



Artigo Original

Plant-based Diets in Type 2 Diabetes Management: Perception of Healthcare Professionals



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Abordagens Dietéticas para Conter a Hipertensão;
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A B S T R A C T

Introduction: Nutrition therapy plays a central role in diabetes management and growing evidence supports the use of plant-based diets for both preventing and treating type 2 diabetes. The aim of this study was to (1) to assess the level of knowledge among healthcare professionals regarding the therapeutic use of plant-based diets in diabetes management and (2) identify the barriers hindering the recommendation of this eating pattern to diabetic patients.

Methods: A nationwide online questionnaire was applied to 254 healthcare professionals, mainly endocrinologists, general practitioners, and nutritionists. The questionnaire evaluated (1) level of knowledge on the subject, (2) dietary recommendation practices, and (3) perceived barriers to the recommendation of plant-based diets to patients.

Results: Fifty-two percent of participants had never heard of the use of plant-based diets in the management of type 2 diabetes and 53% scored ≤ 2 , on a scale of 1 to 5, their own knowledge about plant-based diets. Only 15.4% recommended plant-based diets to their diabetic patients. Healthcare professionals who had knowledge on the use of plant-based diets in diabetes management were 2.5 times more likely to recommend this eating pattern to their diabetic patients. The main barriers identified were lack of support to patients (35.4%), lack of scientific evidence (27.4%), and non-acceptance (23.6%) / noncompliance (24.1%) by the patients.

Conclusion: Knowledge about plant-based nutrition is suboptimal and incorrect or outdated notions on this subject are still prevalent. Future educational interventions targeting healthcare professionals could effectively reduce morbimortality of type 2 diabetes and the associated costs.

Dieta Vegetariana no Tratamento da Diabetes Mellitus Tipo 2: Perspetiva dos Profissionais de Saúde

R E S U M O

Introdução: A nutrição tem um papel central no tratamento da diabetes e existe cada vez maior volume de evidência a comprovar o papel das dietas vegetarianas no tratamento e prevenção da diabetes mellitus tipo 2. Este estudo teve como objetivos (1) avaliar o nível de conhecimento entre profissionais de saúde relativamente ao papel terapêutico das dietas vegetarianas e (2) identificar barreiras e promotores da recomendação deste padrão alimentar às pessoas com diabetes.

Métodos: Foi aplicado um questionário online a nível nacional a 254 profissionais de saúde, nomeadamente Endocrinologistas, médicos de Medicina Geral e Familiar, e Nutricionistas. O questionário avaliou (1) o nível de conhecimento sobre o tema, (2) as práticas de recomendação alimentar, e (3) as barreiras percecionadas na recomendação deste padrão alimentar aos doentes.

Resultados: Cinquenta e dois por cento dos participantes não tinha ouvido falar do uso das dietas

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vegetarianas no tratamento da diabetes *mellitus* tipo 2, e 53% pontuou ≤ 2 , numa escala de 1 a 5, o seu próprio conhecimento sobre as dietas vegetariana. Os participantes que tinham conhecimento sobre o uso das dietas vegetarianas no tratamento da diabetes tinham uma probabilidade 2,5 vezes superior de recomendar este padrão alimentar aos seus doentes. As principais barreiras identificadas foram a falta de apoio aos doentes (35,4%), a falta de evidência científica (27,4%), e a não-aceitação (23,6%) / não cumprimento (24,1%) da dieta pelos doentes.

Conclusão: O nível de conhecimento sobre as dietas vegetarianas é subótimo e noções erradas ou desatualizadas sobre este tema são prevalentes. Futuras intervenções educacionais dirigidas aos profissionais de saúde podem ser eficazes na redução da morbimortalidade da diabetes *mellitus* tipo 2 e custos associados.

Introduction

Diabetes is a serious, chronic disease and it is currently considered to be a global epidemic. It is a major cause of blindness, kidney failure, myocardial infarction, stroke, lower limb amputation and premature death.¹

According to the International Diabetes Federation, in 2017, the prevalence of type 2 diabetes (T2D) in Europe among adults was 9.1%, and the prevalence of impaired glucose tolerance was 5.6%. By 2045 these numbers are expected to increase to 10.8% and 6.6%, respectively.² Importantly, Portugal is the country with the highest non-adjusted prevalence of diabetes in Europe, and in 2017 the prevalence among the adult population was 14.9%.² According to the OECD (Organisation for Economic Co-operation and Development) report, the treatment of diabetes and its complications represented 10% of the health expenditure in Portugal in 2017, which is equivalent to 1% of the nation's GDP.³ It is therefore imperative to design and implement cost-effective measures that help reduce diabetes-associated morbidity and mortality in Portugal.

It is now well-established that nutrition therapy has a central role in diabetes management. Nutrition therapy can reduce glycated hemoglobin by 1.0% to 2.0%, a glucose-lowering effect equivalent to that of metformin.^{4,5} According to the American Diabetes Association (ADA) guidelines, an individualized medical nutrition therapy program is recommended for all people with T2D. Recommended eating patterns in these guidelines include the Mediterranean diet, Dietary Approaches to Stop Hypertension (DASH), and plant-based diets.⁶ In addition, in the 2020 Consensus Statement by the American Association of Clinical Endocrinologists and American College of Endocrinology on the Comprehensive Type 2 Diabetes it is stated that "All patients should strive to attain and maintain an optimal weight through a primarily plant-based meal plan".⁷

In fact, there is growing evidence supporting the use of plant-based diets for both preventing and treating T2D.^{8,9} Plant-based diets are typically defined as eating patterns that promote plant foods such as grains, legumes, vegetables, fruits, and nuts, and avoid or exclude animal products, such as meat, fish, and dairy. Whole-food plant-based diets, in addition, avoid processed, artificial foods and added fats or sugars.¹⁰ Plant-based diets can be further classified according to the amount and type of animal products they include (see Table 1). Interestingly, both the Mediterranean diet^{11,12} and the Dietary Approaches to Stop Hyperten-

sion (DASH)¹³ are frequently described in the literature as plant-based diets.

Several studies have shown that diabetic patients adhering to a plant-based diet will likely decrease their anti-diabetic medication requirements, including both insulin units and oral drugs.¹⁴⁻¹⁷ According to the meta-analysis conducted by Yokoyama *et al*, plant-based diets are associated with greater improvement in glycemic control than diets traditionally recommended to diabetic patients (such as the diet described in the ADA 2003 guidelines).¹⁸ Additionally, plant-based diets are associated with a reduced risk of cardiovascular disease (CVD),^{18,19} which is the number one cause of death in the diabetic population. Some studies have also proven plant-based diets to be beneficial for both preventing and treating diabetic microvascular complications, particularly diabetic neuropathy²⁰ and nephropathy.²¹⁻²⁵ Benefits regarding diabetic retinopathy are yet to be proven.

It is worth of noting that even though plant-based diets are associated with significant weight loss, which is by itself protective against diabetes, the health benefits of plant-based diets are best explained by several independent mechanisms.^{4,10} Other proposed mechanisms include increased insulin sensitivity, improved gastrointestinal hormone response, lower oxidative stress, endothelial dysfunction and inflammation.^{17,26-28} Some recent studies have also hypothesized that changes in the gut microbiome induced by the diet may play a role.^{4,28-30}

Unfortunately, despite the body of evidence supporting the several health benefits of plant-based diets, these are often perceived to be too extreme, difficult, and unacceptable.^{31,32} Health care providers frequently assume their patients will be unwilling to adopt such diets.^{31,33} Contrary to this, several studies have reported high levels of adherence and acceptability^{31,32,34,35} among patients. For instance, the 74-week randomized controlled trial (RCT) conducted by Bernard *et al*, revealed that a low-fat vegan diet can be equally acceptable as the 2003 ADA guidelines diet. The authors have proposed that not limiting portion sizes and not counting calories or carbohydrates, in addition to experiencing new foods and flavors, are some of the factors that explain the reported high acceptability.³²

It is therefore crucial to identify the barriers faced by health-care professionals (HCP) in recommending plant-based diets to their patients and to develop effective strategies to overcome these same barriers.³⁶

The aim of this study was to (1) assess the level of knowledge among HCP regarding the therapeutic use of plant-based diets in diabetes management and (2) identify the barriers hindering the recommendation of this eating pattern to diabetic patients.

Material and Methods

This study was approved by the Ethics Committees of (1) Centro Hospitalar Universitário de São João/Faculty of Medicine, Universidade do Porto; (2) Regional Health Administration of

Table 1. Types of plant-based diets

Vegan	Excludes any food of animal origin.
Ovo-lacto vegetarian	Excludes meat and seafood; includes eggs and dairy.
Pesco vegetarian	Excludes meat; includes seafood, eggs and dairy.
Semi vegetarian	Vegetarian diet with occasional consumption of foods of animal origin. Also known as "flexitarian" diet.

Lisbon and Tagus Valley; and (3) North Regional Health Administration.

An online questionnaire was sent to HCP nationwide, targeting endocrinologists, general practitioners, and nutritionists. The questionnaire was available between October 2018 and February 2019. HCP who did not have regular contact with diabetic patients were excluded. The final sample included 254 participants.

The questionnaire used were carefully designed by our team, having in mind the aim of the study, and using the questionnaire developed by Lee et al³¹ as a reference point. It consisted of eight close-ended items, designed to evaluate: (1) demographic variables, (2) level of knowledge on the subject, (3) dietary recommendation practices, and (4) barriers to the recommendation of plant-based diets to patients.

Absolute and relative frequency counts (n, %) were used to describe categorical variables. All analyses were conducted using IBM SPSS Statistics 24, with significance set at alpha = 0.05.

Results

The HCP sample is described on Table 2. Regarding personal diet, 83.1% of health professionals followed an omnivore diet. Those who reported their diet to be “lactose free” or “gluten free”, for example, were reclassified as omnivores since these diets do not exclude nor avoid animal products.

Table 2. Characteristics of the healthcare professional sample (n=254)

Characteristic	Healthcare Professional Sample (number, %)
Profession	
Endocrinologist	75 (29.5%)
General Practitioner	147 (57.9%)
Nutritionist	22 (8.7%)
Other	10 (3.9%)
Working area (n=218)	
North	56 (25.7%)
Centre	18 (8.3%)
Lisbon and Tagus Valley	142 (65.1%)
Azores and Madeira	2 (0.9%)
Personal diet	
Vegan	3 (1.2%)
Ovo-lacto vegetarian	1 (0.4%)
Pesco-vegetarian	9 (3.5%)
Semi-vegetarian	22 (8.7%)
Omnivore ¹	219 (86.2%)

¹ Of these 8 participants reported adhering to the Mediterranean diet (on the open answer space). Note: Absolute frequencies may not add up to 254 due to missing responses.

A little over half of the participants (52.8%) had not heard of the use of plant-based diets as part of the treatment of diabetes. Of those who did, the most frequently cited source of information were scientific articles (Table 3).

On a scale of 1 to 5 (1 representing the lowest level of knowledge/skills and 5 the highest), 53% of participants scored ≤ 2 their own knowledge about plant-based diets and its benefits on diabetic patients; and 61% scored ≤ 2 their skills of advising on and planning a healthy plant-based diet appropriate for diabetic patients (Fig. 1).

Regarding participants' beliefs about the benefits of plant-based diets in diabetic patients, specifically improvement in gly-

Table 3. Healthcare professional questionnaire results

Question/Answers	Results (number, %)
Have you ever heard of the use of plant-based diets as part of the treatment of diabetes?	
Yes	119 (47.2%)
No	133 (52.8%)
IF YES (n=116), where did you get that information?	
Guidelines	28 (24.1%)
Scientific articles	64 (55.2%)
Lectures/Seminars	37 (31.9%)
Other healthcare professionals	30 (25.9%)
Other	9 (3.5%)
Did you know that the current American Diabetes Association and Canadian Diabetes Association guidelines recommend plant-based diets as an appropriate and desirable option for diabetic patients?	
Yes (Aware of the recommendations of one or both associations)	106 (42.1%)
No	146 (57.9%)
Do you recommend plant-based diets to your diabetic patients?	
Yes	39 (15.4%)
No, I recommend other eating patterns	196 (77.2%)
No, I don't do any recommendation regarding diet	19 (7.5%)
IF YES (n=53), what kind of plant-based diet do you usually recommend?	
Vegan	4 (7.5%)
Ovo-lacto vegetarian	12 (22.6%)
Pesco-vegetarian	22 (41.5%)
Semi-vegetarian	34 (64.2%)
IF YES (n=60), how frequently do you do it?	
Frequently	24 (40.0%)
Occasionally	30 (50.0%)
Rarely	6 (10%)
IF NOT (n=207), why?	
There is not enough scientific evidence about this subject	55 (26.6%)
Adequate guidelines do not exist	39 (18.8%)
Patients cannot carry out this diet	51 (24.2%)
Patients do not accept this diet	50 (24.2%)
Meal planning in this diet is too difficult for the patients	43 (20.8%)
There is not enough support to the patients to help them follow this diet	72 (34.8%)
Other	59 (23.2%)

cemic profile and glycosylated hemoglobin levels, discontinuation of oral antidiabetic agents, BMI, body weight and waist circumference reduction, and total cholesterol and LDL cholesterol reduction, 57%-67% said they “agree” or “strongly agree”, 18%-35% said they “do not agree nor disagree” and 6%-12% said they “disagree” or “strongly disagree” that plant-based diets do exert these effects (Fig. 2).

Regarding guidelines' dietary recommendations, 57.1% of participants were not aware that both the ADA and the Canadian Diabetes Association (CDA) guidelines currently recommend plant-based diets as an appropriate and desirable option for diabetic patients.

In terms of dietary advice practices, 15.4% of participants rec-

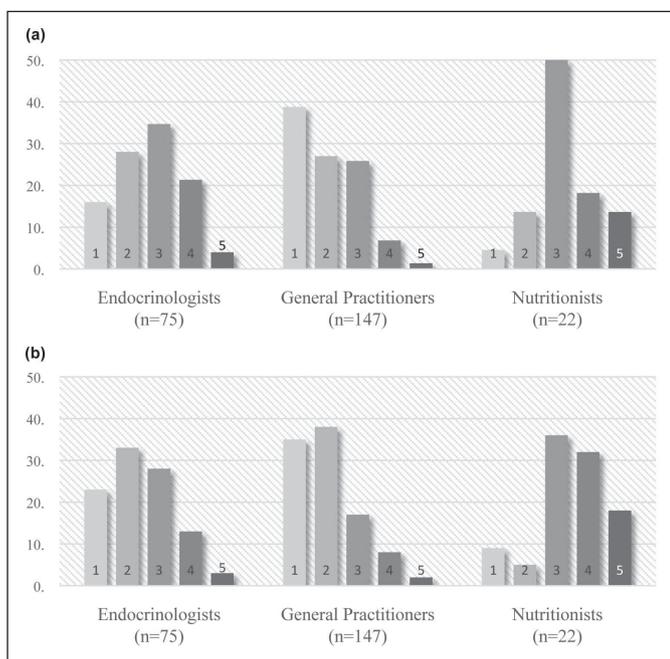


Figure 1. Healthcare professional self-reported level of (a) knowledge regarding the effects of plant-based diets on diabetic patients, and (b) skills of advising on and planning a healthy plant-based diet appropriate for diabetic patients, on a scale of 1 to 5 (1 representing the lowest level of knowledge/skills and 5 the highest).

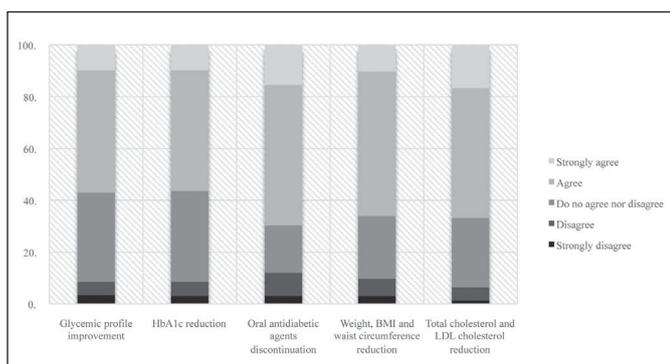


Figure 2. Healthcare professional beliefs regarding the effects of plant-based diets on several cardiometabolic endpoints

ommended plant-based diets to their diabetic patients. Of these, only 7.3% (4/53) recommended vegan diets. Less strict regimens, such as the semi-vegetarian or pesco-vegetarian were found to be more frequently recommended. Of the remaining 84.7%, 77.2% recommend other dietary patterns and 7.5% did not make dietary recommendations at all (Table 3).

Comparing areas of specialization, both endocrinologists and nutritionists reported significantly higher levels of awareness about plant-based diets (70%-74%). Interestingly, despite the lower level of awareness (31%), general practitioners reported levels of recommendation similar to those of other areas of specialization (Table 4).

HCP who had heard of the use of plant-based diets in diabetes management or those who were aware of ADA/CDA guidelines were 2.5 times more likely to recommend plant-based diets to their patients. However, rates of recommendation in this group were still low (22-24%) (Table 5).

No significant association was found between HCP personal

Table 4. Knowledge and dietary advice given by healthcare professionals according to area of specialization.

Knowledge and dietary advice given by healthcare professionals	Area of specialization			p^1
	Endocrinologists (n=75)	Nutritionists (n=22)	General Practitioners (n=147)	
Have heard of using plant-based diets as part of the treatment of diabetes	69.7%	73.9%	30.6%	< 0.01
Are aware ADA and/or CDA guidelines recommend plant-based diets to diabetic patients	63.2%	47.8%	29.9%	< 0.01
Recommend plant based-diets to their diabetic patients	15.7%	9.5%	18.7%	0.72

¹ Refers to Fisher's exact test.

Table 5. Dietary advice given by healthcare professionals according to knowledge

Knowledge	Recommend plant-based diets to diabetic patients		p^1
Have heard of using plant-based diets as part of the treatment of diabetes	Yes (n=119)	22%	
	No (n=133)	9%	
Are aware ADA and/or CDA guidelines recommend plant-based diets to diabetic patients	Yes (n=106)	24%	< 0.01
	No (n=146)	10%	

¹ Refers to Fisher's exact test.

Table 6. Knowledge and dietary advice given by healthcare professionals according to personal diet.

Knowledge and dietary advice given by healthcare professionals	Personal diet		p^1
	Omnivore (n=212)	Plant-based diet (n=42)	
Have heard of using plant-based diets as part of the treatment of diabetes	70%	31%	0.69
Are aware ADA and/or CDA guidelines recommend plant-based diets to diabetic patients	63%	30%	0.77
Recommend plant based-diets to diabetic patients	15%	17%	0.75

¹ Refers to Fisher's exact test.

diet and knowledge about the therapeutic use of plant-based diets in diabetic patients or its recommendation (Table 6).

Among those who did not recommend plant-based diets, the most commonly cited barriers were lack of support to patients (35.4%), lack of scientific evidence (27.4%), and nonacceptance (23.6%) / noncompliance (24.1%) by the patients.

Questionnaire results are described in detail on Tables 3-6 and Figs 1-2.

Discussion

The main finding in our study was that having knowledge on the benefits of plant-based diets for diabetic patients significantly increases the likelihood of recommending this dietary pattern. This solidifies the importance of investing in medical student's nutrition curricula.³⁷

An unexpected result was the similar recommendation rate reported by general practitioners, despite lower levels of knowledge compared to endocrinologists and nutritionists. This might be explained by the large focus general practitioners tend to give to preventive medicine, which often involves allocating more time and resources to promoting lifestyle changes among patients. Another possible explanation is that general practitioners recommend plant-based diets to diabetic patients for other health benefits other than improved glycemic control. It is possible that they do so with the goal of lowering the risk of cardiovascular disease, which is the number one cause of death among diabetic patients.

The barrier most frequently cited by HCP was lack of support to patients. Unfortunately, this is a major problem in most countries. Promoting diet changes is time-consuming and this is an impeditive barrier even for the most motivated physicians.^{4,37} However, some tools do exist to help physicians educate their patients about plant-based diets. There are plenty of already existing resources that can be referred to patients, these include meal-planning guides and websites that list vegetarian restaurants. For example, in 2016 the Portuguese Directorate-General of Health (DGS) elaborated a guide for adopting a healthy vegetarian diet that is available online for anyone wishing to expand their knowledge on this diet.³⁸ Alternatively, patients can be referred to a nutritionist with experience in plant-based nutrition.^{36,39}

Other prevalent barriers were non-adherence and non-compliance by patients, despite the evidence consistently reporting otherwise. Several studies have shown that a large portion of patients is in fact willing to adopt a more plant-based diet.^{31,32,34,35} Hence, presumed unwillingness should not be used as a reason for not addressing plant-based nutrition.

Presumed non-compliance should also not be used as a deterrent. In 2015, Moore *et al* randomized 63 overweight and obese adults to five different diets: vegan, vegetarian, pesco-vegetarian, semi-vegetarian and omnivore. At six months, non-adherent vegan/vegetarian participants lost significantly more weight than non-adherent omnivore participants and had a significantly greater decrease in cholesterol intake than nonadherent pesco-vegetarian/semi-vegetarian or omnivore participants. Importantly, no differences were found in dietary adherence among the five dietary patterns. The authors therefore concluded that, even among non-adherent patients, recommending vegan or vegetarian diets may have a greater impact on health outcomes than recommending more moderate dietary patterns that include meat.³⁴

Finally, 26.6% of healthcare professionals cited “not enough scientific evidence about this subject” as a barrier. This statement is categorically wrong and reflects how many physicians hold outdated beliefs about nutrition. Investment in healthcare professional’s education is warranted. By doing so, more physicians will be propelled to implement this cost-effective, efficient strategy in their daily practice.³⁷

Curiously, on open-ended questions, eight participants cited following a Mediterranean diet, and three participants mentioned recommending this eating pattern to their patients. Similarly to plant-based diets, there are numerous published papers showing the beneficial effect of the Mediterranean eating pattern (MEP) on both diabetes-related and cardiovascular outcomes. For example, in the *PREDIMED* study, a multi-center randomized controlled trial including 7447 participants, after 4.8 years of follow-up, participants in the Mediterranean diet group had a hazard ratio of 0.69 of having cardiovascular events, compared to those in the control diet group.⁴⁰ Admittedly, the MEP has not a consensual definition. However, according to both the ADA and the Portu-

guese Directorate-General, the Mediterranean eating pattern (MEP) is, in fact, plant-based (abundant in fruits, vegetables, cereals, beans, nuts and seeds), and red meat and eggs are consumed in small amounts and with low frequency.¹¹ Importantly, low meat consumption is one of the main proposed mechanisms for the health benefits of the MEP. Not stressing the importance of actively avoiding both processed and unprocessed meat might dampen the benefits obtained with the diet.

A similar study to ours was conducted in 2015 by Lee *et al*, in Canada, but because of the small sample size (n=25 HCP) strong conclusions could not be drawn. In this study, despite 72% of HCP reporting knowledge in the use of plant-based diets in diabetes management, only 32% recommended this dietary pattern to their patients. The most commonly cited barriers were plant-based diets not being realistic/being too difficult, low perceived acceptance by patients, and lack of clear clinical practice guidelines and diet-specific educational support.³¹ These findings are in accordance with ours. The higher rates of knowledge and recommendation among Canadian HCP were expected since the vegan and vegetarian dietary patterns have been included in the CDA guidelines since 2013.

Importantly, the adoption of vegetarian diets is increasing worldwide, in fact, the prevalence of vegetarianism in Portugal has increased four-fold from 0.3% in 2007 to 1.2% in 2017.⁴¹ Nevertheless, many individuals may be getting information about plant-based diets from sources that are not trustworthy and may therefore be at risk of following an unhealthy vegetarian diet, which includes added sugars or refined grains, for example.^{42,43} Therefore, both physician and medical student education on plant-based nutrition is warranted. To minimize the risk of nutrient deficiencies and maximize glycemic control it is essential for physicians to understand the principles of a well-balanced, healthy plant-based diet, which focus on whole foods, and steers away from added fats and sugars. Specifically, education should focus both on the theoretical principles of plant-based nutrition, but also on the practical aspects of giving dietary advice, i.e., easy substitutes for animal source foods. Only then will HCP be able to provide dietary advice to motivated patients. In addition, it would be very helpful if hospitals could provide balanced and flavorful plant-based meals to hospitalized patients. This is not common practice in Portugal, yet it could be a possible way to familiarize both patients and physicians with plant-based diets. It is worth noting that in our study 92.5% participants reported recommending some dietary pattern (15.4% plant-based diets and 77.2% other dietary patterns), implying high rates of motivation to give dietary advice to patients, despite the mentioned barriers.

As most guidelines are in agreement that patients should follow the diet that they feel they can adhere to,^{5,6,42,44} dietary advice should focus on motivating patients to reduce or exclude deleterious animal products and promote the consumption of protective foods, such as whole grains and vegetables,^{36,37,42} while ensuring and adequate intake of both micro- and macronutrients.

Remarkably, despite somewhat high levels of awareness of guideline recommendations, only a fraction of HCP put these to practice. For example, among knowledgeable endocrinologists (63.2%), only one in four do recommend plant-based diets to patients. Future research should further investigate how to address barriers hindering faced by HCP when recommending plant-based diets and shape practical and effective strategies to motivate patients to adhere and maintain long-term adherence to plant-based diets.

One important limitation of this study is the convenience sampling method used. It can result in selection bias and thus limit the

generalization of the results. In fact, voluntary participants may be more knowledgeable about plant-based nutrition and thus the sample would be less representative of the population in study. Another limitation is the cross-sectional design of the study, which allows for associations to be drawn but not causation. The main strength of this study is having participants from different backgrounds. This was achieved by recruiting HCP from different areas of specialization and different localizations across the country.

Conclusion

The level of knowledge is suboptimal and incorrect or outdated notions on this subject are still prevalent among Portuguese HCP. Future educational interventions targeting HCP could effectively reduce the morbimortality of T2D and associated costs. Importantly, education of HCP on plant-based nutrition should cover both strict and flexible plant-based diets, such as the vegan diet on the one hand, or the DASH and Mediterranean diets on the other hand.

Responsabilidades Éticas

Conflitos de Interesse: Os autores declaram a inexistência de conflitos de interesse na realização do presente trabalho.

Fontes de Financiamento: Não existiram fontes externas de financiamento para a realização deste artigo.

Confidencialidade dos Dados: Os autores declaram ter seguido os protocolos da sua instituição acerca da publicação dos dados de doentes.

Proteção de Pessoas e Animais: Os autores declaram que os procedimentos seguidos estavam de acordo com os regulamentos estabelecidos pelos responsáveis da Comissão de Investigação Clínica e Ética e de acordo com a Declaração de Helsínquia de 2013 da Associação Médica Mundial.

Proveniência e Revisão por Pares: Não comissionado; revisão externa por pares.

Ethical Disclosures

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Confidentiality of Data: The authors declare that they have followed the protocols of their work center on the publication of data from patients.

Protection of Human and Animal Subjects: The authors declare that the procedures were followed according to the regulations established by the Clinical Research and Ethics Committee and to the 2013 Helsinki Declaration of the World Medical Association.

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