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Glycemic control in patients with Type 1 Diabetes Mellitus (T1DM) using Diabetes/Diabetic Alert Dogs (DADs): A scoping review

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Abstract

Purpose: The purpose of this scoping review is to present the advantages and disadvantages of using Diabetes/Diabetic Alert Dogs (DADs) and to highlight the gap in the literature resulting from the small number of studies that have been conducted, in order to trigger conduct new studies.

Methods: This scoping review was conducted in the Pubmed, Scopus, and Google Scholar databases, and 13 studies were included for further analysis.

Results: The accuracy of hypoglycemia or hyperglycemia detection by DADs varied greatly between studies. The variability was due to the different training they received, as well as the nature of their relationship with their owner. Almost all studies highlight significant psychological benefits from the use of DADs through the testimonies of participants, with increased mental well-being, reduced anxiety, and increased physical activity.

Conclusions: The use of DADs for the management of type 1 diabetes mellitus (T1DM) is a promising method. The results are encouraging as they appear to help detect extreme blood glucose levels and support the individual by offering psychological well-being. However, it is necessary to conduct more randomized controlled studies with a larger sample size and to develop guidelines for DAD training. Finally, it can be concluded that DADs cannot replace traditional methods of glycemic control but can be used as an adjunct to the optimal management of T1DM.

Keywords: Diabetes mellitus; Diabetes alert dogs; Diabetic alert dogs; Hypoglycemia; Hyperglycemia

1. Introduction

Diabetes mellitus (DM) is defined as: "a chronic metabolic disorder that occurs either when the pancreas does not produce enough insulin or when the body cannot effectively use the insulin it produces. Over time, it can lead to serious damage to the heart, blood vessels, eyes, kidneys, and nerves". Diabetes is classified into four categories: 1) Type 1 diabetes (juvenile diabetes), 2) Type 2 diabetes, 3) Gestational diabetes, 4) Other specific types of diabetes. [1]

Type 1 diabetes mellitus is a chronic metabolic disorder in which the immune system attacks and destroys the beta cells that produce insulin in the pancreas, leading to a complete or near-complete lack of insulin in the body. It is characterized by rapid onset of symptoms, such as excessive thirst, frequent urination, and unexplained weight loss. People with type 1 diabetes require external insulin administration to maintain their blood glucose levels at normal levels. [1]

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According to the American Diabetes Association (ADA), blood glucose levels can be monitored using two methods. The first is the most common method of monitoring, self-monitoring of blood glucose (SMBG). The second method involves a continuous glucose monitoring/recording device (CGM), which monitors blood glucose levels throughout the day and night, providing real-time feedback on glucose fluctuations. In some cases, the two methods may be combined [2]

The above methods mentioned for self-treatment of diabetes are methods of choice. However, both are invasive methods requiring either finger pricking or catheter insertion, resulting in discomfort and often aversion to their use. For this reason, Diabetes/Diabetic Alert Dogs, or DADs, have been proposed as an innovative means of supporting glycemic control in people with type 1 diabetes. DADs have the ability to detect changes in glucose levels through olfactory signals associated with hypoglycemia or hyperglycemia [3] [4] [5]

Therefore, the purpose of this scoping review is to present the advantages of using DADs in individuals with type I diabetes mellitus, as well as the disadvantages that arise in relation to the conventional methods used for glycemic control. It is important to highlight the gap in the literature due to the small number of studies conducted on DADs and to encourage new studies to be conducted.

2. Methods

This scoping review was conducted in the Pubmed, Scopus, and Google Scholar databases to find published articles on the use of DADs and their contribution to glycemic control in individuals with type 1 diabetes mellitus. The following keywords were used in the literature search:

- Alert dogs,
- Diabetes alert dogs,
- Diabetic alert dogs,
- Service dogs,
- Mellitus diabetes type 1,
- Diabetes type 1,
- Hypoglycemia,
- Hyperglycemia.

The search yielded a set of articles that were included in the review based on the inclusion and exclusion criteria defined (Table 1).

Table 1 Inclusion and Exclusion criteria

Inclusion criteria	Exclusion criteria
Publication period 2010-2025	Articles outside a specific publication period
Full text published in Greek and/or English	Inability to obtain full text published in Greek and/or English
Research studies conducted on dogs	Research studies not conducted on dogs
Primary research studies	Reviews, meta-analyses, case studies
	Duplicate articles

The quality of the review was assessed using the PRISMA-Scr 2020 method to ensure transparency and reliability of the process. According to this method, the selection of articles was carried out in three stages. The first stage involved evaluating the titles, the second stage involved checking the abstracts, and the third stage involved reading the entire text. The process of selecting and rejecting the articles is presented in detail in the flowchart below [Figure 1].

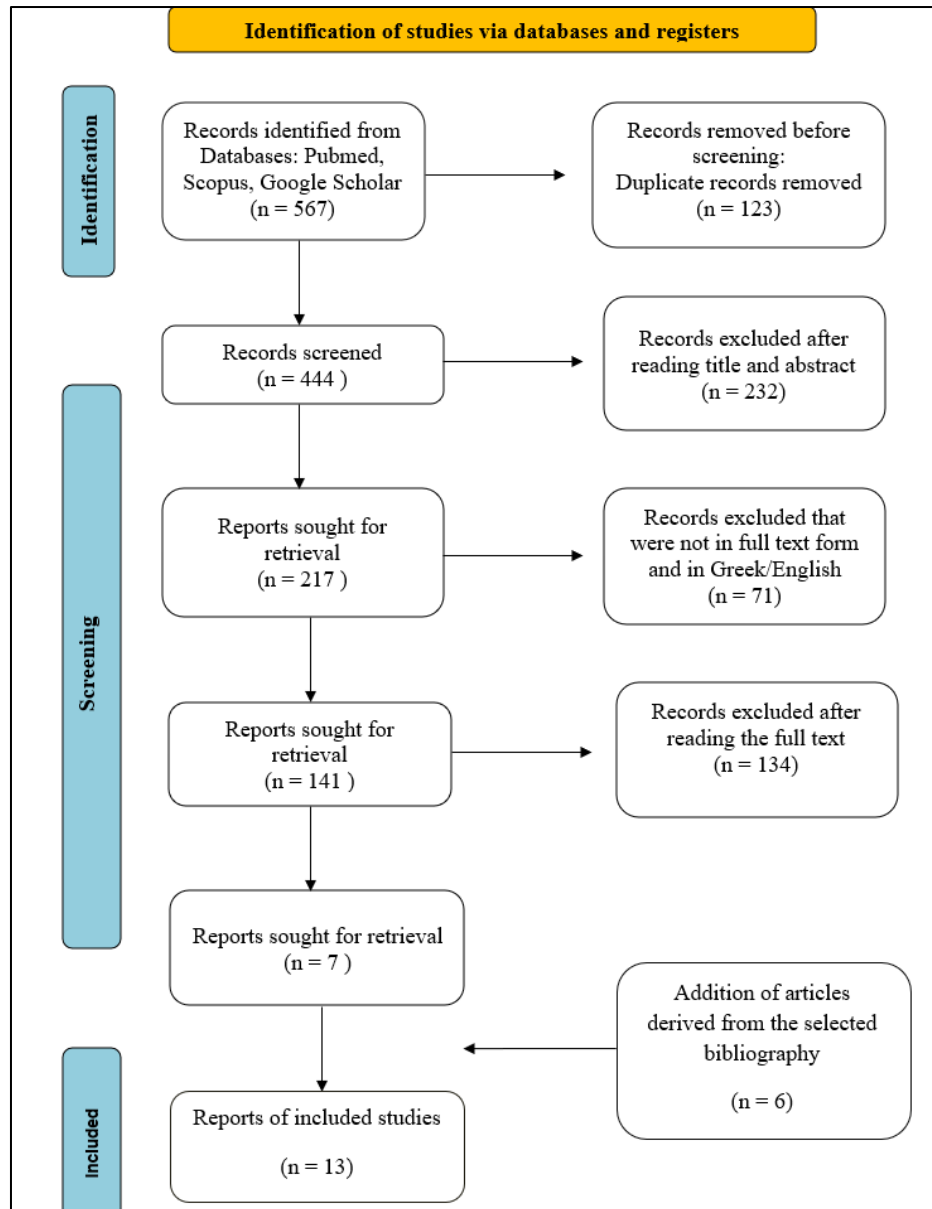


Figure 1 Prisma-Scr flow chart for selecting appropriate studies [6]

3. Results

3.1. Characteristics of studies

The selected studies from the scoping review are presented in Table 2. The Table 2 lists the basic information extracted from each study in order to be used subsequently for grouping and classification based on criteria. Analysis of the studies shows that all of them were conducted in high-income countries, with the largest percentage of studies conducted in the US (69.2%, n=9), UK (15.3%, n=2), Sweden (7.6% n=1), and Canada (7.6% n=1). Finally, two studies were conducted in 2013, two studies were conducted in 2015, one study was conducted in 2016, three studies were conducted in 2017, one study was conducted in 2018, two studies were conducted in 2019, one study was conducted in 2020, and one study was conducted in 2021 (Table 2).

Table 2 Characteristics of the studies fulfilled the insertion criteria of the scoping review

1st Author Year/Country	Title	Purpose	Sample	Methods	Results/Conclusions
Gonder-Frederick et al. (2013) USA	Diabetic alert dogs: a preliminary survey of current users	Investigating the experiences and perceptions of individuals with diabetes mellitus who use diabetic alert dogs (DADs), focusing on accuracy, reliability, and impact on quality of life	36 participants (adults with diabetes or parents of children with diabetes). Most had type 1 diabetes mellitus and were already using DADs.	Descriptive, online questionnaire survey.	Over 70% of users believe that their dogs alert them in a timely and reliable manner and feel safer, less anxious, and have an improved quality of life. However, their effectiveness is mainly based on subjective reports, so controlled scientific studies and standardized training protocols are needed to confirm their accuracy and clinical value.
Rooney et al. (2013) United Kingdom	Investigation into the Value of Trained Glycaemia Alert Dogs to Clients with Type 1 Diabetes	The aim of this study was to evaluate the reliability of trained hypoglycemia alert dogs and to investigate whether their presence is associated with improved glycemic control and psychological well-being in individuals with type 1 diabetes.	17 owners/users of DADs (adults with type 1 diabetes mellitus)	Descriptive and comparative analysis	DADs appear to reliably detect changes in blood sugar levels and contribute positively to the sense of security and psychological well-being of individuals with type 1 diabetes. However, due to the small sample size and lack of controls, further research with objective measurements and larger samples is needed.
Petry et al. (2015) USA	Perceptions about professionally and non-professionally trained hypoglycemia detection dogs	Evaluation of perceptions regarding dogs that have been professionally trained or not to detect glucose levels.	135 individuals, 63 of whom responded on behalf of their child with T1DM.	Descriptive, online survey	DADS can have a significant positive effect on the owner's perception of diabetes control, safety, and quality of life. The study is based on self-reports, possible bias, and it is unclear how generalizable the findings are.
Hardin et al. (2015) USA	Dogs Can Be Successfully Trained to Alert to Hypoglycemia Samples from	The purpose is to expand evaluation of DAD sensitivity and specificity using a method	6 dogs aged 1-10 years that had received an average of 6 months of training to alert for	Experimental, controlled laboratory study	All DADs showed statistically significant ($p < 0.05$) greater sensitivity (minimum 50.0%–maximum 87.5%) in detecting the

	Patients with Type 1 Diabetes	that reduces the possibility of trainer bias.	hypoglycemia using positive training methods		hypoglycemia sample compared to the expected random correct alert rate of 14%. Specificity ranged from a minimum of 89.6% to a maximum of 97.9%. The results suggest that properly trained DADs can successfully recognize and alert for hypoglycemia in an in vitro setting.
Los et al. (2016) USA	Reliability of Trained Dogs to Alert to Hypoglycemia in Patients With Type 1 Diabetes	Study of the reliability of DADs in warning of hypoglycemia in people with type 1 diabetes in real-world conditions using capillary blood glucose (CBG) and blind continuous glucose monitoring (CGM) as comparators.	8 individuals aged 4-48 years. 8 DADs aged 1 year and 9 months to 5 years and 10 months, and the duration of training was 6-24 months.	Exploratory experimental study in a laboratory environment	Trained dogs provided early warning (within 10 minutes before and up to 30 minutes after the onset of hypoglycemia) in 36% (sensitivity) of all hypoglycemic events. The false positive rate was 14.5 false positive alerts per week. Due to the high rate of false positives, a dog's alert alone is unlikely to be useful in differentiating between hypo-/hyper-/euglycemia.
Siegel (2017) USA	Analyzing breath samples of hypoglycemic events in type 1 diabetes patients: towards developing an alternative to diabetes alert dogs	Efforts to expand the search for breath biomarkers for hypoglycemia beyond acetone and isoprene, which can be used to predict hypoglycemia in human breath.	52 individuals with T1DM aged 7-21 years	Experimental study with collection of respiratory samples during hypoglycemia	Sensitivity of 91% and specificity of 84% for distinguishing hypoglycemia, with corresponding 95% confidence intervals. The study shows that it is possible to distinguish between breath samples in a hypoglycemic state and those in a normal state.

Gonder-Frederick et al. (2017) USA	Variability of Diabetes Alert Dog Accuracy in a Real-World Setting	Examined DADs accuracy and variability in performance in real-world conditions using a convenience sample of owner-report diaries.	18 individuals with T1DM who had DADs	Descriptive study using a questionnaire.	The overall sensitivity was 57.0%, with increased sensitivity in low blood glucose (59.2%) compared to high blood glucose (56.1%). Overall specificity was 49.3% and Positive Likelihood Ratio (PLR) = 1.12. However, high variability in accuracy was observed among DADs, with low blood glucose sensitivity ranging from 33% to 100%. The number of DADs that achieved true positive rates of \geq 60%, 65%, and 70% were 71%, 50%, and 44%, respectively.
Gonder-Frederick et al. (2017) USA	Diabetes Alert Dogs (DADs): An assessment of accuracy and implications	Accuracy check of DADs by comparing recorded alerts with continuous glucose monitoring (CGM) device measurements during waking and sleeping hours.	Fourteen individuals (seven adults with type 1 diabetes and seven young people with type 1 diabetes/parents) who had had DAD for \geq 6 months wore CGM devices for several weeks while recording DAD alerts electronically and in paper diaries.	Observational study using online and paper diaries	During waking hours, sensitivity scores for participants were 35.9% for low glucose events and 26.2% for high glucose events. The accuracy of DADs was highly variable, with 3/14 individual dogs performing statistically better than chance. Sensitivity scores were lower during the diabetic individual's sleeping hours (22.2% for low glucose events and 8.4% for high glucose events). The accuracy of DADs during sleep hours was also highly variable, with 1/11 individual dogs performing statistically better than chance.
Lundqvist et al. (2018) Sweden	The impact of service and hearing dogs on health-related quality of life and activity level: a Swedish longitudinal	Describe and explore potential consequences for health-related quality of life, well-being and activity level, of having a	55 individuals aged 17-68 years old who owned dogs completed the study (30 assistance dogs, 20 diabetes alert dogs, 2 epilepsy alert dogs, and 3 hearing dogs).	Long-term prospective intervention study with pre- and post-intervention design.	Initially, participants reported a lower quality of life compared to the general population. After the dog was certified, a significant improvement in quality of life, well-being, and level of physical activity was observed.

	intervention study	certified service or hearing dog.			In the subgroup analysis, physical assistance dog owners had a lower quality of life than hypoglycemia detection dog owners. The improvement from baseline to follow-up on the EQ-5D differs statistically between subgroups. Owning a certified service or hearing dog can have a positive impact on health-related quality of life, well-being, and activity level.
Rooney (2019) United Kingdom	How effective are trained dogs at alerting their owners to changes in blood glycaemic levels?: Variations in performance of glycaemia alert dogs	Assessment of the reliability of a large number of trained dogs for detecting glycaemic episodes, in terms of their response to episodes of hypoglycemia and hyperglycemia (reported as out of range, OOR), and investigating factors related to variations in their performance.	Twenty-seven dogs, which were trained by a British organization.	Prospective, observational, analytical study	The dogs showed varying performance, with an average sensitivity to out-of-range episodes of 70%. In hypoglycemic episodes, the average sensitivity was 83% (66-94%), while in hyperglycemic episodes it was 67% (17-91%). The mean positive predictive value (PPV) was 81% (68-94%), meaning that on average 81% of alerts occurred when glucose levels were outside the desired range. For four dogs, the PPV was 100%. Individual dog characteristics, cooperation, and housekeeping were significantly associated with performance. The large sample size indicates that individual dog performance is variable, but overall their sensitivity and specificity for OOR episodes are better than previous studies suggest.
Wilson (2019) USA	An Owner-Independent Investigation of Diabetes	Quantifying the performance of DADs using	8 people with certified DADs	Prospective, experimental, observational study	Sensitivity to hypoglycemic episodes ranged from 33.3 to 91.7%, with a mean of

	Alert Dog Performance	owner-independent measurements			55.9%. The mean PPV for OOR episodes was 69.7%. Sensitivity and PPV were associated with aspects of dog and owner behavior, as well as owner adherence to the training protocol. The performance of DAD is influenced by the characteristics and behaviors of both the dog and the owner.
Reeve (2020) Canada	An Idiographic Investigation of Diabetic Alert Dogs' Ability to Learn From a Small Sample of Breath Samples From People With Type 1 Diabetes	Investigating the ability of DADs to detect hypoglycemic episodes through the breath of individuals with type 1 diabetes, evaluating both the sensitivity and specificity of detection in real-world conditions.	2 trained DADs and 3 participants, from whom breath samples were collected	Prospective, experimental study	One dog had a sensitivity of 62% and a specificity of 89% for samples from the same person, while the second dog was unable to transfer detection to samples from the same person. The transfer of detection to samples from other individuals was unclear. Some dogs can detect hypoglycemic breath in one person, but the ability may not transfer to different individuals.
Nieforth et al. (2021) USA	Benefits and challenges of mobility and medical alert service dogs for caregivers of service dog recipients	Analysis of caregivers' testimonies in order to understand their views on the benefits and challenges they face with mobility and medical alert dogs	117 caregivers of individuals who have received service dogs	Qualitative study	Key themes were identified in relation to caregivers and service dogs: (1) family benefits, (2) benefits for caregivers, (3) assistance through service dog training, and (4) disadvantages. The findings suggest that the benefits and challenges of mobility and medical service dogs extend beyond the recipient of the dog's service, also affecting the caregiver and other family members.

3.2. Accuracy and reliability of DADs

The accuracy of hypoglycemia or hyperglycemia detection by DADs varied greatly between studies. Specifically, in a laboratory study conducted by Hardin et al. [5], much higher accuracy was recorded, with sensitivity of 50–87.5% and specificity of 89.6–97.9%, while in the study by Gonder-Frederick et al. [3] [4] reported that during waking hours, the sensitivity scores in participants were 35.9% for hypoglycemia and 26.2% for hyperglycemia. The accuracy of DADs was highly variable, with 3/14 individual dogs performing statistically better than chance. Sensitivity scores were lower

during the individual's sleep hours (22.2% for low glucose events and 8.4% for high glucose events). The accuracy of DADs during sleep hours was also highly variable, with 1/11 individual dogs performing statistically better than chance. In the study by Los et al. [7], it appears that DADs provided timely alerts within 10 minutes before and up to 30 minutes after the onset of hypoglycemia with 36% sensitivity of all hypoglycemic events. However, the false positive rate was 14.5% per week. According to Rooney et al. [8], whose study included a sample of 27 dogs, found an average sensitivity of 83% for hypoglycemic episodes and 67% for hyperglycemic episodes, with a positive predictive value of 81%. Similarly, the study by Wilson et al. [9] confirmed similar results with an average sensitivity of 55.9% and Positive Predictive Value (PPV) of 69.7%, while it was found that performance depends on the dog's behavior and the owner's adherence to the training protocol. Finally, according to Reeve [10], whose study sample consisted of two trained DADs and three participants, one dog had a sensitivity of 62% and specificity of 89% for samples from the same person, while the second dog was unable to detect samples from the same person.

3.3. Effect of DADs on psychological well-being

Almost all studies highlight significant psychological benefits from the use of DADs through the testimonies of participants. Specifically, Gonder-Frederick et al. [11] report that over 70% of users believe that their dogs alert them in a timely and reliable manner, thus making them feel safer, less anxious, and improving their quality of life. The study by Rooney et al. [12] emphasizes that DADs contribute positively to the sense of security and psychological well-being of people with type 1 diabetes. Similarly, Lundqvist et al. [13] reported an improvement in the quality of life and personal well-being of individuals, with an increase in the level of physical activity.

4. Discussion

According to the World Health Organization [1], in 2017 there were approximately 9 million people with Type 1 Diabetes Mellitus (T1DM), the majority of whom live in high-income countries. These epidemiological records highlight the need for technological advances in the management of the disease, as well as the search for alternative methods that will contribute to improving the management of T1DM. One such method is the use of Diabetic/Diabetes Alert Dogs (DADs), which has attracted research interest over the years. In this scoping review, systematic methods were applied to extensively investigate the use of DADs and their contribution to glycemic control in people with T1DM.

Many studies included in the review, such as those by Gonder-Frederick et al. [3] [4][11], Rooney et al. [8] [12], and Petry et al. [14], were based on descriptive studies and observational studies, usually using questionnaires or diary entries. In this way, they focused more on the experience and perceptions of DADs users. These studies show that more than 70% of participants believe that their dogs alert them in time for impending hypoglycemic episodes, offering a sense of protection and reducing the fear that accompanies the daily management of T1DM. It is important to note that although these data are subjective, they are particularly important, as it appears that DADs offer psychological well-being to users, a fact that is often overlooked in technological interventions such as continuous glucose monitoring (CGM) sensors. However, the interpretation of these findings requires caution, as most studies did not use objective biomedical criteria to confirm the effectiveness of DADs.

In contrast, studies by Hardin et al. [5] and Los et al. [7] evaluated the sensitivity and specificity of DADs in controlled environments. The results of these studies are encouraging, as they show sensitivity ranging from 50% to 87.5% and specificity between 89.6% and 97.9%. However, even in these studies, there are variations in performance between DADs, indicating that their effectiveness depends on many factors, such as the quality of training, the trainer's experience, and the dog's relationship with its owner.

One of the most important issues arising from this limited review is the variability of results. Research by Gonder-Frederick et al. [11] showed that the sensitivity of DADs in detecting hypoglycemia in real-world conditions ranged from 33% to 100%, while specificity remained relatively low at 49.3%. Similarly, Wilson's [9] study showed a sensitivity range of 33.3% to 91.7% specifically for hypoglycemia. These results confirm the existence of variation among DADs. Furthermore, they indicate that although DADs have impressive olfactory abilities, their performance and success can be influenced by a number of factors, such as the adherence to the training program, the different training protocols, the environmental conditions, and the behavior of the owner themselves.

Subsequently, the study by Siegel et al. [15] reinforced the idea that breath contains volatile organic compounds (VOCs) that can serve as biomarkers for glycemic control. In this particular study, breath samples were collected and used for this purpose. The findings may explain the olfactory ability of DADs to detect such changes. At the same time, Reeve's [10] (2020) study, which was conducted with breath samples in hypoglycemia, euglycemia, and hyperglycemia, confirmed that the detection ability of DADs through breath samples can be effective at the individual level, but it

appeared that generalization to other people is limited. These results raise further questions about whether DADs can be trained based on general biomarkers or whether training should be individualized for each person.

A common finding presented by the majority of studies included in this scoping review was the effect of DADs on the mental well-being of individuals with T1DM. In particular, the study by Lundqvist et al. [13] was decisive, as it showed that acquiring a certified assistance dog is associated with a significant improvement in quality of life, well-being, and physical activity levels. According to this study, participants reported that after training their assistance dog, they had more confidence and independence and less fear and anxiety related to hypoglycemia. Based on these results, it's clear that DADs can be used not only for glycemic control but also as a "tool" to support the mental health of people with T1DM.

Although the above findings are encouraging, this review highlighted significant limitations in the existing literature. Specifically, most studies consist of a small sample size, which significantly reduces the statistical power and the generalizability of the results. It has also been observed that several studies use not only children with T1DM as a sample, but also adults with T1DM and their caregivers, while also comparing them with other dogs used as service dogs for people with conditions such as epilepsy or mobility problems. Specifically, in the study by Nieforth et al. [16], data is collected from caregivers of individuals who use service dogs in general, without specific reference to DADs, while a comparison is made between the various services offered by dogs.

Furthermore, there is heterogeneity in the training methodology of DADs, given that there are no international guidelines. This makes it difficult to compare studies and therefore draw reliable conclusions. Some studies are based on data from self-reports by the owners themselves, which may be subject to bias or overestimation of the effectiveness of DADs. [3] [4] [11] [14] [16]

An additional issue is the lack of randomized controlled trials (RCTs). Several of the studies included are observational, descriptive studies, and although they provide valuable information, they do not allow causal relationships to be established. Consequently, it is recommended that future studies with a specific and rigorous design be conducted to compare the effectiveness of DADs with technological monitoring methods (such as CGM) and to examine their combination as a possible best practice.

Finally, the findings of the review have important practical and theoretical implications. It is important that the training and certification of DADs should be carried out by specialized bodies, with clear specifications and evaluation of each dog's performance. At the same time, international guidelines need to be developed to ensure consistency and quality of training. The study of DADs opens up new horizons for diabetes management through a combination of methods and practices.

5. Conclusion

In summary, the results of this scoping review indicate that Diabetic/ Diabetes Alert Dogs can play an essential role in improving the management of type 1 diabetes, not by replacing traditional monitoring methods but by acting as an adjunct to ensure optimal management and treatment. The use of DADs is an innovative and promising field of research, but one that has not been studied extensively. It is important to highlight the gap in the literature that emerges from this limited review, as since 2021 there have been no additional clinical trials on the use of DADs, only literature reviews. This highlights the need for further research to improve the management of type 1 diabetes mellitus using DADs in combination with conventional methods of glycemic control.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

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