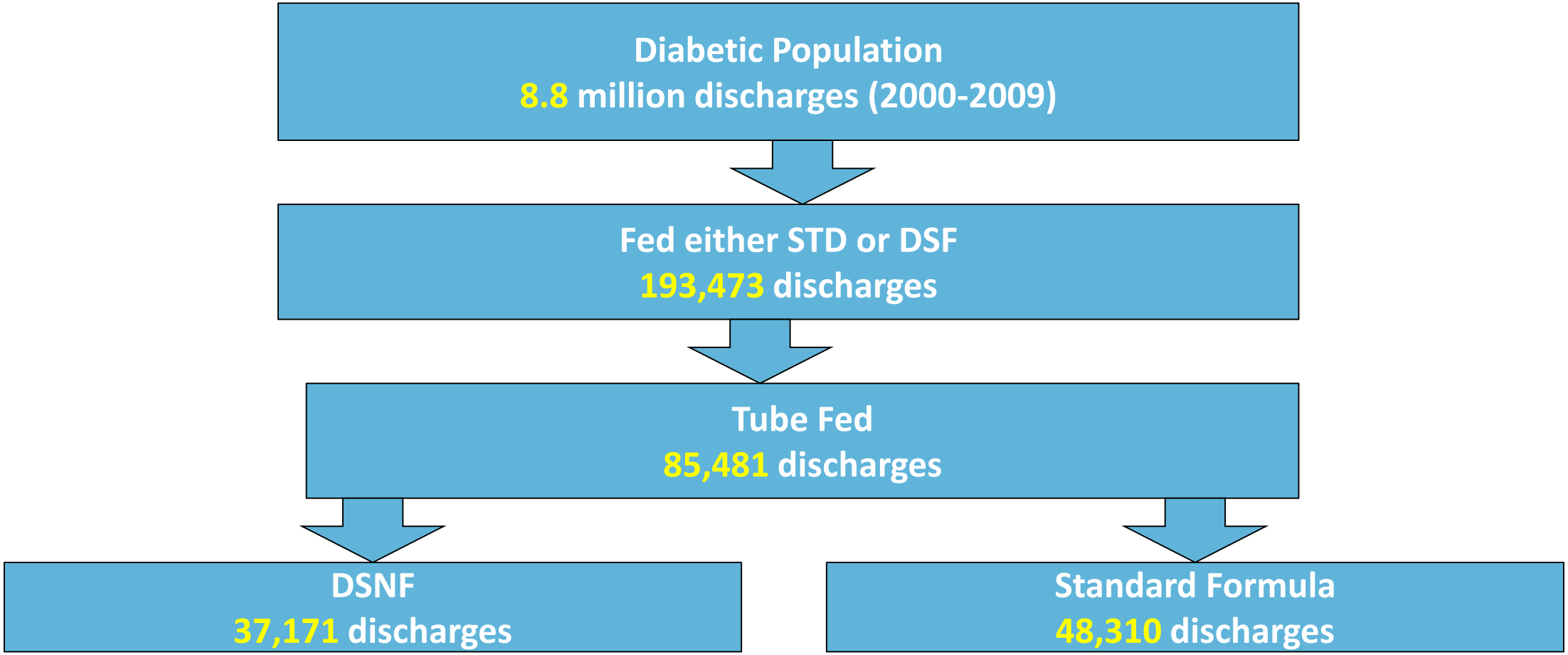


Differences in Resource Utilization Between Diabetic Patients Receiving Diabetes-Specific Nutrition Formula Versus Standard Nutrition Formula In US Hospitals

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



Results

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

	Savings from feeding DSF rather than STD formula
Per patient	Tube Fed DSNFs
Average Length of Hospital Stay	-0.9 days
Total Hospital Costs	-$2,586

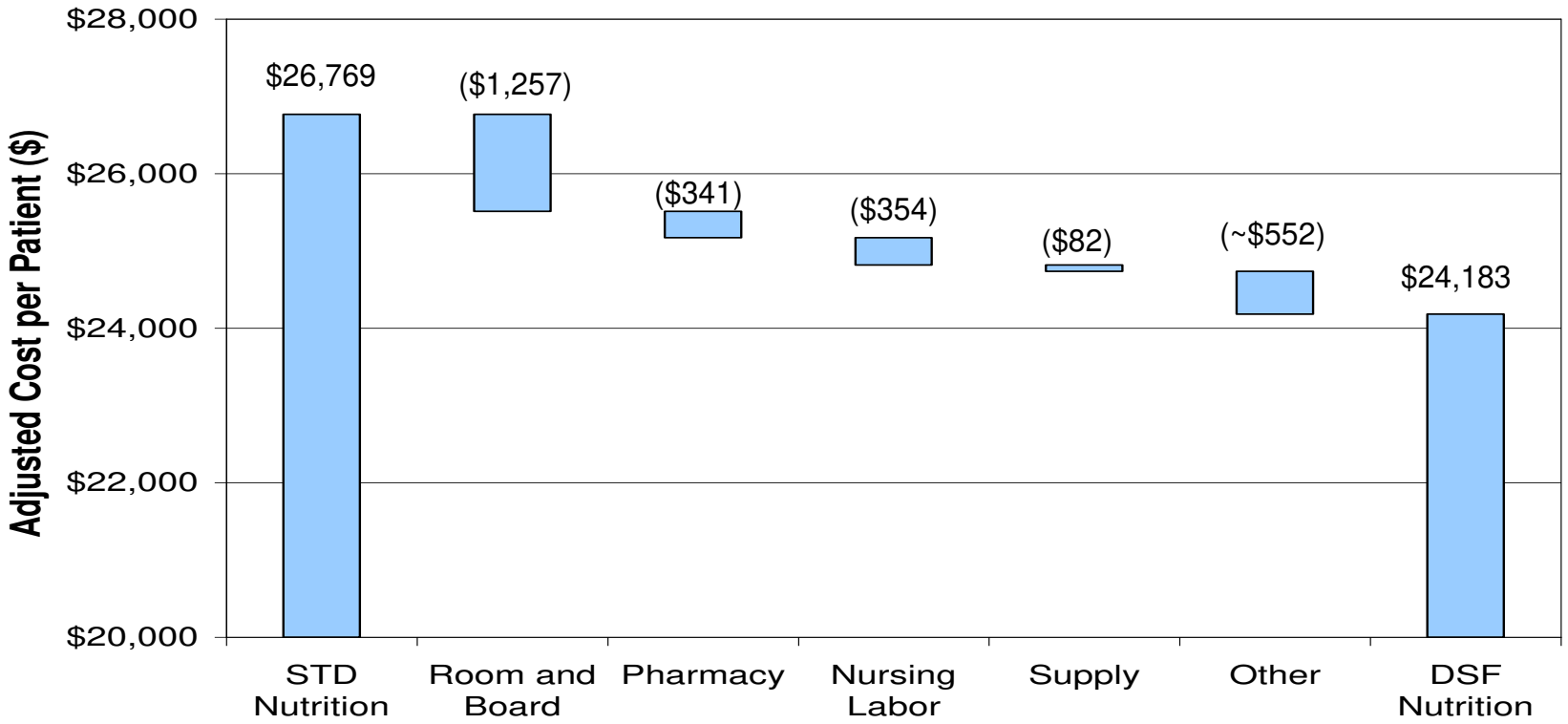
* Average LOS and hospital cost statistically significant at $P < 0.001$

Per patient	Oral Fed DSNFs
Average Length of Hospital Stay	-0.17 days
Total Hospital Costs	-$1,356

Hamdy O et al. JPEN J Parenter Enteral Nutr. 2014; 38(2 Suppl):86S-91S.

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

Expert recommendations for DSF

14. Diabetes Care in the Hospital: *Standards of Medical Care in Diabetes—2018*

Diabetes Care 2018;41(Suppl. 1):S144–S151 | https://doi.org/10.2337/dc18-S014

American Diabetes Association®

*"Regarding enteral nutritional therapy, **diabetes-specific formulas appear to be superior** to standard formulas in controlling postprandial glucose, A1C and the insulin response."*

Review

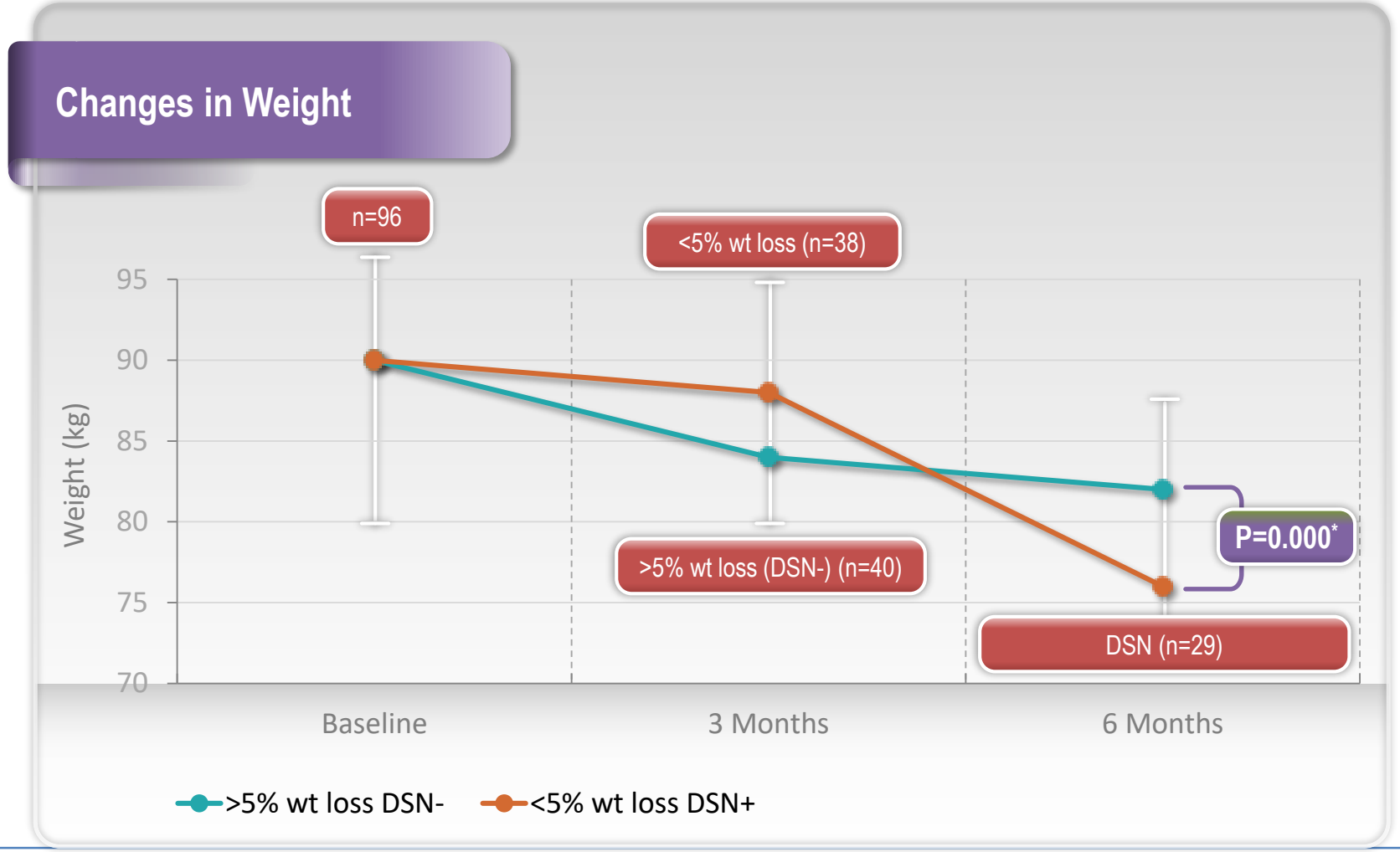
Clin Nutr. 2017 Apr;36(2):355-363

Carbohydrates and insulin resistance in clinical nutrition: Recommendations from the ESPEN expert group

ESPEN
The European Society for Clinical Nutrition and Metabolism

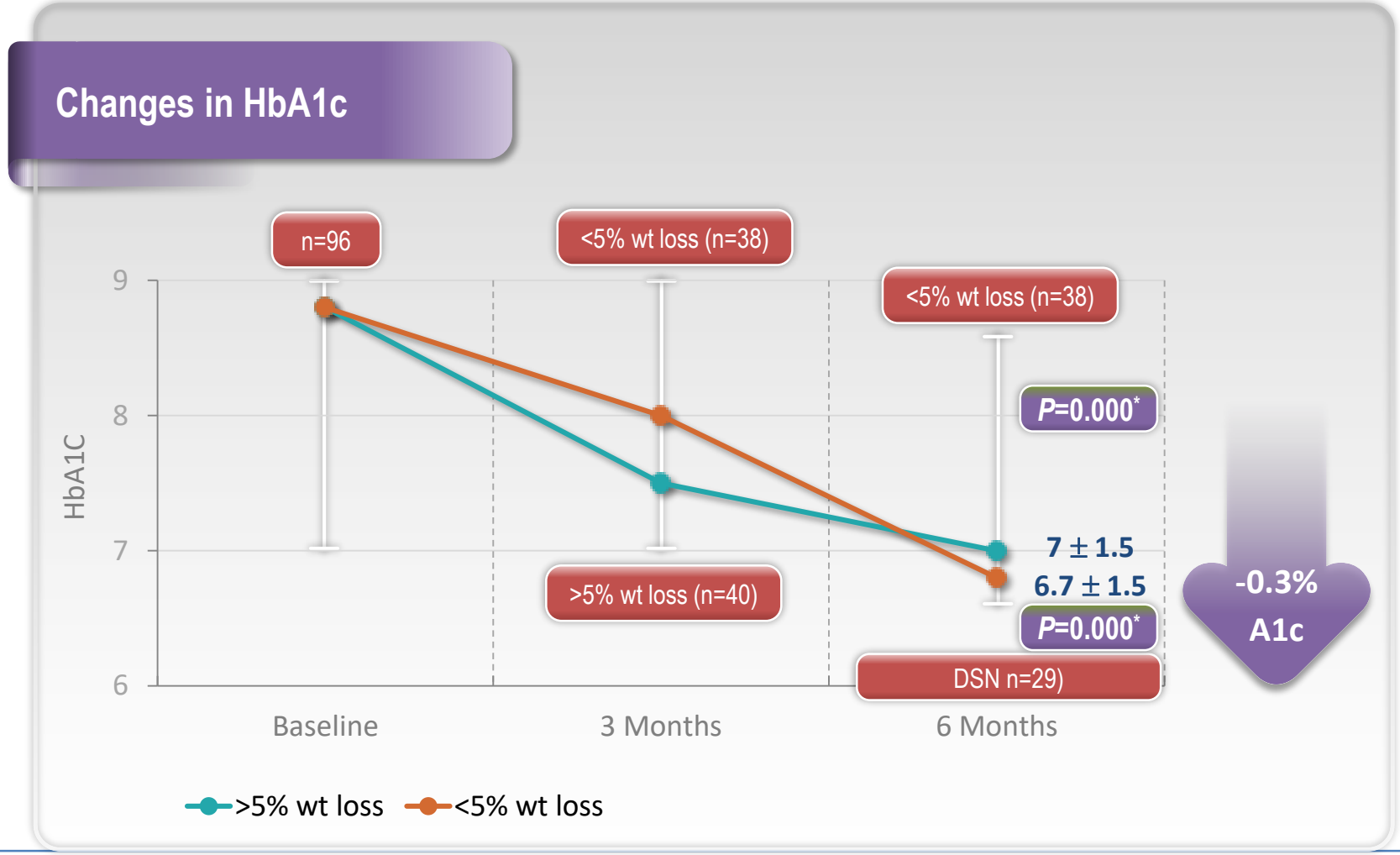
*"Based on this available evidence, the ESPEN expert group **endorses the utilization of DSFs for nutritional support of people with obesity and diabetes**."*

Significant Reduction in Weight By DSF in Patients With Diabetes in Association With Reduction in Glycemic Variability



DSN = diabetes-specific nutrition.
*Data logarithmically transformed for analysis.
Tatti P, et al. *Med J Nutrition Metab*. 2010;3:65-69.

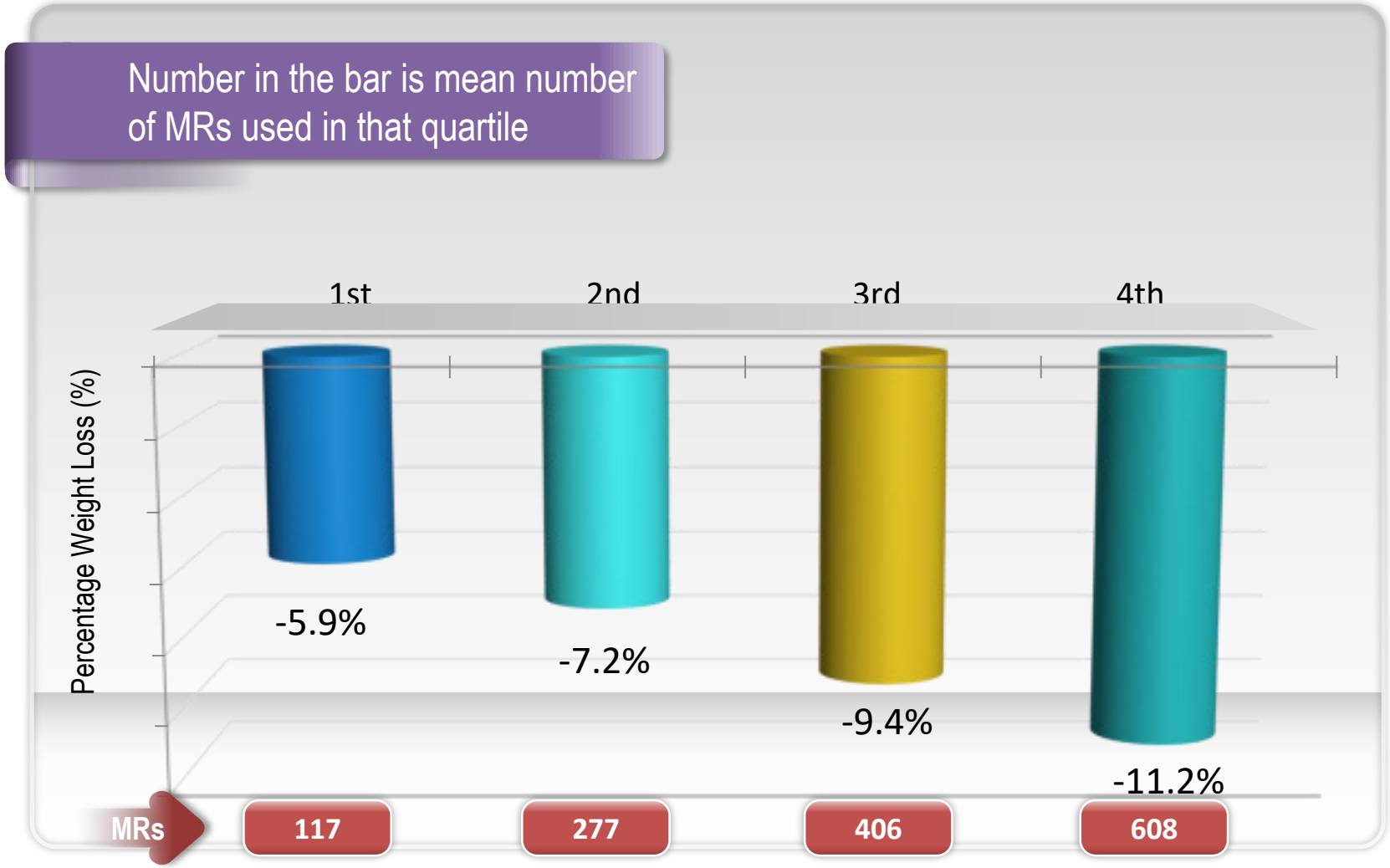
Significant Reduction in HbA1c By DSF in Patients With Diabetes in Association With Reduction in Glycemic Variability



*Data logarithmically transformed for analysis.

Tatti P, et al. *Med J Nutrition Metab*. 2010;3:65-69.

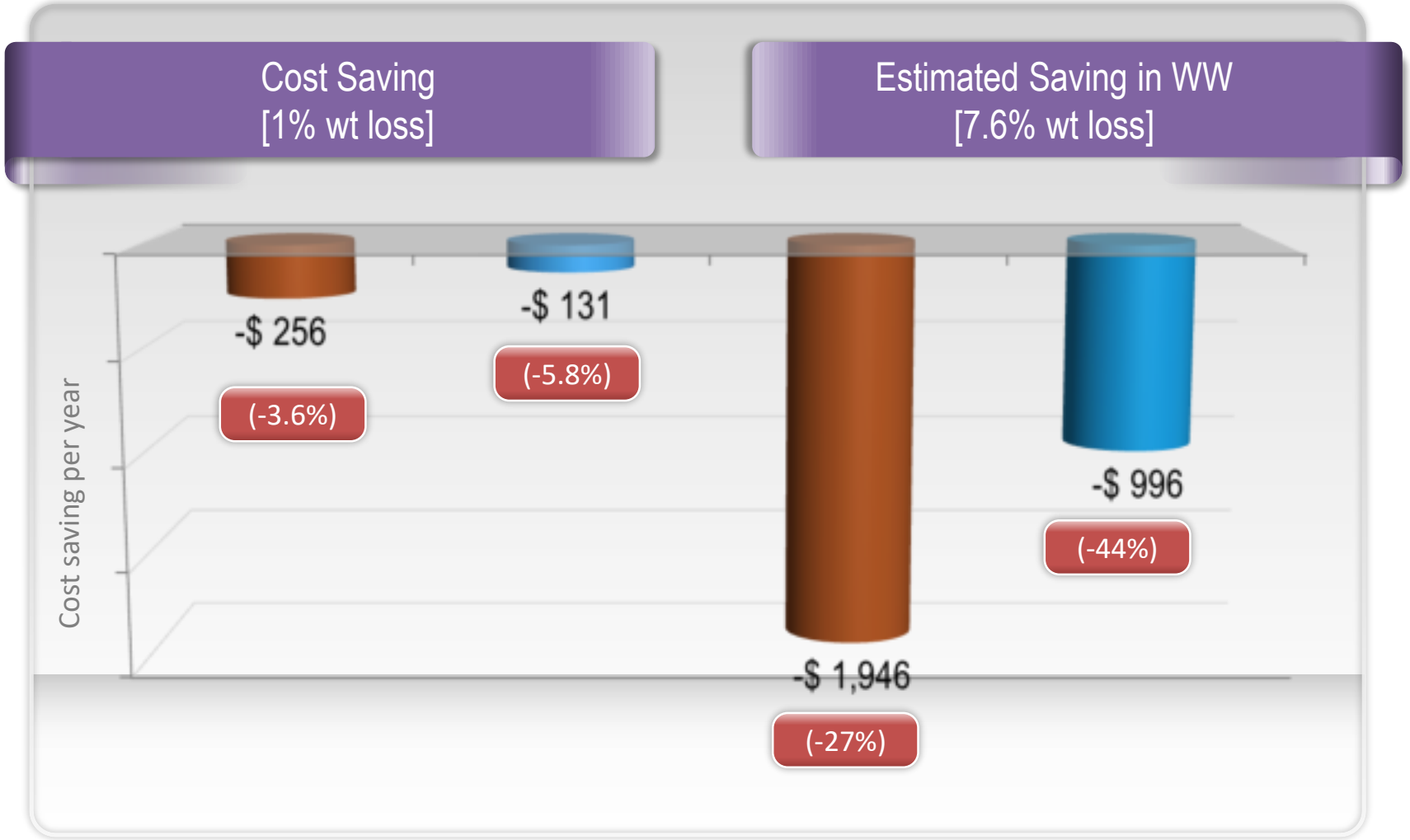
Strong Correlation Between Meal Replacements and Weight Loss (Look AHEAD Study)



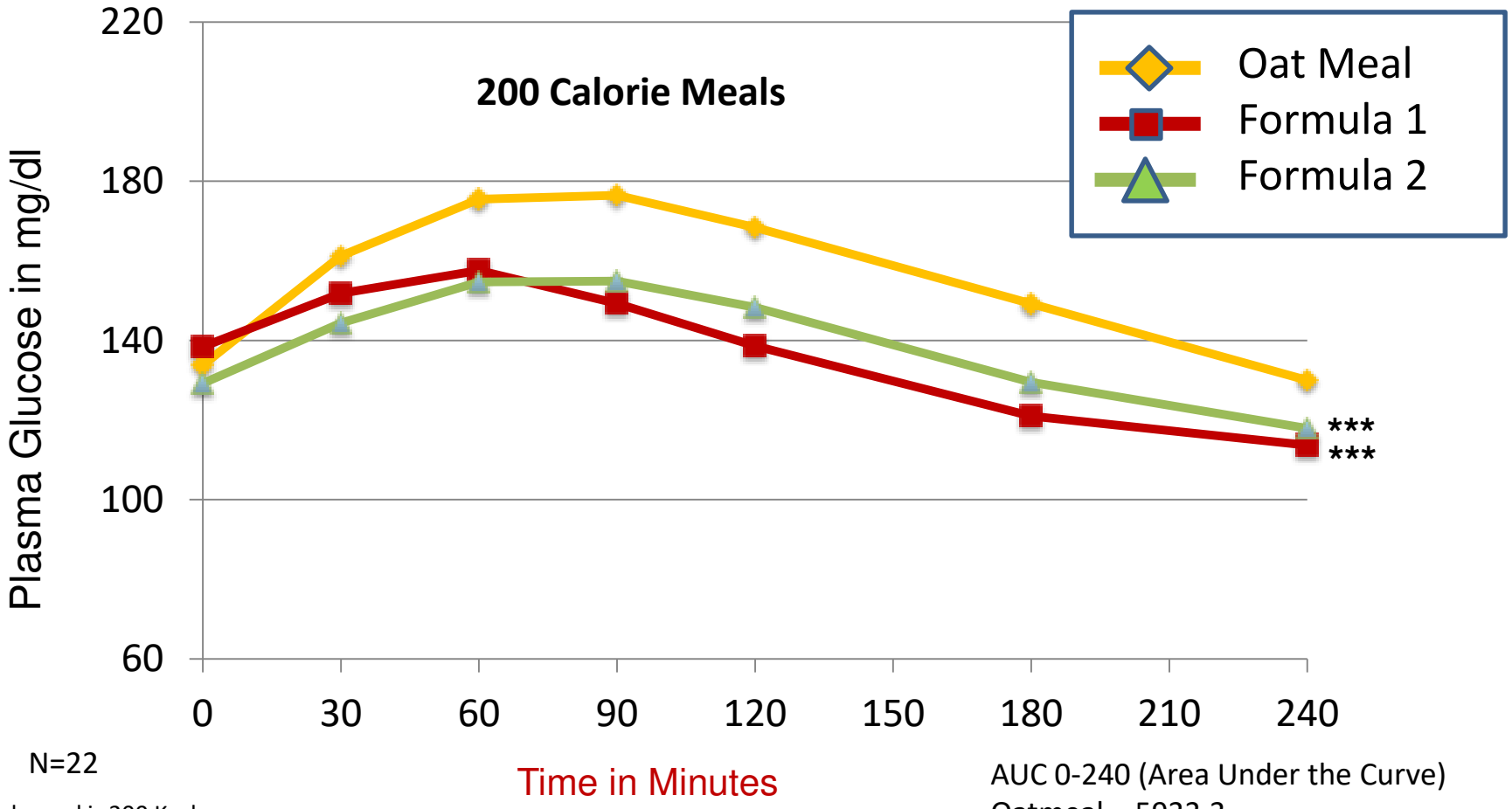
MRs = meal replacements

Reproduced with permission from Wadden TA et al. Obesitiy 2009; 17:713-722

Estimated Cost-Saving After Why WAIT Program for 1 Year



Effect of Different Diabetes-specific Formulas Versus Oatmeal on Plasma Glucose Area Under the Curve (AUC)

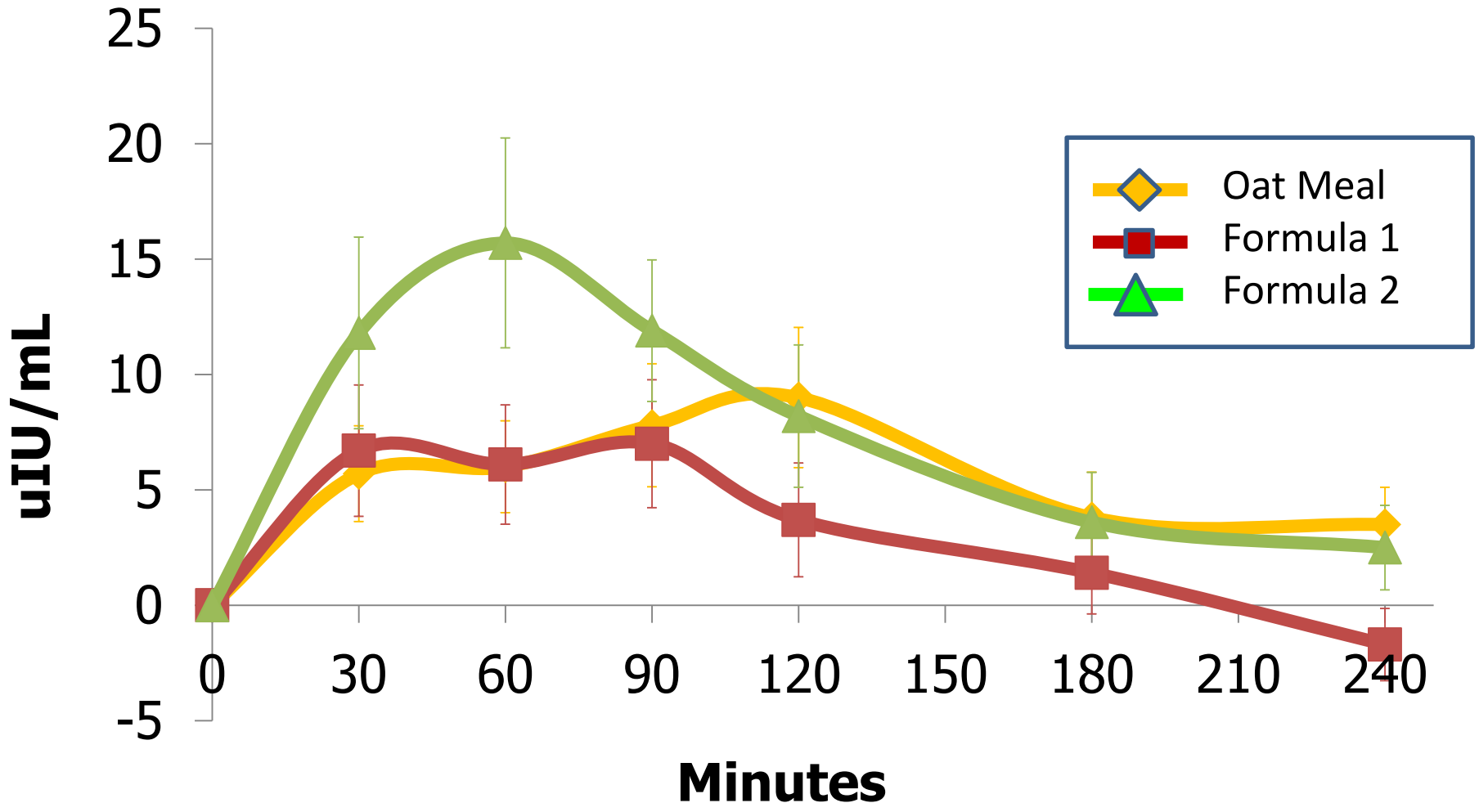


N=22

Each meal is 200 Kcal
*p<0.05, **p<0.01, ***p<0.001 Versus Oatmeal
$^{\dagger}P$<0.05 , $^{\dagger\dagger}P$<0.01, $^{\dagger\dagger\dagger}P$<0.001 Between Glucerna & Ultra-Glucose control

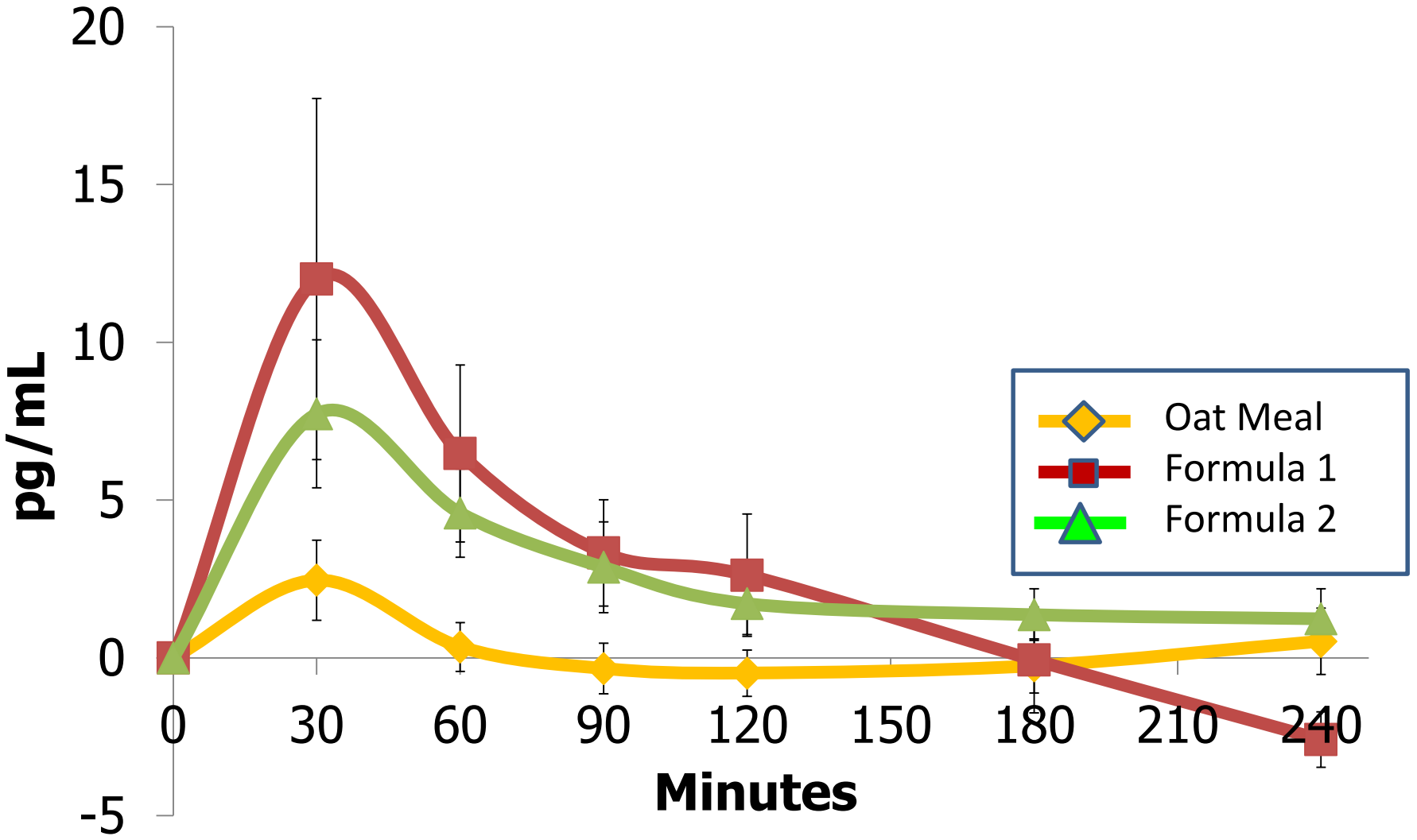
AUC 0-240 (Area Under the Curve)
Oatmeal = 5933.3
Glucerna = 1684.2***
Ultra-Glucose Control = 3351.1***

Insulin



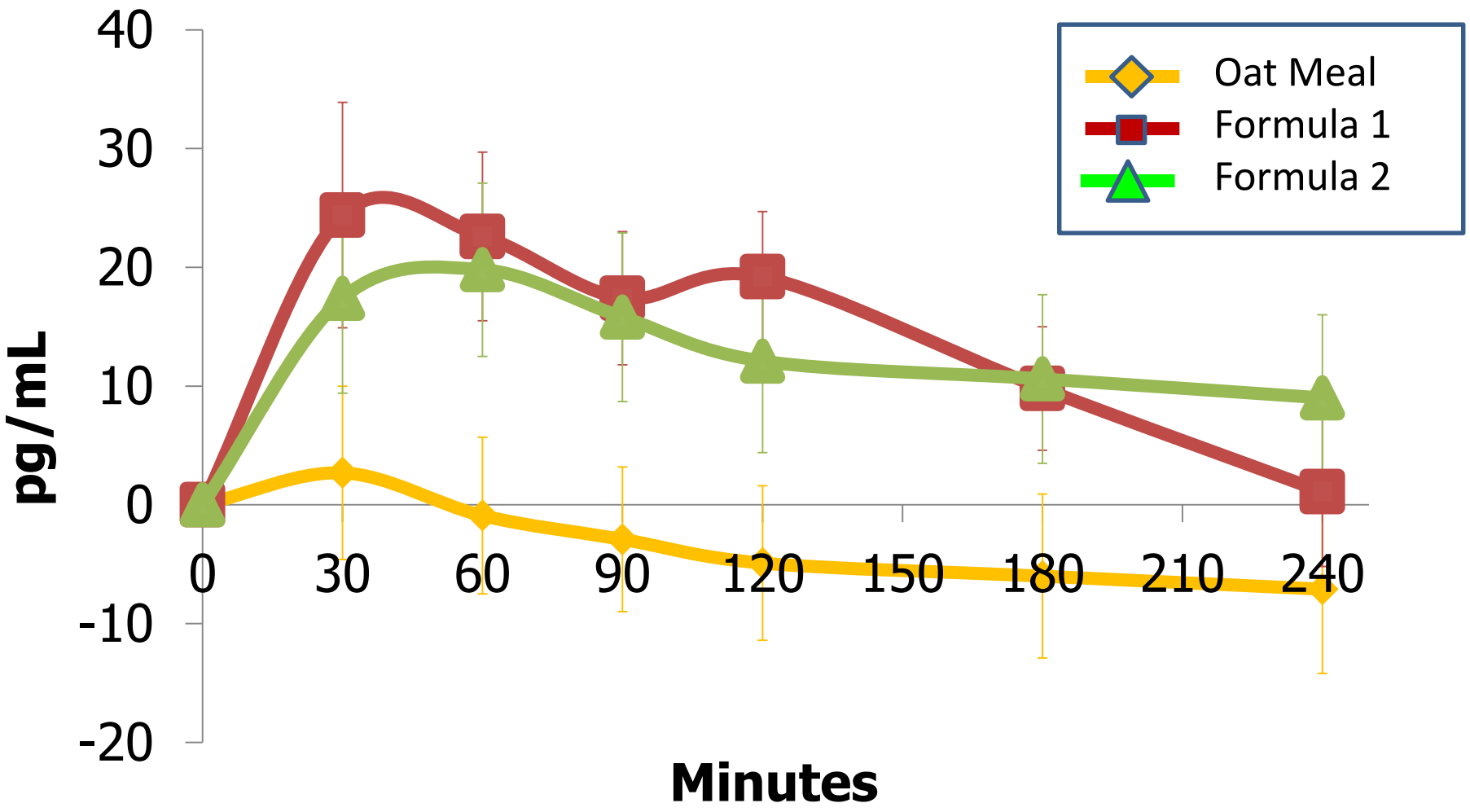
Positive AUC0-120 was significantly higher Formula 2 than after OM (p=0.02)

GLP-1



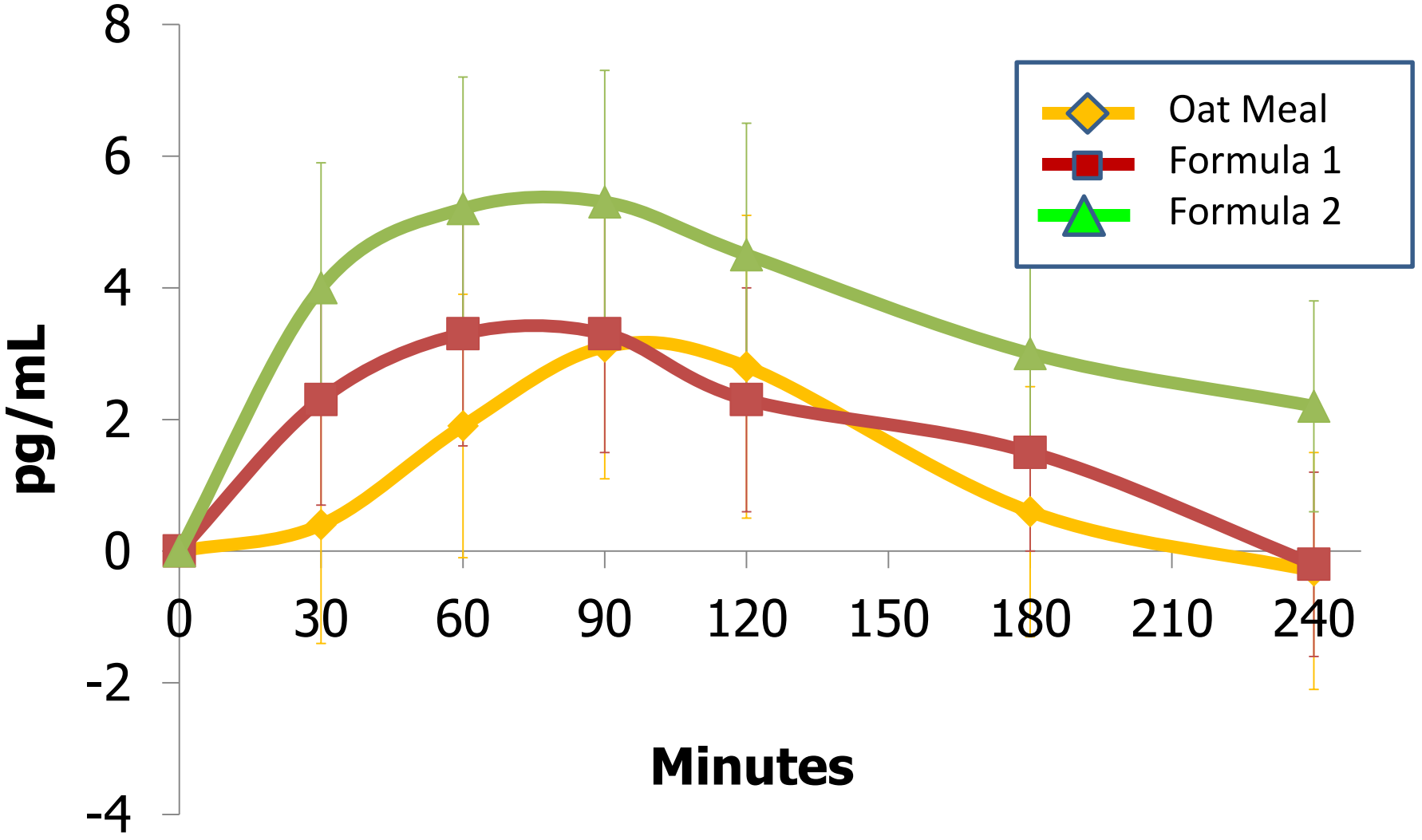
Positive $AUC_{0\text{-}240}$ was significantly higher after both formulas than after OM (p<0.001 for both)

PYY



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

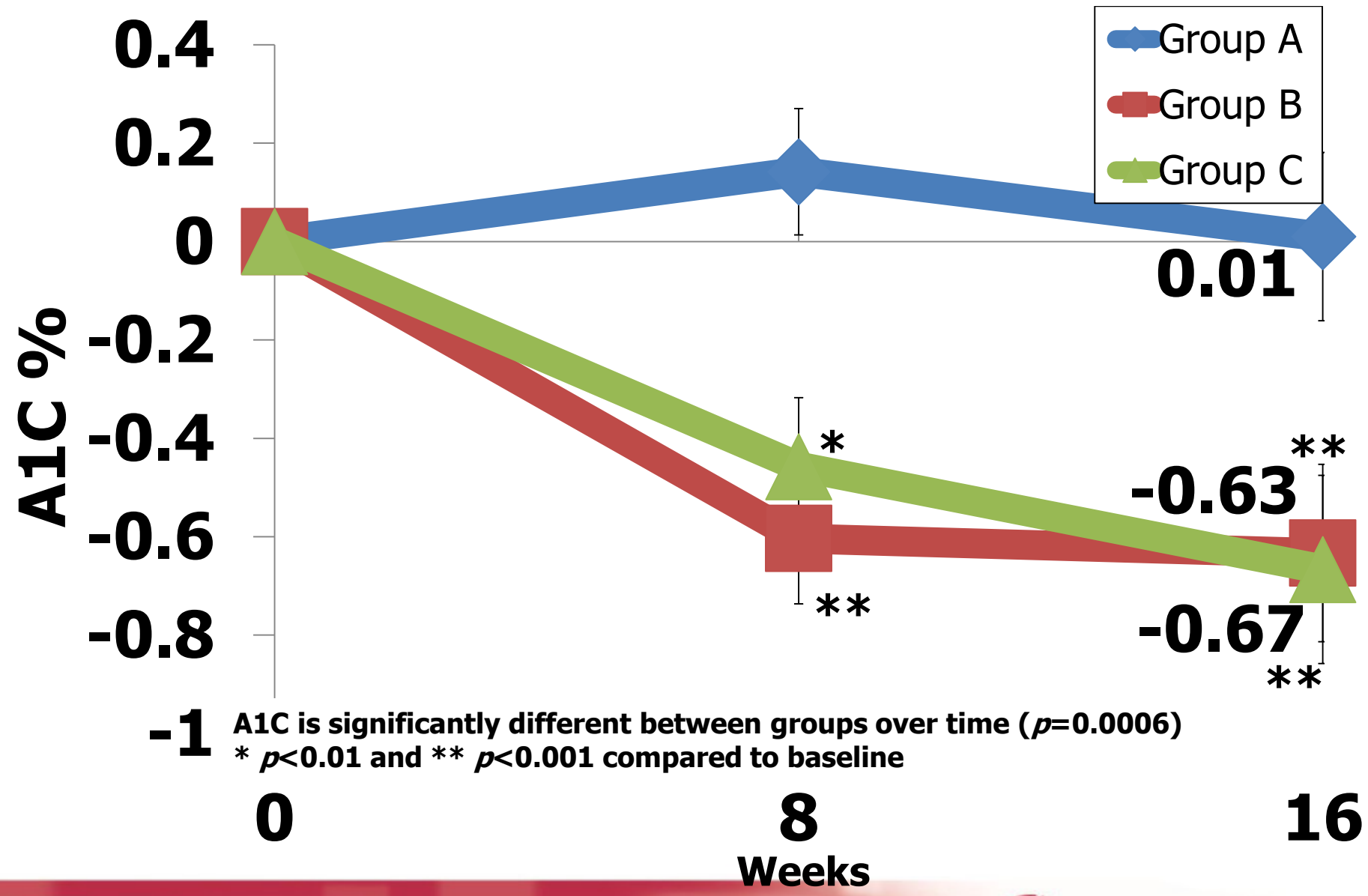
Includes 100 and 200 calorie snacks

Nutrition Therapy

Group A	Group B	Group C
Meet RD	Meet RD	Meet RD
		
Individualized Meal Plan	Structured Meal Plan	Structured Meal Plan +  Weekly phone call

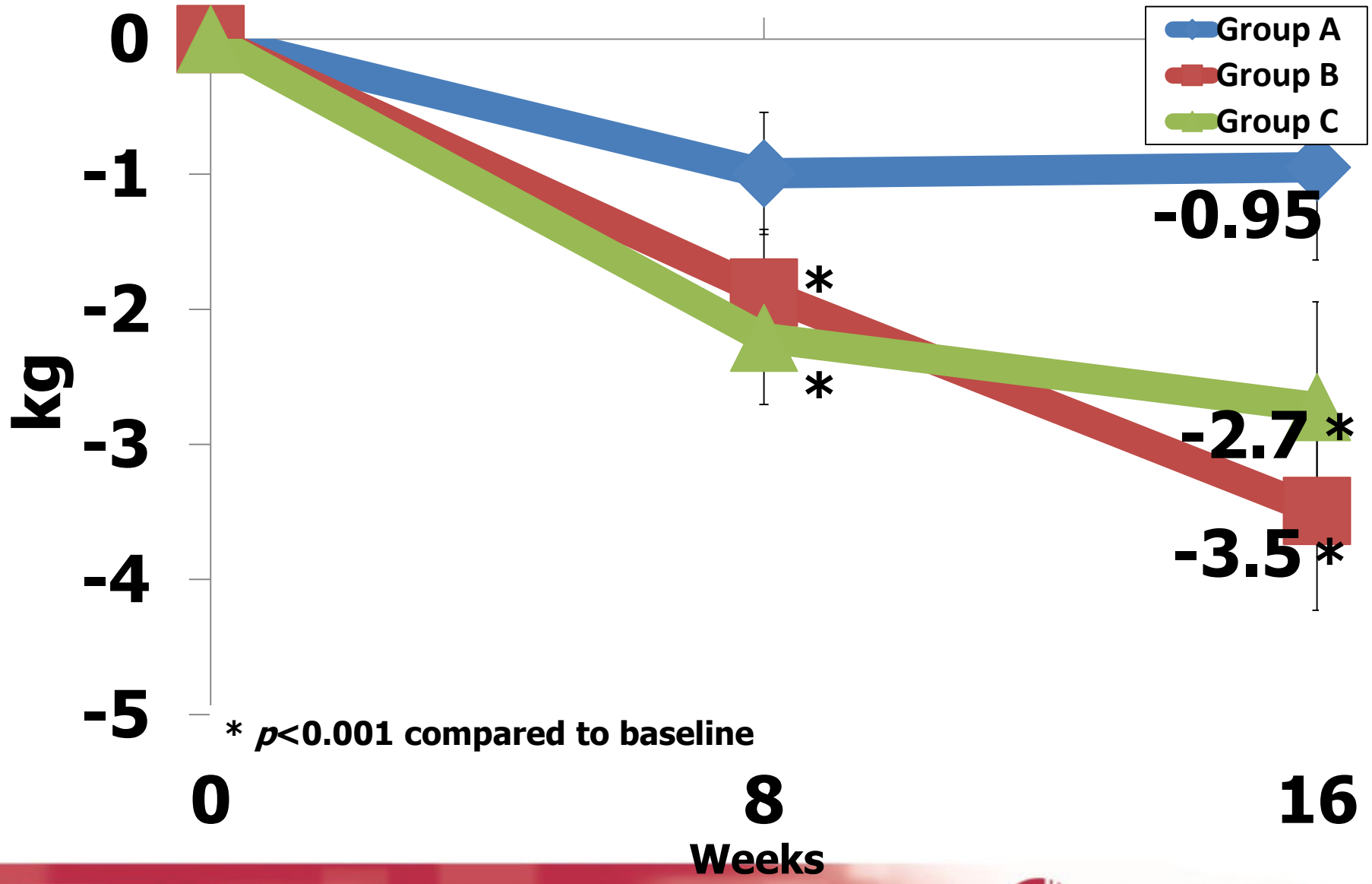
Mottalib A, Hamdy O. et al. Nutr J. 2018;17(1):42. doi:10

A1C



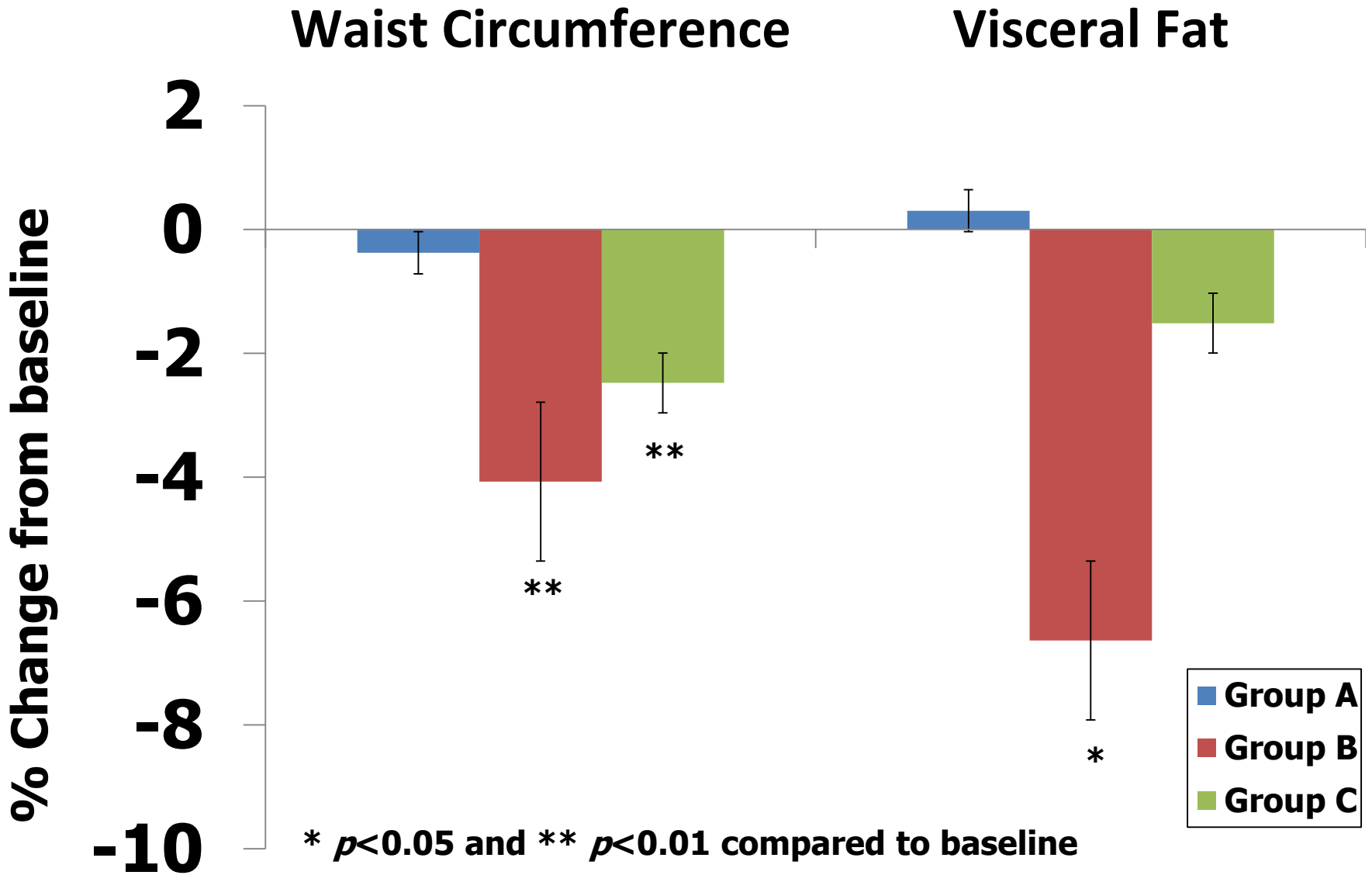
A1C is significantly different between groups over time (p=0.0006)
* p<0.01 and ** p<0.001 compared to baseline

Weight loss



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

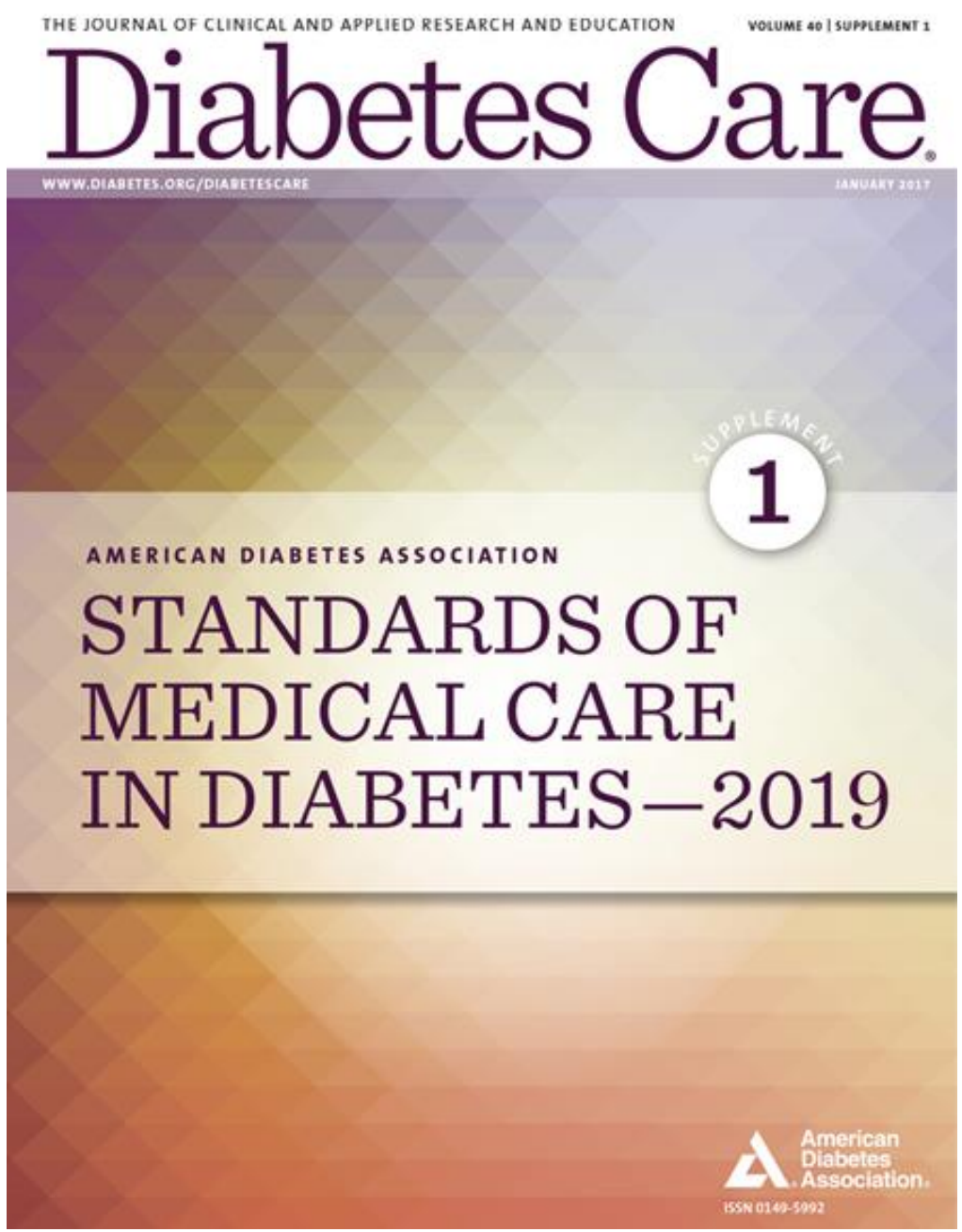
Abdominal Adiposity



Incretin Therapies: Major Differences

	Properties/Effect	GLP-1 Receptor Agonists[1,2]	DPP-4 Inhibitors[1,2]	MNT with DSF
	↑ Insulin production	+++	++	++
	↑ Amylin	NO	NO	+
	↑ GLP-1 ↑ PYY	- NO	+ NO	++ ++
	Gastric emptying	Delayed	No effect	NO
	Food intake	↓	No effect	↓
	Body weight	↓	No effect	↓
	Visceral Fat	NO	NO	↓
	Side effects	Nausea, vomiting	Minimal	NO

1. DeFronzo RA et al. *Curr Med Res Opin.* 2008; 24:2943-2952.
2. Drucker DJ &Nauck MA. *Lancet.* 2006;368:1696-1705.



"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**"

ADA Standards of Diabetes Care 2019. Diabetes Care. 2019, 1 (supplement 1)
Mottalib A et al. Nutr J. 2018;17(1):42. doi:10

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.

1. Elia M, et al. *Diabetes Care*. 2005;28(9):2267–2279. **2.** Alish CJ, et al. *Diabetes Technol Ther*. 2010;12(6):419–425. **3.** Mesejo A, et al. *Crit Care*. 2015;19:390. doi.10.1186/s13054-015-1108-1.
2. **4.** Vaisman N, et al. *Clin Nutr*. 2009;28(5):549555. **5.** Voss AC, et al. *Nutrition*. 2008;24(10):549–555.

Thank You