JOSLIN DIABETES CENTER and JOSLIN CLINIC CLINICAL NUTRITION GUIDELINE FOR OVERWEIGHT AND OBESE ADULTS WITH TYPE 2 DIABETES, PREDIABETES OR THOSE AT HIGH RISK FOR DEVELOPING TYPE 2 DIABETES 10-19-16

The Joslin <u>Clinical Nutrition Guideline for Overweight and Obese Adults With Type 2 Diabetes</u>, <u>Prediabetes or Those at High Risk for Developing Type 2 Diabetes</u> is designed to assist primary care physicians, specialists, and other healthcare providers in individualizing the care of and set goals for adult, non-pregnant patients with type 2 diabetes or individuals at high risk for developing type 2 diabetes. This guideline focuses on the unique needs of those individuals. Several components of these guidelines complement the 2015 Dietary Guidelines for Americans, which is jointly developed by the Department of Health and Human Services and the Department of Agriculture. It is not intended to replace sound medical judgment or clinical decision-making and may need to be adapted for certain patient care situations where more or less stringent interventions are necessary.

The objectives of the Joslin Clinical Diabetes Guidelines are to support clinical practice and to influence clinical behaviors in order to improve clinical outcomes and assure that patient expectations are reasonable and informed. Guidelines are developed and approved through the Clinical Oversight Committee that reports to the Chief Medical Officer. The Clinical Guidelines are established after careful review of current evidence, medical literature and sound clinical practice. These Guidelines will be reviewed periodically and the Joslin Diabetes Center will maintain, upgrade or downgrade the rating for each recommendation when new evidence mandates such changes.

Joslin's Guidelines are evidence-based. In order to allow the user to evaluate the quality of the evidence used to support each standard of care, a modification of the GRADE system has been adopted. The table provided on page 6 describes the categories in which methodological quality and strength of recommendations have been classified. Evidence levels are graded 1A through 2C, as indicated in brackets.

Target Individuals					
*Target Population	BMI e 25 kg/m ²		Type 2 Diabete	es	
	or	and	or		
	Waistline e 40"/102 cm (men) [1B] e 35"/88 cm (women)		Prediabetes	IGT (impaired glucose tolerance) [1A] IFG (impaired fasting glucose)	
	, ,		or	, , , , , , , , , , , , , , , , , , , ,	
			High Risk for 1	Гуре 2 Diabetes	
				The Metabolic Syndrome (AHA/NHLBI criteria) [1B] Family history of type 2 diabetes mellitus (first degree relative) Confirmed diagnosis of insulin resistance (e.g., high basal insulin)	
	* For Asian populations (South Asian Indians, East Asians and Malays) a BMIe 23 kg/m² and a waistline e 35"/90 cm in men or e 31"/80 cm in women. [1B]				

General Guidelines

- There is strong evidence that weight reduction improves insulin sensitivity and glycemic control, lipid profile, and blood
 pressure in type 2 diabetes and decreases the risk of developing type 2 diabetes in pre-diabetes and high-risk
 populations [1A]
- Refer individuals to a registered dietitian (RD) experienced in diabetes and weight management for individualized medical nutrition therapy (MNT); care should be coordinated with an interdisciplinary team including the patient's PCP [1B]
 - 1. To enhance effectiveness of MNT, it is recommended there be a series of 3-4 encounters with an RD lasting from 45-90 minutes beginning at diagnosis.
- Priorities for this population include:
 - 1. Weight reduction.
 - 2. Glycemic control as well as achieving blood pressure and LDL-cholesterol goals.
 - 3. Meal to meal consistency in carbohydrate distribution for those with fixed medication/insulin programs.

- 4. Individualization for cultural and food preferences (e.g. vegetarian)
- 5. Adoption of a healthy eating pattern that is sustainable over time (The Mediterranean diet, the DASH (Dietary Approaches to Stop Hypertension) diet and a plant-based or vegetarian diet are examples of healthy dietary patterns)
- 6. Integration of behavior change therapies in order to adopt healthy eating behaviors and sustainable weight loss
- The meal plan composition, described below, is for general guidance only and may be individualized by the RD or other healthcare provider according to clinical judgment, individual (patient) preferences and needs, and metabolic response.
- Physical activity is an integral component of a weight loss program for both initial weight loss and for weight maintenance.

Weight Reduction

- 1. A structured lifestyle plan that combines dietary modification, activity, and behavioral modification, along with ongoing support, is necessary for weight reduction. **[1B]** To maintain long-term weight loss; ongoing weight maintenance counseling and support is recommended.
- 2. A modest and gradual weight reduction of one to two pounds every one to two weeks should be the optimal target. **[2A].** Reduction of daily caloric intake should be between 250 750 calories. **[1C]** Total daily caloric intake should not be less than 1000-1200 for women and 1200-1600 for men, or based on a RD assessment of usual intake. **[1C]**
- 3. A 5-10% weight loss may result in significant improvement in blood glucose control among patients with diabetes and help prevent the onset of diabetes among individuals with pre-diabetes. **[1B].** Weight reduction should be individualized and continued until an agreed upon BMI and/or other metabolic goals are reached.
- 4. Target individuals should meet with a RD to discuss a structured MNT plan for weight management that includes menus and snacks and to learn and practice portion control as effective ways of weight management. [1B]
- 5. Diabetes-Specific Meal Replacements (DSMR) in the form of shakes, bars, ready-to-mix powders, and pre-packaged meals that match these nutrition guidelines may be effective in initiating and maintaining weight loss.
 - Meal replacements should be used under the supervision of a RD.
 - When meal replacements are initiated, glucose levels should be carefully monitored and if needed, antihyperglycemic medications should be adjusted.
 - Meal replacements should be used with caution by those with hyperkalemia.
- 7. Bariatric surgeries, although not without medical and nutrition risks, are effective options and may be discussed when indicated (consider in individuals with BMI e40 kg/m² and those with BMI e35 kg/m² with other comorbidities, reduce by 2.5kg/m² for Asians). [2B] To date, there is limited evidence to support the recommendation of bariatric surgeries for patients with BMI <35 kg/m² even if a person has diabetes or other co-morbid conditions.
- 8. Anti-obesity medications may be considered for patients who were not able to lose weight through lifestyle modifications, but the long- term risks and benefits of these medications are unclear [2C].
- 9. The effect of diabetes medications should be evaluated throughout the weight loss program and adjusted as necessary to avoid hypoglycemia.

TICCC	saily to avoid hypogryc	ornia.
Macronut	rient Composition	
Fat	Amount	 There is general agreement that the type of fat consumed is more important than the quantity (generally 30-40% total calories). (2,4,5). Trans fat from partially-hydrogenated oil should be eliminated [1B] (16) Monounsaturated and polyunsaturated fats should comprise the majority of fat intake [2B] (3, 8, 16) Limit saturated fat intake to <10 % of total calories. (4, 5, 9, 16). Recent evidence demonstrates saturated fat from dairy foods (milk, yogurt, cheese) may be acceptable within the total daily caloric intake [2B] Despite recent evidence suggesting that saturated fat poses a weak or neutral effect on health, further research in this area is warranted. (2,9) Low-fat diets are generally less effective than low-carbohydrate diets for weight reduction [2 C] (2a, 3, 26, 27, 58, 59, 60)
	Recommended	 Plant fats rich in mono and polyunsaturated fats (e.g., olive oil, canola oil, soybean oil, nuts/seeds, and avocado [2A] (7, 14, 15). Oily fish rich in omega-3 fatty acids (e.g., salmon, herring, trout, sardines, fresh tuna) 2 times/week, as a source of omega-3 fatty acids. [2B]
	Not Recommended	 Foods high in saturated animal fat, including, non-lean pork, lamb, and beef, processed meat, butter and cream Foods high in trans-fats (e.g., fast foods, commercially baked goods, margarines

		from partially-hydrogenated oil)
Protein	Amount	Protein intake should range between 1.0-1.5gm/kg of adjusted body weight [(Adjusted Body Weight = IBW (Ideal Body Weight) + 0.25 of excess weight (Excess weight = Current Weight - IBW)]. This amount generally accounts for 20-30% of total caloric intake.
		 A modest increase in protein reduces appetite and assists in achieving and maintaining weight reduction. [2B] Protein also helps to minimize loss of lean body mass during weight reduction [2 B] (10, 26, 38) There is no reliable scientific data to support a protein intake that exceeds 2 gm/kg
		 of adjusted body weight. Reduction of protein intake to less than 0.8 gm/kg day may result in protein malnutrition
	Recommended	Fish, skinless poultry, lean meat, dairy, egg white, nuts, seeds, soy and other legumes [2B]
	Not Recommended	Sources of protein that are high in saturated fat (e.g. non-lean pork, lamb, beef and processed meat) as they may be associated with increased cardiovascular risk. [1B].
	Patients with Renal Issues	Heme iron in meat is also associated with an increased risk of type 2 diabetes (9) [2B] Although reducing total calories may result in a reduction of the total amount of protein intake, any patient with signs of kidney disease (i.e., one or more of the following: proteinuria, GFR<60 ml/min) should consult a nephrologist before increasing the total or percentage of protein in their diet. [1B] Protein intake for these patients should be modified, but not lowered to a level that may jeopardize their overall health or increase their risk for malnutrition or hypoalbuminemia.
Carbohydrate	Amount	 The total daily intake of carbohydrate should be at least 130 gm/day and preferably 40-45% of the total caloric intake Intake should be adjusted to meet the cultural and food preferences of the individual.
	Consideration of Glycemic Index/Glycemic Load	The glycemic index/glycemic load is an important factor that patients should apply in their daily selection of carbohydrates foods. Foods with a lower glycemic index content should be selected [2B] (e.g. whole grains, legumes, fruits, green leafy and non-starchy vegetables, milk and yogurt) (2, 9, 41)
	Recommended	Green leafy and non-starchy vegetables, whole fruits, legumes, whole and minimally processed grains, oats, milk and yogurt [2B] (1,2,6, 9),
	Not Recommended	 Sugar, or added sugar, especially sugar-sweetened beverages, ice-cream, candies, grain-based desserts, milk chocolate should be avoided Refined grain products including white bread, white pasta, white rice, low-fiber wheat cereal, cakes, muffins, pizza, white bagels should be limited High glycemic index carbohydrates including: white potatoes and rice
	Fiber	 Approximately 14gm of fiber /1000 cal (20-35 gm) per day is recommended. [1C] If tolerated, approximately 50 gm/day is effective in improving postprandial hyperglycemia and should be encouraged. [2B] (1, 20, 28, 40) Fiber from unprocessed plant-based food, such as vegetables, fruits, seeds, nuts, and legumes is preferable but, if needed, fiber supplements such as psyllium, resistant starch and beta-glucan can be added. [2B]
Micronutrien	t Composition	
	Sodium	 Daily consumption should be < 2300 mg (about 1 tsp of salt) per day. (1A) Further reduction to 1500 mg is recommended in people > 50 yr of age including those with hypertension or chronic kidney disease. [2B] (2, 57)
	Potassium	 Daily consumption should be a minimum of 4,700 mg unless potassium excretion is impaired e.g. patients with chronic kidney disease and/or patients on certain drugs that retain potassium (2, 6, 57). Potassium helps offset high sodium intake by triggering more sodium excretion by the kidneys. Potassium-rich foods include fruits and vegetables like bananas, mushrooms, spinach, and almonds.

Vitamin and Mineral Supplements

- In individuals who are not deficient, there are no significant data supporting the routine use of vitamins or minerals to improve glucose control; however some individuals may benefit from multivitamin supplementation as calorie restricted diets may be inadequate in some nutrients such as calcium.
- There are no significant data to support the use of herbal supplements or spices to improve glucose control.

Non-nutritive Sweeteners

All FDA- approved non-nutritive sweeteners are permissible in moderate quantities

Alcohol

- If consumed, alcohol consumption must be moderate. No more than 1 drink a day for women and no more than 2 drinks a day for men (One drink is equal to 12 ounces of regular beer, 5 ounces of wine, or 1.5 ounces of 80-proof distilled alcohol).
- Alcoholic beverages contain calories and are low in nutritional value. They may contribute to both hypoglycemia or hyperglycemia (high carbohydrate alcoholic beverages).
- It is not advisable to increase alcohol consumption for the purpose of deriving health benefit claims.

Healthy Dietary Pattern

The following dietary pattern were shown to be effective in the prevention and management of diabetes

- Mediterranean diet
- DASH diet
- Plant-based, vegetarian and vegan diet
- Moderately low carbohydrates and high plant-based protein and fat

The following particular foods were shown to be associated with a reduced risk of developing type 2 diabetes in some studies:

- Oat cereal
- Yogurt
- Dairy products
- Tea, coffee and decaffeinated coffee
- Green leafy vegetables
- Fish and seafood (only in Asia)
- Red grapes, apples, blueberries
- Nuts (especially walnuts)

Physical Activity

- Physical activity should be an integral component of the weight loss and diabetes care plan to optimize glucose control, decrease cardiovascular risk factors, and achieve or maintain optimal body weight.
- All adults should consult their healthcare provider and/or see an exercise physiologist to discuss a safe exercise program that is appropriate to their abilities. [1C]
- To increase lean body mass, full body resistance training should be incorporated into the activity plan 3-4 days per week, and include upper, core and lower body strengthening exercises using free weights, resistance machines or resistance bands. [1B]

Guidelines for healthy adults with diabetes or pre-diabetes:

- A moderate-intensity aerobic (endurance) physical activity a minimum of 30 minutes 5 days per week or vigorous-intensity aerobic physical activity for a minimum of 20 minutes 3 days per week should be achieved unless contraindicated. Activity can be accumulated toward the 30-minute minimum by performing bouts, each lasting 10 or more minutes. [1A]
- A target of 60-90 minutes, 6-7 days per week is encouraged for weight loss if overweight or obese [1B]
- Stretching exercises should be done when muscles are warm or at the end of the activity plan to loosen muscles and prevent soreness. [1B]

Additional Guidelines for adults with medical or physical limitations:

- Incorporate balance exercises to prevent falling and injury.
- Functional Fitness Testing is useful to assess patients' functionality and to track their progress. Testing such as 6-Minute Walk Test, 2-Minute Step Test, Balance Assessment and Hand strength should be included at baseline and post intervention [1C]
- For those with proliferative diabetic retinopathy, retinal traction, or severe nonproliferative diabetic retinopathy, activity programs that involve strenuous lifting, harsh, high-impact components, or activities that place the head in an inverted position for extended periods of time may need to be revised depending on the level of retinopathy and other retinal disease. Consultation with an eye doctor expert in diabetes eye care is advised.

Appendix A

Suggested Approximate Macronutrient Distribution According to Clinical Guideline (15)

Calorie Level	Carbohydrate		Protein		Fat	
	Grams	%	Grams	%	Grams	%
1000	130	~50 *	75	30	27	20
1200	135	45	75-90	25-30	40	30
1500	150-170	40-45	75-110	20-30	50	30
1800	180-200	40-45	90-135	20-30	60	30
2000	200-225	40-45	100-150	20-30	70	~30

^{*}A minimum of 130grams of carbohydrate per day, in a 1000 calorie meal plan, calculates to ~50% of the total daily calories.

Abbreviations				
AHA: American Heart Association	LDL: low density lipoprotein			
BMI: body mass index	mg: milligram			
cm: centimeter	ml/min: millimeter per minute			
DASH: Dietary Approaches to Stop Hypertension	MNT: medical nutrition therapy			
DSMR: Diabetes-Specific Meal Replacements	NHLBI: National Heart, Lung and Blood Institute			
FG: fasting glucose	PCP: primary care provider			
GFR: glomerular filtration rate	RD: registered dietitian			
Gm: gram				
GRADE: Recommendation, Assessment, Development and				
Evaluation				
IGT: impaired glucose tolerance				
IBW: ideal body weight				
Kg/m^{2*}kilogram per meter ²				

Approved by the Joslin Clinical Oversight Committee on 09/16/2016

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Grading System Used in Guideline

Grade of Recommendation	Clarity of risk/benefit	Quality of supporting evidence
1A Strong recommendation High quality of evidence	Benefits clearly outweigh risk and vice versa.	Consistent evidence from well performed randomized, controlled trails or overwhelming evidence of some other form. Further research is unlikely to change our confidence in the estimate of benefit and risk.
1B Strong recommendation Moderate quality of evidence	Benefits clearly outweigh risk and burdens, or vice versa.	Evidence from randomized, controlled trials with important limitations (inconsistent results, methodological flaws, indirect or imprecise), or very strong evidence of some other research design. Further research is likely to have an impact on our confidence in the estimate of the benefit and risk and may change the estimate.
1C Strong recommendation Low quality of evidence	Benefits outweigh risk and burdens, or vice versa.	Evidence from observational studies, unsystematic clinical experience, or from randomized controlled trails with serious flaws. Any estimate of effect is uncertain.
2A Weak recommendation High quality of evidence	Benefits closely balanced with risks and burdens.	Consistent evidence from well performed randomized controlled trials or overwhelming evidence of some other form. Further research is unlikely to change our confidence in the estimate of benefit and risk.
2B Weak recommendation Moderate quality of evidence	Benefits closely balanced with risks and burdens; some uncertainly in the estimates of benefits, risks and burdens.	Evidence from randomized controlled trials with important limitations (inconsistent results, methodological flaws, indirect or imprecise), or very strong evidence of some other research design. Further research is likely to have an impact on our confidence in the estimate of benefit and risk and may change the estimate.
Weak recommendation Low quality of evidence	Uncertainty in the estimates of benefits, risks and burdens; benefits may be closely balanced with risks and burdens.	Evidence from observational studies, unsystematic clinical experience, or from randomized controlled trails with serious flaws. Any estimate of effect is uncertain.

Evidence graded less than "A" is acceptable to support clinical recommendations in a guideline. It is also assumed that for many important clinical recommendations, it would be unlikely that level A evidence be obtained because appropriate studies may never be performed.

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