CONSENSUS STATEMENT:

The Use of Diabetes Specific Nutritional Formulas in Type 2 Diabetes

This consensus statement has been written for healthcare professionals who manage people with type 2 diabetes (T2D), including general practitioners (GPs) and other primary healthcare team members.

ABSTRACT

Type 2 diabetes (T2D) is a complex disease caused by the interaction between environmental insults (poor energy dense diets and lack of exercise) in a permissive genetic predisposition. Current evidence suggests that nutritional management of T2D can improve blood glucose levels and lead to a reduction in medication use.

In this consensus statement we review the current evidence for diabetes specific nutritional formulas that when used as an alternative way to support people with diabetes in optimising their nutritional intake, can improve blood glucose management and overall health outcomes when wholefood options are not feasible. Furthermore, diabetes specific nutritional formulas may be a valuable consideration to enhancing overall protein and nutritional intake for individuals following metabolic surgery or treated with GLP-1 Receptor Agonist (GLP-1a) medications who are at increased risk of lean muscle mass loss.

Developed by an expert working group of representatives from the Australian Diabetes Society (ADS), Australian Diabetes Educators Association (ADEA), Royal Australian College of General Practitioners (RACGP) and Dietitians Australia, the consensus statement aims to provide healthcare professionals with a comprehensive understanding of Diabetes Specific Nutritional Formulas (DSNFs) and their potential role in managing T2D, and to offer guidance for their application in clinical practice, based on a review of the current evidence as well as expert opinions.

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RECOMMENDATIONS

1. For people with T2D, a healthy diet based on wholefoods remains the primary goal and first-line management for improving blood glucose levels (BGLs) and overall health.
2. Diabetes Specific Formulas (DSNFs) can be a valuable short-term option for:
   - those in special circumstances whereby adherence to a healthy diet is not always possible,
   - a wholefood diet is not achieving desired health outcomes, and/or
   - whereby current dietary intake is not sufficient to meet recommended nutrient intake.
3. DSNFs are distinct from Very Low Energy Diets (VLEDs) in that they are not intended to be used as total diet replacements, rather they may replace up to two meals or snacks a day as part of a low-calorie diet.
4. DSNFs should be integrated into a holistic diabetes management plan that includes blood glucose monitoring, healthy wholefoods diet, physical activity, sleep management, and medication adherence, rather than being relied upon as a stand-alone approach.
5. Evidence supports the use of DSNFs as an alternative way to support people with diabetes in optimising their nutritional intake, improving glycaemic management and overall health outcomes when wholefood options are not feasible.
6. When using a DSNF, an Accredited Practising Dietitian (APD) can provide professional guidance on their appropriate use including dosage, frequency and duration, while considering an individual's overall dietary intake and health needs. In addition, APDs can collaborate with the diabetes healthcare team to discuss the overall health impacts of using a DSNF, including any required changes to medications and transitioning back to a wholefood diet, if desired.
7. Incorporating DSNFs may be a valuable consideration to enhancing overall protein and nutritional intake for individuals following metabolic surgery or treated with GLP-1 Receptor Agonist (GLP-1a) medications who are at increased risk of lean muscle mass loss.

Background

Type 2 diabetes is a complex metabolic disorder characterised by impaired glucose metabolism as a result of reduced insulin secretion in the presence of insulin resistance. The long-term impacts of having blood glucose levels (BGLs) outside the desirable range include cardiovascular disease, chronic kidney disease, retinopathy, dementia, peripheral neuropathy and peripheral vascular disease. Effective glycaemic management can assist in the prevention and/or improvement of these complications, thus improving morbidity, mortality and quality of life in people with T2D.

The Australian Diabetes Society T2D Glycaemic Management Algorithm recommends that lifestyle interventions, including diet, exercise and weight management, be the initial approach for glycaemic management.[1] The algorithm further highlights the continued importance of lifestyle interventions throughout all stages of T2D management, with a recommendation to review and reinforce these regularly if haemoglobin A1c (HbA1c) is not within target or reducing towards it.

Whilst a healthy diet based on wholefoods continues to be prioritised, there is a growing body of evidence supporting the use of Diabetes Specific Nutritional Formulas (DSNFs) for improving BGLs, HbA1c, glycaemic variability, and other health benefits in a select group of individuals, particularly those with T2D.[2-6] With approximately half of individuals with T2D able to adhere to dietary recommendations, complementing a healthy wholefoods diet with DSNFs may offer a simple and practical solution to improving both nutrition and glycaemic outcomes.[7,8]

Evidence of using diabetes specific nutritional formulas in diabetes management

The use of DSNFs to improve glycaemic outcomes and other clinical markers in people with T2D has been demonstrated in the following settings:

a) When a DSNF replaces a meal (usually breakfast) and/or snack with a higher 'glycaemic load' (i.e., a meal that has a higher total carbohydrate, a higher glycaemic index (GI), a lower protein, and/or a lower unsaturated fat content); or

b) When the use of one or more serves of DSNFs reduces total daily energy and/or carbohydrate intake; or

c) When a DSNF replaces a 'standard' nutrition supplement formula (SF)

When a DSNF replaces a meal and/or snack with a higher 'glycaemic load'

In a cross-over trial involving people with T2D, replacing oatmeal with a DSNF at breakfast resulted in reduced postprandial BGLs and increased secretion of the hormone Glucagon-Like Peptide 1(GLP-1).[3] In this trial, the oatmeal and DSNF had an equivalent caloric value (200 kCal), but the DSNF had lower total carbohydrate (26 g vs 36 g) and a higher protein (10 g vs 6.7 g) and monounsaturated fat (5.2 g vs 1 g) compared to the oatmeal.[3,4]

Similarly, in a randomised controlled study (RCT) in drug-naïve participants with T2D, those who replaced breakfast with a DSNF as part of lifestyle intervention (the DSNF group) for a duration of 4 weeks showed greater improvements in Time-in-Range (TIR) (13.8% vs 7.3%) and reduced glucose variability, measured using continuous glucose monitoring (CGM), compared with those receiving lifestyle intervention only (the control group).[6] Of note, the DSNF was lower in total energy (925kJ vs. 1450kJ) and carbohydrates (29g vs. 46g), compared with the average breakfast consumed by the control group participants. There were no differences in energy and macronutrient intake for lunch and dinner between the DSNF and the control group.[6]

When the use of one or more DSNFs reduces total daily energy and/or carbohydrate intake:

A RCT involving participants with T2D showed that a low-calorie diet using DSNF to replace one or two meals/snacks per day (the DSNF group) resulted in greater improvements in HbA1c (1.1% reduction), fasting blood glucose and systolic blood pressure as well as weight loss after the 6-month intervention period, compared with a traditional low-calorie diet that did not include DSNF (the control group).[5] Almost 20% of participants in the DSNF group were able to lower their need for oral hypoglycaemic agents (OHAs) during the intervention, whereas over 37% of participants in the control group required an increase in OHAs. Again, it is important to note that the DSNF group consumed significantly less total energy (1,091 Kcal vs 1562 Kcal) and total carbohydrate (155g vs. 209g) and engaged in more physical activity during the 6-month intervention compared with the control group.[5] Once the 6-month intervention was complete and DSNFs were discontinued, both the control and DSNF groups experienced increased HbA1c and weight towards baseline level5. However, only those in the DSNF group who received motivational interviewing during the intervention period

were able to maintain significant reductions in HbA1c and weight from baseline after 12 months.[5]

When a DSNF replaces a standard nutrition supplement formula (SF): A recent meta-analysis demonstrated that when a DSNF replaced a standard formula (SF) (i.e. not specifically designed for people with diabetes) this was associated with improvements in HbA1c, post-prandial BGLs, incremental glucose response, mean blood glucose, glucose variability and insulin excursions, as well as mean blood triglycerides (TG) and mean high-density lipoproteins (HDL).[2]
The above evidence suggests that:

- DSNFs may be used as part of a healthy diet to reduce overall energy intake and glycaemic load, thereby, improving the glycaemic management of T2D.
- DSNFs should be used in conjunction with lifestyle counselling incorporating motivational interviewing may support long-term health benefits once their use is discontinued.
- When considering an appropriate nutrition supplement formula for people with diabetes, healthcare professionals should consider the differences in glycaemic outcomes between DSNFs and SFs in their decision-making.
- It is also important to note that the glycaemic and health benefits might not be sustainable when the DSNFs discontinue, according to the current available evidence.[2-4,6]

Definition of diabetes specific nutritional formulas

DSNFs are specialised forms of nutrition therapy that consist of macro and micronutrient ingredients to manage malnutrition, dysglycaemia, and other cardiometabolic risk factors. These formulas have a low GI and complement dietary recommendations for people with T2D. They contain fibre, monounsaturated fatty acids (MUFAs) and/or polyunsaturated fatty acids (PUFAs), proteins, vitamins, and minerals in palatable, calorie-controlled portions that are used as:
a) iso-or hypocaloric meal and snack replacements
b) hypercaloric supplementation for malnourished people
c) enteral nutrition support
to an extent determined by clinical circumstances and the discretion of prescribing healthcare professionals.[21]

How diabetes specific nutritional formulas differ from VLEDs

It is important to distinguish between a DSNF and Very Low Energy Diet (VLED) product, as their nutritional composition and therefore intended uses differ considerably. VLED products are designed for the management of obesity and are generally recommended for people with diabetes who have a Body Mass Index (BMI) greater than 30 kg/m^2, as per the Australian Obesity Management Algorithm.[25] VLED products are safe to use as a total diet replacement under medical supervision and have a macronutrient composition that is low in carbohydrate and fat as well as high in protein to promote ketosis and reduce hunger. In contrast, DSNFs are formulated primarily to assist those with diabetes or impaired glucose tolerance with nutritional adequacy and glycaemic management, weight loss is not their primary aim. DSNFs can be used independent of BMI and therefore can be tailored to meet the needs of people with low, healthy or elevated BMI. When used for the purposes of weight management, DSNFs are not intended to be used as a total diet replacement, rather it is suggested that DSNFs may replace breakfast and/or a snack (not more than two meals a day), as part of a low-calorie diet.[24]

Indications for use of diabetes specific nutritional formulas

DSNFs are indicated for people with diabetes or those with impaired glucose tolerance (pre-diabetes) as part of a diabetes management plan, including diet and exercise. DSNFs may be most useful or applicable for people with diabetes under specific circumstances, in which their ability to adhere to healthy diet choices, manage their weight or glycaemia, and/or maintain adequate nutritional intake is compromised. For example, DSNFs can be used:

- as a meal and/or snack replacement in the short-term for those who find preparing a healthy, low GI meal challenging due to various limitations such as lack of time and resources, low confidence/anxiety, lower nutrition health literacy, and limited cooking skills.
- as a dietary supplement in the setting of malnutrition or poor oral intake, including dental issues or post-surgery recovery.

Diabetes specific nutritional formulas and micronutrients
Adequate intake of micronutrients is important for people with diabetes, particularly when these nutrients are cofactors in glucose metabolism. Evidence has shed light on the potential benefits of specific micronutrients for improved insulin sensitivity and secretion – including minerals (magnesium, calcium, potassium chromium and zinc), trace elements (copper, vanadium, iron, and selenium), vitamins (D and B-group vitamins), pre and/or probiotics and inositol.[12-18] Many DSNF formulations will include some or all of the above micronutrients.

It is important to note that, in the absence of underlying nutrient deficiencies, there is currently no clear or conclusive evidence supporting the use of dietary micronutrient supplementation to improve outcomes in people with diabetes.[19,20] However, people with diabetes are prone to develop micronutrient deficiencies due to altered protein metabolism, increased fluid losses and inadequate or unbalanced dietary intake.[21,22] Whilst DSNFs should not be used in isolation to correct any specific, diagnosed micronutrient deficiencies – they can be valuable inclusions in treatment plans devised by healthcare professionals, especially when dietary intake is poor.[10,11]

Use of diabetes specific nutritional formulas with metabolic surgery and Glucagon-Like Peptide-1 (GLP-1) receptor agonists-induced weight loss and T2D

Bariatric/metabolic surgery is effective in achieving significant long-term weight loss and weight loss maintenance and remission in T2D.[26] This is due to the reduction of fat and lean (muscle) mass.[27] Post-surgery, there is often nausea and vomiting and issues with malabsorption of macro and micronutrients that can contribute to complications, including fatigue, hair loss, cramps, paraesthesia, anaemia, bone loss and neuropathies.[28] Specific nutritional support is required to mitigate these complications and muscle loss and prevent sarcopenia.

There has been a significant increase in the prescribing of glucagon-like peptide 1 receptor agonists (GLP-1a) in T2D, due to their benefits in glycaemic management and potential reduction of cardiovascular and renal complications. In addition to their glucose-lowering effects, GLP-1a can reduce appetite, increase satiety and therefore lead to substantial and rapid weight loss.[29] This weight loss is associated with a decrease in both fat mass and lean mass.[30]

Preserving lean mass is important in cases where appetite and the capacity to increase food volume is low, particularly for elderly people or those with low mobility. The protein requirement is often increased at ageing due to the blunted muscle protein synthesis response to anabolic stimuli (anabolic resistance to protein consumption).[31] A DSNF can play a significant role in not only aiding glycaemic management but also in enhancing protein and overall nutritional intake, crucial for protecting against loss of muscle mass. It is important to note that, at present, the specific interaction between DSNFs and GLP-1a is unknown and future research is needed to understand the potential synergies and implications of combining DSNFs with GLP-1a to optimise therapeutic approaches.

Future directions and research needs

While the benefits of DSNFs have been observed in various populations, there are still knowledge gaps that require further investigation. The following areas have been identified by the working group:

- Determining the optimal dose, frequency, and composition of DSNFs, as variations in protocols and formulations across studies make it difficult to establish standardised recommendations[9,19]. Future research should explore the individualisation of use, timing and frequency of DSNFs, as well as the specific meal components that provide the best glycaemic outcomes.
- Exploring the use of DSNFs following metabolic surgery or pharmacotherapy-induced weight loss in people with T2D, particularly in people over the age of 65 years.
- Investigating the role of DSNFs in vulnerable populations including those with disabilities, First Nations peoples and people from culturally and linguistically diverse backgrounds.
- The impact and timing of DSNF consumption in relation to medications, particularly insulin and oral anti-hyperglycaemia medications.
- Understanding the timing of DSNF consumption in relation to physical activity and glycaemic outcomes.
- Comparisons between DSNFs and meals of equal nutritional value, as well as daily intakes with equivalent calorie and macronutrient profiles, need to be further explored.
- Long-term outcomes of glycaemia, such as at 3, 6, and 12 months after DSNF intervention, also require investigation.
- Noronha and Mechanick (2022)[24] summarised the research gaps as: "Implementation and adherence to the tDNA (transcultural diabetes nutrition algorithm) will also vary depending on cultural, psychological, ethnic, nutritional, and lifestyle factors, as well as the economic and social environment". In other words, it is essential to consider cultural, psychological, ethnic, nutritional, and lifestyle factors when incorporating DSNFs into clinical practice and tailoring recommendations to individuals' needs.[23]

Future research is needed to address these knowledge gaps and establish evidence-based guidelines for using DSNFs in specific populations.

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