

REVIEW

Fasting, Diabetes, and Optimizing Health Outcomes for Ramadan Observers: A Literature Review

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ABSTRACT

Introduction: Globally, and in Australia, diabetes has become a common chronic health condition. Diabetes is also quite prevalent in culturally and linguistically diverse pockets of the Australian population, including Muslims. There are over 90 million Muslims with diabetes worldwide. Diabetes management and medication use can be affected by religious practices such as fasting during Ramadan. During Ramadan, Muslims refrain from oral or intravenous substances from sunrise to sunset. This may lead to many potential health or medication-related risks for patients with diabetes who observe this religious practice. This literature review aimed to explore (1) health care-related interventions and (2) intentions, perspectives, or needs of health care professionals (HCPs) to provide clinical services to patients with diabetes while fasting during Ramadan with a view to improve health outcomes for those patients.

Methods: Using a scoping review approach, a comprehensive search was conducted. Databases searched systematically included PubMed,

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Medline, Embase, and International Pharmaceutical Abstracts. Studies published in English that described interventions or intentions to provide interventions regarding diabetes and Ramadan fasting were included.

Results: Fourteen published articles that met the inclusion criteria were retrieved and content analyzed. Of those, nine intervention studies regarded diabetes management education. Five studies described professional service intention, four of which were related to the role of pharmacists in diabetes management in Qatar, Australia, and Egypt, and one French study examined the general practitioners' (GPs) experiences in diabetes management for Ramadan observers. The intervention studies had promising outcomes for diabetes management during Ramadan. Effect sizes for improvement in HbA1c post intervention ranged widely from -1.14 to 1.7 . Pharmacists appeared to be willing to participate in programs to help fasting patients with diabetes achieve a safe therapeutic outcome. Service intention studies highlighted pharmacists' and GPs' need for training prior to providing services from a clinical as well as cultural competence perspective.

Conclusion: Interventions research in this area requires robustly designed and structured interventions that can be tested in different contexts. This literature review revealed many gaps regarding diabetes management in Ramadan. Health professionals are willing to provide services for fasting diabetes patients, but need upskilling.

Keywords: Fasting; HbA1c; Hypoglycemia; Pharmacist; Ramadan; Type 1 diabetes; Type 2 diabetes

INTRODUCTION

Internationally, the prevalence of diabetes is approximately 8.3%; 382 million people live with diabetes [1]. Of these, nearly 90 million are Muslims [2]. Diabetes is also increasingly becoming a common disease among the Australian adult population. In 2011–12, for example, 4.7% of the Australian population were reported to have type 2 diabetes (T2D) [3]. Diabetes is particularly prevalent in culturally and linguistically diverse (CALD) Australians. Many of these CALD populations follow different religious beliefs. Islam is one of the key religions followed by CALD populations. For example many of those who have migrated to Australia from the Indian subcontinent, central and far east Asian countries (Indonesia/Malaysia), Europe, and from the middle-eastern and North African regions are Muslims [4]. There has been an estimated 69% increase in the Australian Muslim population from 2001 to 2011, with the total current number of Muslims believed to be approximately 476,300 [5]. Although the prevalence of diabetes in Australian Muslims is not known directly, indirect markers point to the fact that diabetes may be fairly common in this population. Studies indicating, for example, that Australian women and men born in the Middle East or North Africa were 2.4 and 3.6 times more likely to have diabetes than those who were born in Australia [6]. Given that about 42% of Australian Muslims are of North African or Middle Eastern origin, these data suggest the possibility that diabetes may be quite prevalent in Australian Muslims [4]. This population group is also likely to have socio-religious practices that may impact on their beliefs about health and health management practices [6]. Religious fasts, such as Ramadan, are a key example of this issue.

Fasts may influence the body's homeostatic rhythms and in those taking chronic medications, fasts may upset established

pharmacokinetic and pharmacodynamics disposition patterns of medications [5–7]. Fasting has the potential to affect glucose control of patients who have diabetes mellitus and it can disrupt the actions of antidiabetic medications [7]. Ramadan is a well-known fast observed by Muslims. Ramadan occurs in the ninth month of the lunar calendar in Islam and lasts 29–30 days [8, 9]. Fasting in Ramadan is one of the principal pillars of Islam; it requires Muslims to fast during daylight hours, abstaining from all food and drink, as well as substances, such as medicines, taken orally or intravenously [10, 11]. Fasting people usually have a post-fast meal (Iftar) after sunset and a pre-fast meal before sunrise (spelt varying in English as Sohour, Suhoor, Suhur, or Sehri) [8, 10]. The absolute refraining from food and drink between sunrise and sunset can lead to disruption of homeostasis [10]. It is worthwhile to consider the impact of fasting on the health of Ramadan observers, as these observers have been reported to have higher prevalence of diabetes. There are, for example, more than 50 million Muslims worldwide who observe Ramadan although they live with diabetes [12]. For instance, an epidemiological study mapping diabetes patients observing the Ramadan fast ($n = 12,914$) in 13 Muslim countries indicated that almost 79% of patients with T2D observed the fast of Ramadan [12].

Diabetes is actually the most common illness studied with regard to Ramadan [13–18]. Fasting has the obvious potential to disrupt diabetes management as a result of the reduced food, drink, and medication intake during certain hours [17]. The practice of observing the month-long fast can affect glucose control [19]. This could lead to avoidable health problems. One of the potential adverse effect risks of taking antidiabetic medications and fasting can be hypoglycemia. Other issues that may occur include hyperglycemia, hyperglycemic-hyperosmolar state, and diabetic ketoacidosis [13, 20]. Several studies have attempted to document the effect of fasting on diabetes. A prospective clinical trial was conducted in Iran to examine the impact of Ramadan fasting on glycemic control in T2D patients ($n = 88$). The trial reported that glycemic control deteriorated

significantly among T2D patients who opted to fast during Ramadan. Nonetheless, hemoglobin A1c (HbA1c) reduced significantly a month after Ramadan from $9.4 \pm 2\%$ to $8.4 \pm 2.5\%$ ($p < 0.001$) [21]. On the other hand, a recent review highlighted that in insulin-dependent patients with diabetes, severe hyperglycemia and ketoacidosis were insignificant concerns, and only minor hypoglycemic episodes were evident in this population, when they reported observing Ramadan [22].

Several studies have illustrated the importance and positive effects of regular glucose monitoring, dietary counselling, drug dosage and timing alteration, and patient education during Ramadan [23, 24]. The International Group for Diabetes and Ramadan (IGDR) consensus diabetes management recommendations during Ramadan (2015 update) reported by Ibrahim et al. suggest several recommendations for adverse event prevention strategies during Ramadan as shown in Table 1 [24]. Also guidelines for medication management during Ramadan have been suggested by a few groups, and key points are summarized in Table 2.

Ahmedani et al. demonstrated in a multicenter prospective study ($n = 682$ patients with diabetes) that most participating patients fasted without any serious acute adverse events during Ramadan when the recommendations mentioned above were provided [25]. In this study,

for example, 91% of fasting patients had their drug dose/timing altered, and physical activity patterns were downgraded from moderate/heavy to lighter levels of exercise; changes were overseen by medical practitioners [25].

One of the health professionals that could play a key role in optimizing the health of those with T2D observing Ramadan may be community pharmacists. Pharmacists are usually consulted far more often than physicians. They are also usually available for consultation without appointments, and in most cases health consults are provided without a fee for service. Robust data from multisite trials suggest that pharmacists' intervention for patients with diabetes can improve clinical and humanistic outcomes for patients [26–31]. However, there has not been much research conducted in Australia on fasting patients with diabetes, nor are there specific medical/allied health professional guidelines for the management of T2D in patients observing Ramadan in Australia. The first exploratory study into pharmacists' perspectives about their role in care of patients with diabetes observing Ramadan was conducted in 2015 [32]. Findings of this qualitative work indicated that pharmacists do not proactively provide care for T2D Ramadan observers, but are keen to do so if supported by training and practice frameworks [32]. To develop guidelines and interventions to optimize

Table 1 Recommendations to prevent diabetes-related adverse events risks during Ramadan (adapted from Ibrahim et al. [24])

Recommendations to prevent adverse events risks

Blood glucose monitoring several times a day depending on treatment regimen for a month prior to Ramadan

Consultation with HCPs for changing medications based at least 1 month before Ramadan begins

Avoiding large pre-dawn (Sohour) meals

Avoiding vigorous physical activities during fasting time

Recording blood glucose readings regularly during Ramadan to determine the occurrence of hypoglycemia

Breaking the fast and eating snacks immediately if hypoglycemic symptoms appear. Further recommendations for hypoglycemia treatment involve consuming 15 g of carbohydrates such as half a cup of orange, apple juice or regular soda, three or four glucose tablets, a table spoon of honey or sugar, five or six hard candies, a cup of milk, or a serving of glucose gel

HCP health care professional

Table 2 Medication adjustment suggestions during Ramadan (adapted from Karamat et al. [49] and Ali et al. [2])

Type of antidiabetic medication	Dose before Ramadan	Medication adjustment suggestions Note: Sohour implies a.m. dose and Iftar implies p.m. dose
Metformin	500 mg tds	This needs to be changed to 1000 mg taken at sunset meal (Iftar) and 500 mg at predawn meal (Sohour)
Short-acting sulfonylurea	For example, gliclazide 80 mg bd For example, gliclazide 80 mg a.m. + 40 mg p.m.	Change to gliclazide 80 mg at Iftar, 40 mg at Sohour Change to gliclazide 80 mg at Iftar, 40 mg at Sohour
Long-acting sulfonylurea	For example, glimepiride 4 mg od	Switch to repaglinide or short-acting sulfonylurea, if possible, otherwise dose should be taken with Iftar
DPP-4 inhibitors	For example, vildagliptin 50 mg bd, sitagliptin 100 mg od, saxagliptin 5 mg od, and linagliptin 5 mg od	No change in dose is required but caution around dehydration and syncope in warm countries is advised. Patients are also requested to pay close attention for any signs of ketoacidosis and be provided with ketone testing kits
Glucagon-like peptide 1 agonist	For example, liraglutide 1.2 mg od, exenatide 10 µg bd, lixisenatide 20 mg od, exenatide qw	With exenatide it should be ensured that the duration between the daily doses is >6 h. This may be affected when duration of fast is >18 h
Sodium-glucose co-transporter 2 inhibitors	For example, dapagliflozin, canagliflozin	No change needs to be made for the doses of this type. However, patients should pay attention to any sign of ketoacidosis and they can be given ketone kits. Also, caution is required regarding syncope and dehydration in warm countries
Insulin	Long-acting (basal) insulin, e.g., glargine Rapid-acting (meal-time) insulin, e.g., Novorapid/Humalog 10 U tds with meals Mixed insulin, e.g., Novomix 30–30 U a.m. and 20 U p.m. Mixed insulin, e.g., Humalog Mix 25–20 U a.m. and 20 U p.m. Mixed insulin, e.g., Humulin M3–32 U a.m. and 24 U p.m.	Long-acting insulin dose should be reduced by 20% and taken at Iftar, e.g., glargine dose can be reduced from 20 to 16 U and taken with evening Iftar meal Lunchtime dose can be omitted and insulin can be taken twice daily with meals at Sohour and Iftar, e.g., Novorapid/Humalog 10 U with Sohour and Iftar Consider reversing doses so that the usual morning dose is taken at Iftar and half of the usual evening dose is taken at Sohour, e.g., Novomix 30–10 U at Sohour and 30 U at Iftar For example, Humalog Mix 25–10 U a.m. and 20 U p.m. For example, Humulin M3–12 U a.m. and 32 U p.m.

tds 3 times a day, *bd* twice a day, *od* once a day, *qw* once a week

diabetes management during Ramadan in Australia, an important step would be to utilize research from international settings. International reviews have been conducted to investigate pharmaceutical interventions (e.g., medicine related trials) for patients observing Ramadan, but none have looked at educational or supportive interventions provided by health professionals [1]. This literature review aimed to explore (1) health care-related interventions and (2) intentions, perspectives, or needs of health care professionals (HCPs) to provide clinical services to patients with diabetes while fasting during Ramadan with a view to improving health outcomes for those patients.

METHODS

Description of Search Strategy for Literature Review

Given the diverse nature of interventions expected, a scoping review method was applied for the conduct of this review. A scoping review generally maps out the literature to address a broader research question and clarifies the key concepts of a research area. It helps identify gaps in the research topic based on the available literature [33]. Studies exploring the effects of fasting on patients with diabetes were searched in various online libraries and databases such as PubMed, Medline, CINAHL, EMBASE International Pharmaceutical Abstracts, and COCHRANE. The search initially used MeSH terms and keywords in combination, such as “[fasting OR Ramadan], [diabetic patients OR diabetes], [fasting in Australia OR Ramadan in Australia], [diabetes AND Ramadan], [diabetes AND Fasting], [diabetic patients AND Ramadan], [diabetic patients AND Fasting], [diabetic patients AND Fasting AND health care professionals (HCPs)],” which yielded 1469 articles. Filtration was then applied by using keywords and Boolean operands, e.g., “Fasting during Ramadan AND Diabetic patients,” which resulted in 592 articles. The search was further refined by using key terms in combination “Fasting AND diabetic patients.” The reference lists of articles at this stage were scoured for

further relevant articles. Duplicate removal was followed by application of inclusion/exclusion criteria to all identified abstracts by the research team. Selected articles were read by the first and last author and data extracted using a tabular framework.

Exclusion and Inclusion Criteria

Inclusion Criteria

Only articles published in the English language from 1986 to August 2016 were selected for the review. The period spanned 30 years as there appeared to be limited research published on the topic, so a broader period was selected to encompass as much research as possible in the scope of our review. The articles selected were reviewed to ensure that they were original studies, and that they were published in peer-reviewed journals. Interventions delivered by all health professionals were included in the review, with a specific focus on those delivered by pharmacists. Intervention research is informed by needs analysis conducted pre-intervention. A key component of needs analyses includes the willingness of providers to engage in intervention delivery. Therefore, research conforming to this description was also included in the review, in addition to intervention trials.

Exclusion Criteria

Several exclusion criteria were applied. For example, research pertaining to other health conditions or fasts other than Ramadan was excluded from selection. Literature reviews, consensus guidelines, and case or meeting reports were also excluded.

RESULTS

A total of 596 articles were extracted from the original search. Upon further refining, as shown in Fig. 1, 14 relevant articles were obtained and included within this literature review. The study author, year, country, research methods, sample size, response rate, and the outcomes of the study were tabulated (Tables 3, 4). These 14

studies had utilized heterogeneous research methods including cross-sectional observational surveys or qualitative data gathering. In most studies data were collected via self-administered survey instruments, focus groups sessions, and face-to-face or telephone interviews.

Of the 14 articles, nine involved intervention studies regarding diabetes management education, and a further four studies were related to the role of pharmacists in providing or being willing to provide diabetes management interventions in Qatar, Australia, and Egypt. A French study that examined the GPs'

experiences in diabetes management for Ramadan observers was also included in the review.

Intervention-Based Studies

These studies led to safer fasting during Ramadan, weight loss, and improved glycemic control among the intervention group. The care provided in some of the interventions, however, was not standardized; and some studies did not attempt to quantify the effect of interventions.

None of these studies had a robust design and response rates were either low or not provided. Power calculations were not reported in

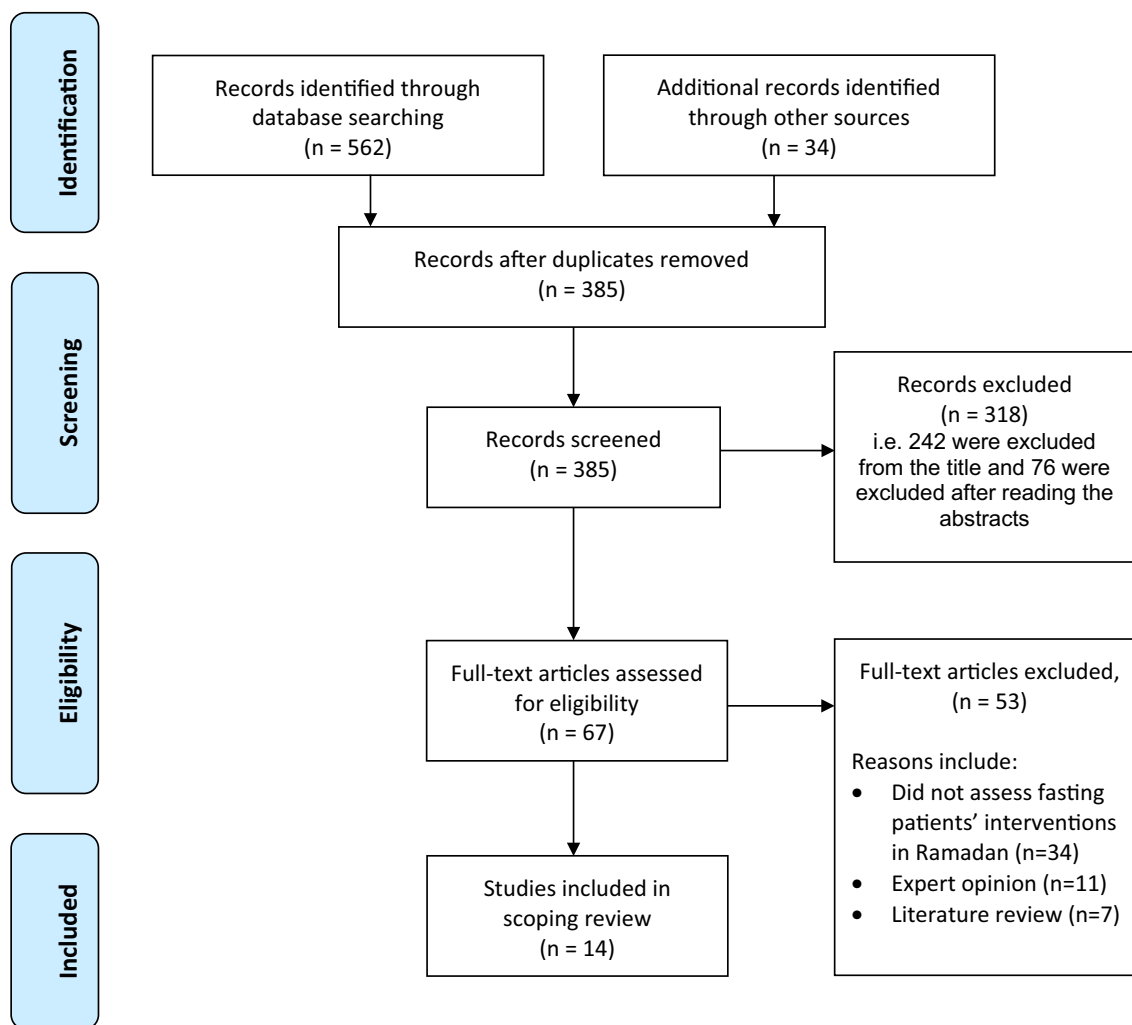


Fig. 1 Flow chart of the search strategy

Table 3 Characteristics of included interventions

References	Country	Methods	Sampling	Participants	Response rate	Results/outcomes
Bravis et al. [39]	London, UK	Parallel control group trial testing the effects of the READ education program on diabetes outcomes (i.e., weight and hypoglycemic episodes during Ramadan), which was delivered a fortnight to a month before Ramadan by doctors, specialist nurses, dietitians, and link workers	Patients with diabetes who were observed during Ramadan, self-selected (i.e., responded to posters or advertisements) or referred by GPs to the study. The intervention was a 2-h education program that included education on meal planning, physical activity, glucose monitoring, hypoglycemia, dosage, and the timing of medications	111 patients with T2D, planning to fast during Ramadan—57 patients receiving the intervention and 54 as controls. They were recruited from public venues including local mosques or referred by their GPs	NM	HbA1c reduction was sustained in the intervention group (-0.13% , $p = 0.07$), while it increased by 0.33% ($p = 0.03$) in the control group at 12 months (effect size, $d = 0.44$). There was a mean weight loss of 0.7 kg after Ramadan in the intervention group ($p < 0.001$) vs. 0.6 kg mean weight gain in the control group ($p < 0.001$). Significant decrease in total hypoglycemic episodes was observed in the intervention group, whereas there was 4-fold increases in controls ($p < 0.001$) during Ramadan
Fatim et al. [38]	India	Prospective observational study testing the effect of a counselling and education program on diabetes. Outcomes measured using a questionnaire. Focussed on key Ramadan-related health behaviors and events	Purposive sample involving patients who visited a hospital's outpatient clinic before Ramadan in 2009. They were provided a structured education program 2–4 weeks prior to Ramadan, and knowledge outcomes and adverse event diaries were collected post-Ramadan	96 patients with T2D intending to fast during Ramadan	NM	Awareness scores increased significantly from 6.81 ± 1.63 pre-Ramadan to 9.15 ± 0.95 post-Ramadan (effect size, $d = 1.7$). Less adverse effects and more fasts were kept than last year. The maximal increase of awareness of 26% from baseline was seen in the patients aged between 40 and 60 years

Table 3 continued

References	Country	Methods	Sampling	Participants	Response rate	Results/outcomes
Siaw et al. [35]	Singapore	Prospective study that focussed on counselling by HCPs, and medication dose adjustment. Study questionnaire and HbA1c completed by patients before, during, and after Ramadan; patients recruited from an outpatient endocrine clinic	All Muslim patients attending this outpatient endocrine clinic who were over 21 years of age with T2D and who fasted for at least 10 days during Ramadan	153 patients who completed the study	61%	Significant reduction in HbA1c from $8.9 \pm 2.0\%$ before Ramadan to $8.6 \pm 1.8\%$ during Ramadan ($p < 0.05$) (HbA1c effect size, $d = 0.16$). Significant improvements in HbA1c also observed in subgroups where the dose of antidiabetic was adjusted during Ramadan ($p < 0.001$)
McEwen et al. [36]	Egypt, Iran, Jordan, and Saudi Arabia	Prospective study of patients with T2D attending clinics ($n = 12$) who received individualized education from clinic staff. To explore whether individualized education before Ramadan can lead to a safer fast for T2D patients. Each participant received an average two sessions of 0.5–1 h individualized face-to-face education sessions conducted by diabetes specialist nurses, dietitians, or trained link workers. The education sessions delivered before and during Ramadan covered issues including physical activity, meal planning, blood glucose monitoring, and acute metabolic complications	Purposive sampling of T2D patients recruited from 12 clinics	774 patients—515 represent the intervention group who received individualized education that was delivered one-to-one or in a group in the patient's preferred language. 259 (control group) received usual care and they were given an English or Arabic copy of the 2010 American Diabetes Association (ADA) guidelines diabetes management while observing the Ramadan fast	NM	The intervention group were more likely to adjust their diabetes treatment plan during Ramadan (97% vs. 88%, $p < 0.0001$) and were able to self-monitor their blood glucose at least twice daily during Ramadan (70% vs 51%, $p < 0.0001$). They also have enhanced their knowledge about hypoglycemic signs and symptoms ($p = 0.0007$). It resulted in reduced body mass index (BMI effect size, $d = 0.43$) and glycated hemoglobin of the intervention group during Ramadan compared to control group (HbA1c effect size, $d = 0.66$)

Table 3 continued

References	Country	Methods	Sampling	Participants	Response rate	Results/outcomes
Susilparat et al. [34]	Thailand	Prospective study to investigate the effectiveness of contextual education for self-management in patients with T2D during Ramadan. The outcomes were measured after Ramadan using interviews with patients, weight and waist measurements, blood pressure, and blood tests	Purposive sampling of T2D patients aged 35–65 years old, with no diabetes-related complications such as kidney and heart diseases, and capable of reading and writing in Thai	90 T2D patients—62 patients were educated prior to Ramadan in diabetes management and how to adjust their antidiabetics accordingly. 28 patients received usual care	NM	No severe hypoglycemia events were reported by the experimental or control group. There was a decrease in the number and portion of patients with hypoglycemic symptoms in the experimental group compared to the control group ($p = 0.013$) (HbA1c effect size, $d = 0.14$ and basic knowledge about diabetes effect size, $d = 0.34$). Sweetened food consumption was reduced in the experimental group after Ramadan ($p = 0.002$)
Ahmedani et al. [23]	Karachi, Pakistan	Prospective study to find out the effects of glucose monitoring, drug dosage and timing adjustments, patients' counselling and education regarding diet and complications that might occur while fasting during Ramadan. Two educational sessions were conducted separately with each patient on a one-to-one basis, one was conducted by a doctor (lasted for 20–25 min) and the other by a dietician (lasted for 20–25 min)	Purposive sampling from the outpatient department of the Baqai Institute of Diabetology and Endocrinology	110 patients with diabetes—107 T2D patients and 3 T1D patients	NM	Glucose monitoring, drug dosage and timing adjustment, and patient education led to decrease in the occurrence of serious acute complications of diabetes during Ramadan among most of the participants. In general, a significant improvement was found in the mean blood glucose during Ramadan (8.67 ± 1.92 mmol/l) compared to the estimated average glucose (12.47 ± 3.94 mmol/l) before Ramadan ($p < 0.000$) (effect size, $d = 1.23$)

Table 3 continued

References	Country	Methods	Sampling	Participants	Response rate	Results/outcomes
Ahmedani et al. [25]	Pakistan	Prospective study to examine the implementation outcomes of Ramadan-specific diabetes management recommendations by HCPs in patients with diabetes. It was conducted in two stages; first was pre-Ramadan recruitment interview (visit A) in which individualized counselling and educational material were provided to each patient. Second stage is a post-Ramadan follow-up interview (visit B) of the same patients. Pre-Ramadan	Purposive sampling from nine diabetes specialist centers in four provinces of Pakistan	682 patients with diabetes—655 T2D patients and 27 T1D patients	NM	Alterations of drug dosage and timing were undertaken by about 91% patients with T2D and 80% patients with T1D during Ramadan. No hospitalizations were required because of symptomatic hypoglycemia or hyperglycemia and no diabetic ketoacidosis, hyperglycemic, and hyperosmolar states were experienced during Ramadan. The study highlighted the acceptability of HCPs' recommendations by patients with T2D fasting during Ramadan/as well as the benefits of advice provided to patients

Table 3 continued

References	Country	Methods	Sampling	Participants	Response rate	Results/outcomes
Ahmedani and Alvi [40]	Seven Countries (i.e., Pakistan, Bangladesh, Afghanistan, Saudi Arabia, Oman, Egypt, and Sri Lanka)	Observational study of the characteristics of fasting patients, trends of Ramadan-specific diabetes education, and implementation of diabetes management recommendations in patients with diabetes during Ramadan. This study was undertaken mainly by general practitioners, diabetologists, and internists using standardized questionnaire-based, face-to-face interviews conducted on one-to-one basis	Convenience sampling after the end of Ramadan 2014 (August–December). The included participants were patients with diabetes who fasted for at least 10 days during Ramadan of 2014	6610 patients with diabetes—6350 T2D patients and 260 T1D patients	NM	Before Ramadan, approximately 48% of participants received Ramadan-specific diabetes education and nearly 66% patients were recommended to alter their medications timing and dosage, while about 70% received dietary advice. Receiving Ramadan-specific diabetes education helped participants to follow Ramadan-specific diabetes management recommendations during Ramadan better than those who did not receive such education

Table 3 continued

References	Country	Methods	Sampling	Participants	Response rate	Results/outcomes
Lee et al. [37]	Malaysia	A pilot randomized controlled study to evaluate the short-term benefits of a telemonitoring-supplemented focused diabetic education compared with education alone in participants with T2D who were fasting during Ramadan	Random selection from five primary health care provider practices to telemonitoring group (TG) or a usual care group (UC)	37 T2D patients: in the tele-monitoring group ($n = 18$) who received goal-setting and personalized feedback and 19 T2D patients receiving Ramadan-focused pre-education only, i.e., usual care	NM	The TG experienced fewer hypoglycemia symptoms compared to the UC during the study period (88 vs. 157 episodes), (OR 0.1273; 95% CI 0.0267–0.6059, $p > 0.01$) (effect size = -1.14^*). However, there was no significant difference observed in glycemic control at the end of study between the two groups. Telemonitoring might be a convenient addition to improve glucose monitoring and reinforce Ramadan-focused education. Educational initiatives and monitoring are essential for patients with diabetes willing to observe Ramadan

READ Ramadan education and awareness in diabetes, CS cross-sectional study, OS observational study, NM not mentioned, OR odds ratio, CI confidence interval

Effects sizes were based on Cohen's d values and some effect sizes calculations are for differences between pre- and post-measures rather for between control and intervention groups

* This effect size value was calculated on the basis of Chinn's explanation [50]

Table 4 Characteristics of included needs analysis (pre-intervention) of research studies

Author	Country	Methods	Sampling	Participants	Response rate	Results/outcomes
Amin and Chewing [13]	Alexandria, Egypt	CS; self-administered custom developed survey. This survey had a knowledge section comprising 3 items testing awareness around clinical management of diabetes in fasting patients and a behavior section with items constructed using the theory of planned behavior	Random sampling out of a list of 3309 community pharmacies in Alexandria	277 pharmacists	93%	16% of participating pharmacists could not answer any question correctly in the knowledge section and only 8.5% answered all the questions correctly. Most reported being willing to attend a workshop to learn about the adjustment of medication regimens during Ramadan
Amin and Chewing [20]	Alexandria, Egypt	CS; analyzed the responses from the above study to explore the utility of the planned behavior theory model in predicting the behavior of pharmacists towards adjusting medication regimens for patients during Ramadan	Random sampling out of a list of 3309 community pharmacies in Alexandria	277 pharmacists	93%	Sample pharmacists were more likely to change simpler aspects of patient medications (e.g, dose regimen changes, rather than recommending a different class of medications). In this sample, current practice was limited to minimal intervention delivery, which is perhaps reflective of provider confidence

Table 4 continued

Author	Country	Methods	Sampling	Participants	Response rate	Results/outcomes
Wilbur et al. [45]	Qatar	CS descriptive study using a Web-based custom developed questionnaire that contains items focussed on pharmacist attitudes towards appropriate patient care and knowledge about medication adjustments for patients with diabetes who were undertaking the Ramadan fast. This was completed by participants 3 months prior to Ramadan 2012	Convenience sample obtained from Qatar University College of Pharmacy—internal pharmacist database	178 pharmacists	31%	Pharmacists reported frequent encounters with patients who have diabetes during Ramadan. Only 7% of pharmacists achieved a good score on knowledge questions. In a specific case question pertaining to antidiabetic medication adjustment, only 43% of sample pharmacists provided the correct response. Several barriers were identified but there was an overall desire to assume greater roles in assisting patients with diabetes fasting during Ramadan

Table 4 continued

Author	Country	Methods	Sampling	Participants	Response rate	Results/outcomes
Almansour et al. [32]	Australia, Sydney	CS; analyzed pharmacists' perspectives regarding their role in care of patients with T2D who choose to fast during Ramadan	Convenience sample obtained from areas of ethnic diversity in Sydney	21 pharmacists	75%	Most participants encountered fasting patients and were willing to engage in diabetes care services. However, thematic analyses indicated reactive counselling, lack of perceived need for counselling patients or delegation of patient care (to physicians) in a few instances as well as organizational issues as a practice barrier. Authors concluded that professional awareness/training of the impact of religious practices such as Ramadan fasting is essential and health care services should be developed to help these patients to practice their religious practices including Ramadan fast without affecting their health

Table 4 continued

Author	Country	Methods	Sampling	Participants	Response rate	Results/outcomes
Gaborit et al. [42]	Marseilles, France	CS was conducted 3 month prior to Ramadan; study 1 with patients was conducted via face-to-face interviews with the aim of exploring attitudes of patients and study 2 examined physicians' attitudes regarding Ramadan fasting and diabetes control. In study 2, the physicians filled out the questionnaires on their own for a max. time of 30 min each	Purposive sampling of patients with diabetes and GPs recruited during four randomly selected medical training sessions that were part of a continuing medical education programme	101 patients—81 T2D patients and 20 T1D patients. 101 GPs	NM	77% of GPs stated they had not read about diabetes control during Ramadan and only 15% had managed some acute diabetic issues during Ramadan. Almost 52% of patients continued to fast during Ramadan and only about 64% of patients had discussed fasting and diabetes management during Ramadan with their GPs. GPs advised 36 patients to not fast, but 19 of those patients fasted in spite of their GPs' recommendations. Consequently, six fasting patients experienced hypoglycemia as they persisted taking oral hypoglycemic medications or insulin at midday each day. The study demonstrated that for more culturally sensitive care for these patients and more medical training for physicians are needed

CS cross-sectional study

many instances. None of the included interventions were large robust randomized control trials (RCTs), some were pre–post studies and others were parallel group quasi-experimental studies [23, 25, 34–40].

Intervention Specifics

Most interventions targeted patients with diabetes who intended to or have the intention to fast during Ramadan. Interventions were mostly delivered by HCPs such as GPs, dieticians, and link workers and a few involved spiritual leaders to recruit or motivate patients to participate in such interventions. Most intervention studies stated focussing on patients' education on meal planning, physical activity, glucose monitoring, hypoglycemia, dosage, and the timing of medications. However, in most instances, the details of the educational intervention, e.g., the format of delivery, props used to support the education, or the clinical guidelines which informed the educational interventions, were not detailed. A few studies reported the language and the duration of the education sessions [34, 36, 39]. In multicenter studies, no quality audits were considered [36, 40]. Hence in these instances protocol fidelity is not known.

Key Outcomes Measured

Intervention assessment is best served by measuring a balanced set of outcomes that include clinical measures, economic benefits as well as functional health status and well-being [41]. Key clinical outcomes measured in the reviewed studies included weight or BMI, HbA1c, and adverse events occurrence. However, humanistic outcomes (e.g., adherence, quality of life, satisfaction, health beliefs, awareness, behaviors, and attitudes) were not considered to assess the effects of the interventions. Therefore, these studies did not look into details of whether participating patients learnt/benefited from these studies outside the bounds of clinical improvement. In most instances, the follow-up period was short and only one study looked into the sustainability of the outcomes 12 months after patients attended the education [39]. In

this study, i.e., the Ramadan Education and Awareness in Diabetes (READ) program, HbA1c reduction was sustained in the intervention group (-0.13% , $p = 0.07$), while the mean HbA1c in the control group increased by 0.33% ($p = 0.03$) [39].

Effect sizes of the educational interventions on key outcomes, where calculable, ranged between -1.14 and 1.7 .

Needs Analysis (Pre-intervention) Studies

Needs analysis research studies were conducted both with GPs and pharmacists, and patients. None of these included active intervention studies. Non-validated instruments, self-reporting methods, sampling in one area, and limited scope of questions on diabetes knowledge were issues that restricted the generalizability of the results. While most HCPs were willing to provide health care services, clearly their knowledge of how such services will be provided was suboptimal, and most were open to more training about their role in managing diabetes during Ramadan. There was a wide variation in the knowledge of participating HCPs (GPs and pharmacists) about managing diabetes for patients with diabetes intending to fast during Ramadan. For example, the majority of the French GPs interviewed by Gaborit et al. lacked the clinical awareness about medical management in T2D patients observing Ramadan and cultural awareness about the relevance of the fast [42].

DISCUSSION

This is the first literature review to focus specifically on the health educational interventions, and intentions of HCPs such as general practitioners (GPs) and pharmacists, to provide clinical services to patients with diabetes while fasting during Ramadan. The review revealed a paucity of research in this area. There were only a few intervention studies located through the search, and the generalizability of these studies was limited. Power calculations were not undertaken for most intervention studies, making it difficult to extrapolate the

significance of findings. Outcome measures collected varied and humanistic outcomes were often not collected. A detailed description of actual intervention or education was lacking, and protocol fidelity (e.g., checks to see if intervention providers followed research protocols) and assessment of patient adherence (checks to see if patients adhered to recommended interventions) to recommendations were not measured in any of the reviewed studies. The overall trend, however, indicated that education, counselling by HCPs, and dosage adjustment for oral hypoglycemics in the pre-Ramadan period help decrease adverse events and can thus improve the experience of patients choosing to fast for religious/spiritual reasons. Clearly, robust studies with attention to trial design need to be conducted.

None of the included studies had a robust design, some were pre–post studies and others were parallel group quasi-experimental studies [23, 25, 34–40]. In studies where randomized sampling was undertaken, the randomization method, allocation concealment, or blinded outcome collection are not mentioned. In terms of outcomes, the full gamut of clinical and humanistic outcomes was not covered and certainly economic analyses, e.g., the cost-effectiveness of the educational interventions, were also not conducted. One reason for this of course may have been the lack of validated questionnaires/tools to measure humanistic outcomes such as participants' knowledge, satisfaction, and quality of life with these interventions. These studies used self-developed questionnaires. Future intervention studies in this area should consider adequately powered randomized controlled designs, with blinding of outcome measurements at least as well as a suite of outcomes (clinical, humanistic, and economic) measured using validated instruments or techniques.

In most of the intervention studies, HbA1c or blood glucose level and diabetes-related adverse events were improved in the intervention group. These are promising outcomes, even though study designs were not very robust, as mentioned earlier. The positive trends in the data observed suggested that well-designed health care education models for Ramadan

observers with diabetes should be developed. However, a preceding step that may need research investment is the development and validation of measurement tools that can be used in this population, particularly for measuring humanistic outcomes.

As highlighted in the “Results” section, intervention/education details were not clearly described, which prevents other researchers from using effective materials and having to reinvent the intervention. These details include the period of how long the education took, method of delivery (e.g., power point slides, face to face), and whether clinical guidelines were followed in constructing the educational intervention. Key clinical details of interventions were missing. For example, smoking affects enzymes inducers, and smokers who fast during Ramadan may stop smoking suddenly during the fasting time, which might affect the doses of some medications. However, none of the intervention studies discussed whether dose adjustment in relation to smoking cessation had been advised to patients. This is an issue observed by authors of other systematic reviews, e.g., Okumura et al. reported the same issue in a review of intervention trials focusing on counselling [43]. Future research needs to consider these details to enable other researchers to implement such research in other countries for more global benefits and universal standardization.

Most of the interventions were delivered by physicians and allied health professionals in clinics. In most communities around the world, pharmacists are knowledgeable HCPs, very easily accessible and commonly visited by many people every day. Therefore, pharmacists' valuable contribution to patient care can be better utilized. Research has shown that community pharmacists can help with diabetes management generally [29, 44]. Therefore, it is logical that community pharmacists can help people with diabetes who are observing the fast of Ramadan by providing information and helping to adjust medications. Pharmacists' awareness of and willingness to do so was evident to some extent in the needs analysis studies included in this review [13, 20, 32, 42]. There were no studies describing the effect of well-designed

structured clinical interventions delivered by pharmacists to patients with diabetes fasting during Ramadan.

The studies that were located in the literature had several limitations; however, put together, these needs analysis (pre-intervention), in the case of those conducted with pharmacists', highlighted that pharmacists have the ability to enact specific roles in adjustments of medication regimens for patients observing fasts with concomitant diabetes [13, 20, 32, 45]. Hence, it would be ideal to upskill pharmacists so they can adjust medication regimens for patients to ensure that they take their medications safely and appropriately before, during, and after Ramadan.

Patient education research often highlights the chasm between patient behaviors and professionals' recommendations. Several cultural factors may affect communication and counselling by health professionals and similar factors may also influence patients' knowledge about their condition/medications as well as their help-seeking behaviors. Thus, several types of interventions may be useful: enhancing cultural understanding of professionals about the importance of the fast to patients in developed countries, as well as clinical training about adjustment of medication regimens for patients with diabetes opting to fast during Ramadan in both developed and developing countries. Ultimately, patients themselves can be upskilled to self-manage medications through effective patient education and medication adjustment skills. Very few studies in this review directly addressed both provider and patient attitudes. The work reported by Gaborit and colleagues [42] was the only study in the review which evaluated attitudes of both patients and physicians regarding Ramadan fasting and diabetes control in Marseilles, France. As highlighted in Table 3, the authors reported that many GPs lacked the cultural competency and medical knowledge that are needed to appropriately counsel their patients with diabetes in regards to medication management during Ramadan. This resulted in medically unjustified recommendations against fasting. Culturally insensitive recommendations were ineffective, in that, directing patients peremptorily not to fast did

not appear to deflect vulnerable patients from still undertaking the fast [42]. Generally, patients may choose to ignore HCP advice, especially if they feel the HCP is not culturally attuned to their decisions [42, 46, 47]. In the case of Ramadan fasting, where religious beliefs strongly motivate patients to fast, HCPs (physicians and pharmacists) and religious sources, such as imams (Muslim religious priests), may need to collaborate as important sources of knowledge about fasting and medication use for patients. This is a research area with clear gaps, and further research on both patient-focussed or health professional-focussed research is needed.

A few studies have been carried out in Australia regarding diabetes management in CALD populations (i.e., Maltese immigrants to Australia), but not specifically during fasting. One of these studies reported on interview data from Maltese immigrants in Sydney, Australia. This was a qualitative exploratory study and highlighted how patients in this group have limited diabetes knowledge. Interestingly, this group of patients were interested to receive more diabetes care and counselling from community pharmacists as they are easily accessible [44]. It was concluded that CALD populations have distinctive barriers to health care that might be unknown to HCPs or unrecognized clearly by patients themselves. Some of these barriers could be due to low health literacy or lack of access to educational programs [44]. The effect of a community pharmacy diabetes service model on the outcomes of general patients with T2D in Australia has been assessed. As a result of these significant outcomes, the Australian government provided a clinical intervention fee for pharmacists to provide an abbreviated version of this service in the Fifth Community Pharmacy Agreement [48]. Such programs could also be developed for niche population groups as well, i.e., specifically for Muslim patients with diabetes intending to fast in Ramadan. Also, future research may consider electronic online formats of resources for patient education and awareness such as smartphone apps (for iOS, iPhone, and Android) as digital tools are used commonly worldwide. Contextualized exploratory research seeking patients' perspectives of

problems or cultural issues regarding diabetes self-control would need to be conducted prior to designing such pharmacy-based intervention programs. Pharmacists' perspectives about dealing with cultural concerns that could affect patients' health or clinical confidence in providing specific interventions was investigated in Australia for this group and the findings of such work could be beneficial in the planning phase of such intervention programs [32].

There are a few limitations of this scoping review. Meta-analysis could not be conducted because the reviewed studies had mixed methods/protocols of the interventions. Similarly, a systematic review was not conducted as most of the included studies were not robustly designed clinical trials. Another limitation is that diabetes was considered mostly to be studied with relation to Ramadan fast, because of the possibility of hypoglycemia occurring while fasting. However, other health conditions such as angina, ulcers, asthma, and chronic obstructive pulmonary disease (COPD) should be considered in future studies as fasting may affect health and medication use in relation to other conditions.

CONCLUSION

The results of this literature review revealed numerous gaps in the existing literature. Many HCPs and patients lack the knowledge for the management and modification of medication regimens for patients with diabetes who fast during Ramadan. Addressing the knowledge deficits and enhancing cultural competency are critical for clinicians treating Muslim patients living with chronic illness and observing the fasting practices of their faith. Very few studies, however, have addressed health providers' attitudes, knowledge, and advice with regards to fasting. In Australia, where thousands of Muslims observe the fast of Ramadan each year, this research area is becoming increasingly important.

Pharmacists have been the focus of research in this area in other countries and have been

shown to be willing to provide specialized care for fasting patients with diabetes and willing to upskill themselves in order to provide such specialized care. Hence, there is a need for research that helps to describe the extent to which Australian pharmacists counsel their patients about fasting during Ramadan, their willingness to provide specialized care, and their level of current cultural and clinical skills. Similarly, research with Muslim Australian patients observing Ramadan will help establish their Ramadan-based diabetes self-management behaviors, and their perceptions about, and willingness for receiving specialized help from clinicians, including pharmacists. This research might assist in the development of such programs in Australia.

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