

# Empowerment-Based Diabetes Self-Management Education to Maintain Glycemic Targets During Ramadan Fasting in People With Diabetes Who Are on Conventional Insulin: A Feasibility Study

Yara M. Eid,<sup>1</sup> Sahar I. Sahmoud,<sup>1</sup> Mona M. Abdelsalam,<sup>1</sup> and Barbara Eichorst<sup>2</sup>

## ■ ABSTRACT

**Objective.** This study aims to assess the feasibility of promoting safe Ramadan fasting through diabetes self-management education (DSME) and to determine the effect of such education on hypoglycemic episodes.

**Design and methods.** This prospective study included subjects attending Ramadan reinforcement sessions for participants in the Educational Program for People with Diabetes (EPPWD) at the Ain-Shams University Diabetes Center in Cairo, Egypt. The DSME sessions started 2–3 weeks before Ramadan and included one experimental fasting day during the first week and one during the second week. Participants' A1C and serum fructosamine levels were measured before and after Ramadan, and they completed weekly self-monitoring of blood glucose (SMBG) logs.

**Results.** Among 21 participants who were intending to fast for Ramadan, 14 completed the program. Their mean A1C was  $6.7 \pm 1.6\%$ , and SMBG results showed a statistically nonsignificant difference in mean blood glucose levels before and after Ramadan ( $123.84 \pm 39.96$  and  $123.84 \pm 25.92$  mg/dL, respectively;  $P > 0.05$ ). Serum fructosamine after Ramadan declined by 10% from pre-Ramadan levels. The mean number of hypoglycemic events before Ramadan was  $3 \pm 1.04$ , which declined to  $1.4 \pm 0.5$  during Ramadan. Differences between group 1 (those without hypoglycemia,  $n = 8$ ) and group 2 (those with hypoglycemia,  $n = 6$ ) were nonsignificant for all variables, including A1C.

**Conclusion.** Ramadan fasting is feasible for people with diabetes who are on a multiple daily injection insulin regimen and participate in the EPPWD. The number of hypoglycemic events per month declined with the attainment of DSME.

Ramadan is one of the 12 Arabic months. Fasting during the month of Ramadan, which includes refraining from food, drink, and sexual activity from dawn until sunset daily, is a compulsory requirement for every Muslim adult (1). Depending on geographical area and time of year, the daily fasting period can range from 11 to 19 hours. Although many people with diabetes are exempt from fasting, both adults and children often refuse to take this concession (2).

Data from the Epidemiology in Diabetes and Ramadan study revealed that 78.7% of patients with type 2 diabetes and 42.8% of patients with type 1 diabetes fasted for at least 15 days (2). The practice of daytime fasting influences diabetes control because it results in changes in meal times, types of food eaten, and daily lifestyle (1). Thus, many people with diabetes fast during Ramadan, and these individuals require guidance and advice from their health care providers on how to fast as safely as possible (3).

<sup>1</sup>Department of Endocrinology and Metabolism, Ain-Shams University Hospital, Cairo, Egypt

<sup>2</sup>Healthy Interactions, Chicago, IL

Corresponding author: Yara M. Eid, [dryara\\_eid@med.asu.edu.eg](mailto:dryara_eid@med.asu.edu.eg) or [yaraabukalam@gmail.com](mailto:yaraabukalam@gmail.com)

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The diet during Ramadan for people with diabetes should not differ significantly from a healthy and balanced diet tailored to their individual needs (4). Until recently, patients with type 1 diabetes were expected to follow a rigid meal plan with indicated mealtime insulin readjustments, which tended to be poorly accepted by most patients, who desired a more “normal” lifestyle (5). More flexible intensive insulin therapy through basal-bolus insulin regimens is currently the best way to achieve strict glycemic control for patients with either type 1 or type 2 diabetes who do not reach their glycemic goals with a simpler insulin regimen (5,6). Flexible intensive insulin therapy requires patients to count the carbohydrate in each meal accurately and to adjust their meal-related insulin doses accordingly using a simple algorithm (5).

Few studies have been conducted on Ramadan fasting in people using conventional intermediate- and short-acting insulin (1,4). Most recently, Zabeen et al. (7) conducted such a study with subjects using a conventional twice-daily premixed insulin regimen. Structured diabetes education is recognized as essential to the successful management of diabetes (4). However, research is needed regarding whether DSME that is specifically focused on Ramadan fasting can help people with diabetes who are on conventional insulin (NPH and regular insulin) to achieve their glycemic targets while meeting their social needs during Ramadan.

### Objective

This study was designed to assess the feasibility of safe Ramadan fasting and to determine the effect of Ramadan-related DSME reinforcement sessions on the incidence of hypoglycemia during the month of Ramadan.

### Design and Methods

This open, single-center prospective clinical study included patients with type 1 or type 2 diabetes who were actively participating in the

Educational Program for People with Diabetes (EPPWD) at the Ain-Shams University Diabetes Center in Cairo, Egypt (8). EPPWD participants who were planning to fast during Ramadan were invited to attend weekly education reinforcement sessions before and during Ramadan for assistance with insulin adjustment and blood glucose monitoring.

### Subjects

Adults were eligible to participate in the study if they had a diagnosis of type 1 or type 2 diabetes; were on basal-bolus insulin therapy; intended to fast during Ramadan; were willing to perform frequent SMBG (four to five times daily); were enrolled in and completed the EPPWD program during the 2 months preceding Ramadan; and did not have diabetes complications or concurrent illnesses that could preclude fasting. Prospective participants were excluded if they had not completed the EPPWD program before Ramadan, had diabetes complications that might be worsened by fasting (e.g., renal insufficiency, preexisting autonomic neuropathy, advanced macrovascular complications, or acute complications such as diabetic ketoacidosis [DKA] and hyperosmolar hyperglycemic coma) during the 3 months preceding Ramadan, or were not able to make regular follow-up visits to the clinic during Ramadan.

All patients who participated in the study signed a consent form to share their data and agreed to attend weekly follow-up visits. These visits served two goals: to support the subjects through group education and to review their blood glucose during fasting. The study was conducted during the month of Ramadan (August to September) 2009. The average daytime local temperature was 32.5°C, and daily fasts lasted for an average of 16.3 hours.

The local ethics committee approved the study.

### DSME Program

Subjects who enrolled in the study

had attended the DSME program for 3 months before the start of Ramadan (8). The educational sessions were delivered on a weekly basis for 7 weeks, with each session lasting 3 hours, followed by 5 weeks of follow-up.

Subjects who intended to fast demonstrated adequate knowledge and practical experience regarding:

- What diabetes is, the types of diabetes, insulin types, and injection techniques
- Nutritional facts, the food pyramid, and healthy meal planning
- Carbohydrate counting
- Diabetes complications (acute and chronic)
- How to deal with hypoglycemia (blood glucose <70 mg/dL [mild] or <60 mg/dL [severe]) and hyperglycemia
- Insulin dose adjustment

For each of the 2–3 weeks before Ramadan, these patients gathered for a pre-Ramadan reinforcement course, which included:

- Nutrition and diabetes knowledge
- Meal planning practice, including calculating the insulin-to-carbohydrate ratio for each meal
- Strategies to prevent and treat hypoglycemic events, including:
  - Breaking the fast at any time if blood glucose falls to <70 mg/dL
  - Avoiding strenuous physical activity
  - Confirming the importance of *Fajar* snack (sunrise snack) as a measure to avoid early daytime hypoglycemia
- Instructions for two experimental fasting days during the first and second weeks of the course
- Review of SMBG logs the following week for insulin dose adjustment

During Ramadan, weekly follow-up was provided to:

- Review weekly SMBG logs, meal content, and insulin doses
- Check the occurrence of hypoglycemic events and DKA

### Insulin Regimen

All patients were on a multiple daily injection (MDI) insulin regimen using conventional insulin, which is the only type of insulin prescribed to patients who are receiving financial coverage from Egypt's Ministry of Health.

#### Basal Insulin Regimen

NPH insulin was given three times daily. The total daily dose (TDD) during fasting hours (morning and afternoon injections) was decreased by 25%. In the absence of consensus on dose reduction (1), we resorted to deriving this percentage reduction from results of similar studies and expert recommendations (9,10). The calculated dose was then split into two equal doses given 7 hours apart, at 9:00 a.m. and 4:00 p.m. The third dose was kept unchanged, but its timing was fixed at 1:00 a.m. Doses were adjusted according to SMBG results in increments of 1–2 units. The blood glucose pattern was then monitored for 3 days before another change was made.

#### Bolus Insulin Regimen

Bolus doses using short-acting (regular) insulin were given in doses for *Eftar* (the breakfast taken at sunset) and *Sohor* (the late-night meal) and adjusted according to the carbohydrate content of typical lunch and dinner meals in the pre-Ramadan period. Insulin for extra carbohydrate consumed during *Eftar* was calculated according to an insulin-to-carbohydrate ratio.

### Dietary Protocol

The carbohydrate content of *Eftar* was assumed to be equivalent to the usual lunch carbohydrate content plus two extra points for the Ramadan addition of juice or dates, according to patients' preference. The carbohydrate content of *Sohor* was assumed to be equivalent to the usual dinner carbohydrate content and was timed for 1:00 a.m. so as to have the peak of the regular insulin dose occur before dawn. To help avoid early-morning hypoglycemia,

the *Fajar* was scheduled for 4:00 a.m. and guided by SMBG. Patients recorded the carbohydrate content of their meals, SMBG results, and any notes relevant to hypoglycemia or ketosis in their logs.

### SMBG

Participants performed SMBG five times throughout the day: 9:00 a.m., 3:00 p.m., 2 hours after *Eftar*, before *Sohor* (1:00 a.m.), and before *Fajar* (4:00 a.m.).

### Biochemical Assays

All subjects had blood samples drawn for A1C testing before Ramadan and for serum fructosamine testing 3 days before Ramadan and on the 28th day of Ramadan.

### Outcome Measures

Safe fasting was determined by the number of hypoglycemic events, the number of successful fasting days, and changes in serum fructosamine during fasting.

### Statistical Analysis

Data analysis was performed with the SPSS version 16 software package (SPSS, Inc., Chicago, Ill.). Quantitative variables were expressed as mean and standard deviation, whereas qualitative variables were expressed as number and percentage. An unpaired *t* test was used for comparing the parametric data between the two groups. A Mann-Whitney U test was performed for nonparametric data. Analysis within the same group was carried out using a paired *t* test for the parametric data. A Wilcoxon signed rank test was performed for the nonparametric data. A repeated-measures analysis of variance (ANOVA) was carried out to test the same dependent variable measured on more than one occasion for each subject.

### Results

The EPPWD at Ain-Shams University diabetes research unit started in February 2009. Among those who participated in the program, 21 were intending to fast. Of those intending

to fast, three continued fasting with irregular attendance at education sessions and irregular submission of their follow-up logs for the study; three were lost to follow-up and attended only two sessions; and one abstained from fasting a few days after Ramadan began upon her family doctor's advice. Fourteen participants who intended to fast regularly attended the course and were willing to provide follow-up logs.

Of the 14 fasting participants followed, 4 had type 2 diabetes and 10 had type 1 diabetes; 10 were female (71%); mean age was  $28.2 \pm 13.7$  years; and mean duration of diabetes was  $8.5 \pm 4.6$  years. Descriptive and laboratory data for the study subjects are shown in Table 1.

Regarding glycemic control before Ramadan, the mean A1C was  $6.7 \pm 1.6\%$ . SMBG values showed no difference using repeated-measures ANOVA ( $P = 0.629$ ). Before Ramadan, serum fructosamine was  $201 \pm 59 \mu\text{mol/L}$ , whereas at the end of Ramadan, it was  $182 \pm 55 \mu\text{mol/L}$ . There was a significant 10% decline ( $P = 0.02$ ).

The mean number of successful fasting days was  $26.07 \pm 2.8$ . Eight of the 14 subjects experienced no hypoglycemia, whereas six experienced mild hypoglycemia. The mean number of hypoglycemic events/month for all patients during Ramadan was  $1.4 \pm 0.5$ , whereas the mean number of hypoglycemic events/month 1 month before Ramadan was  $3 \pm 1.04$ . Using a Wilcoxon signed rank test to compare mean hypoglycemic events/month before and during Ramadan showed a highly significant difference ( $P = 0.001$ ).

Across all patients, the mean insulin TDDs before, during, and at the end of Ramadan were  $67.18 \pm 18$ ,  $63 \pm 15$ , and  $62 \pm 15$  units, respectively. The decline in TDD from before to the end of Ramadan was 7%, which was determined to be nonsignificant using repeated-measures ANOVA ( $P = 0.54$ ).

**TABLE 1. Patients' Demographic Characteristics and Comparison of Glycemic Parameters Before and After Ramadan Fasting (n = 14)**

	Mean ± SD	T	P°
Age (years)	28.2 ± 13.7		
Weight (kg)	68.2 ± 14.7		
Diabetes duration (years)	8.5 ± 4.6		
A1C before Ramadan (%)	6.7 ± 1.6		
Insulin-to-carbohydrate ratio (units:g)	1:6		
Successful fasting days (n)	26.07 ± 2.8		
Blood glucose (mg/dL)			
Before Ramadan	123.84 ± 39.96*	0.481	0.629
Week 1	123.84 ± 23.94*		
Week 2	117.9 ± 21.96*		
Week 3	117.9 ± 22.86*		
Week 4	114.84 ± 25.92*		
After Ramadan	123.84 ± 25.92*		
Serum fructosamine (µmol/L)			
Before Ramadan	201 ± 59	2.6†	0.02†
After Ramadan	182 ± 55		
Hypoglycemia events per month (n)			
Before Ramadan	3 ± 1.04	-5.78¶	<0.001¶
After Ramadan	1.4 ± 0.5		
Insulin TDD (units)			
Before Ramadan	67 ± 18‡	0.91	0.54
During Ramadan	63 ± 15‡		
After Ramadan	62 ± 15‡		

°P < 0.05 significant, P < 0.01 highly significant.

\*Using repeated-measures ANOVA (Mauchly sphericity and Greenhouse-Geisser  $\epsilon$  test) to compare SMBG measurements; F = 0.481 and corrected significance was 0.629 (nonsignificant).

†Using paired t test to compare serum fructosamine before and after Ramadan; T = 2.6, P = 0.02 (significant).

¶Using Wilcoxon signed rank test to compare hypoglycemia before and during Ramadan; with Z = -5.78, P < 0.001 (highly significant).

‡Using repeated-measures ANOVA (Mauchly sphericity and Greenhouse-Geisser  $\epsilon$  test) to compare TDD;  $\epsilon$  = 0.91, P = 0.54 (nonsignificant).

Patients were further subgrouped according to the occurrence of hypoglycemic events, with group 1 (n = 8) not experiencing hypoglycemia and group 2 (n = 6) experiencing hypoglycemia. No differences were found between these groups regarding age, sex, weight, or duration of diabetes. There also was no difference in TDDs before or at the end of Ramadan (P = 0.49 and P = 0.8, respectively). However, there was a significant 17% decline in TDD after Ramadan in group 2 (P = 0.045). There was a non-

significant 1.5% decline in TDD in group 1 (P = 0.328) (Table 2).

Analysis of the glycemic control parameters used in this study showed that there was no difference between groups with regard to A1C (P = 0.09), which was lower in group 1 (6%) than in group 2 (7.6%). Also, serum fructosamine did not differ significantly between the groups before or after Ramadan (P = 0.7 and P = 0.36, respectively). There was a significant difference between the groups with regard to the number of successful

fasting days (27.7 in group 1 vs. 23.8 in group 2, P = 0.006).

## Discussion

Some patients with type 1 diabetes prefer to fast at Ramadan, but most change their insulin regimens immediately before, during, and for a few days after this month (4).

In our study, 66% (14/21) of the subjects who intended to fast completed fasting, with a mean of 26.07 ± 2.8 successful fasting days, defined as days without any hypoglycemic

TABLE 2. Subgrouping and Comparison of Subjects According to Hypoglycemic Events

	Group 1: Nonhypoglycemic (n = 8)	Group 2: Hypoglycemic (n = 6)	P
Age (years)	32 ± 14	23 ± 11.5	0.23
Sex (n [%])			
Male	2 (25)	2 (33.3)	0.74
Female	6 (75)	4 (66.7)	
Weight (kg)	69 ± 20	66 ± 7	0.67
Diabetes duration (years)	9.3 ± 4.3	7.5 ± 5.2	0.48
A1C before Ramadan (%)	6 ± 1.1	7.6 ± 1.7	0.09†
Successful fasting days (n)	27.7 ± 2.3	23.8 ± 1.9	0.006
Serum fructosamine (μmol/L)			
Before Ramadan	204 ± 39.34	207.16 ± 73.8	0.7
After Ramadan	170.18 ± 34.8	198 ± 67	0.36
Hypoglycemia events per month (n)			
Before Ramadan‡	1.25	5.33	0.11
During Ramadan‡	0‡	3.3‡	0.001
Insulin TDD (units)			
Before Ramadan	64 ± 15	71 ± 22	0.49*
After Ramadan	63 ± 15**	61 ± 16**	0.8*

†Using Mann-Whitney U test to compare hypoglycemic events before Ramadan between the two groups, there was a nonsignificant difference ( $P = 0.11$ ), whereas during Ramadan, there was a highly significant difference ( $P = 0.001$ ). The difference in A1C between groups was also nonsignificant.

‡Using a Wilcoxon signed rank test to compare hypoglycemic events before and during Ramadan within group 1 (the nonhypoglycemic group), there was a nonsignificant difference ( $P = 0.2$ ). There was also a nonsignificant difference ( $P = 0.11$ ) when comparing hypoglycemic events within group 2 (the hypoglycemic group).

\*Using unpaired t tests, no statistically significant between-group differences were found in TDD before ( $P = 0.49$ ) or at the end of Ramadan ( $P = 0.8$ ).

\*\*Using paired t tests, there was a significant decline in TDD within group 2 ( $P = 0.045$ ) and a nonsignificant decline within group 1 ( $P = 0.328$ ) from before until the end of Ramadan.

events. Of the patients who fasted, 70.1% had type 1 diabetes, with a mean age of  $20 \pm 3.87$  years, whereas 29.9% had type 2 diabetes, with a mean age of  $48.5 \pm 3$  years. The number of fasting days reported in the study conducted by Al-Khawari et al. (10) in adolescent subjects with type 1 diabetes and a mean age of 13.9 years was fewer than 4 days in four patients and >13 days in 18 patients. In the study by AlAlwan and Banyan (2), all subjects in the fasting group (12 children with type 1 diabetes) completed the full month of fasting.

We have included in our protocol control periods before and after Ramadan as well as measurements during each week of Ramadan, which

show that glycemic control remained constant ( $P = 0.629$ ), with no severe hypoglycemic events or DKA and no worsening of glycemic control. Serum fructosamine was reduced by 10% during fasting, which is concordant with other studies showing that serum fructosamine either did not change or decreased (10,11–14).

The effect of fasting during Ramadan on rates of hypoglycemia in patients with diabetes is not known with certainty (4). One study reported a 4.7-fold increase in the risk of severe hypoglycemia during Ramadan in patients with type 1 diabetes, from 3% in the month before to 14% during the month of fasting ( $P = 0.017$ ) (15). Also, a

study by Bin-Abbas (16) comparing adolescents with type 1 diabetes on conventional therapy to those on pump therapy reported that hypoglycemic events per patient per month increased from 18 to 29 in the conventional group and from 11 to 16 in the pump therapy group before and during Ramadan, respectively. A more recent study by Zabeen et al. (7) reported a lower rate of hypoglycemic episodes in the group who completed fasting compared to the group who broke the fast (7).

Remarkably, hypoglycemic events in the current study were significantly reduced during Ramadan. The mean number of events before Ramadan was  $3 \pm 1.04$ , whereas during Rama-

dan it was  $1.4 \pm 0.5$ . Comparable to our results are those of a recent study that compared the patients with diabetes who participated in the READ (Ramadan Education and Awareness in Diabetes) program with patients with diabetes who did not participate (17). That study found a significant decrease in the total number of hypoglycemic events in the educational program group, from nine before Ramadan to five during Ramadan. It should be noted that, in the current study, occurrence of hypoglycemic events in some subjects could be attributed to missing the *Fajar* snack or to unscheduled exercise. On the other hand, the lack of hypoglycemia seems to be the result of the education provided, weekly follow-up, and insulin dose management.

Some trials have suggested possible insulin regimens for use during the fasting period and discussed the advantages and disadvantages of various insulin regimens and types of insulin (9). The current understanding is that a basal-bolus regimen is the preferred protocol for diabetes management (4). In our study, there was a nonsignificant decline of 7% in insulin TDD from before Ramadan to the end of Ramadan ( $P = 0.54$ ). In a study conducted by Khairallah et al. (18) using insulin lispro or aspart and insulin glargine, there was a 28% decrease in insulin requirement from baseline. Other studies have recommended that the insulin TDD be reduced for Ramadan to 85% of the pre-Ramadan dose (19). The study conducted by Zabeen et al. (7) applied a conventional regimen of premixed, twice-daily insulin with an increase in dose after Ramadan for the group who completed the fast, but the authors did not indicate whether the dose increase was for the meal corresponding to *Eftar* or *Sohor*.

For the current study, basal insulin (NPH) constituted 55% of the TDD before Ramadan, and regular insulin constituted 45%. The ratio during Ramadan was 47% NPH and 53% regular insulin; at the end

of Ramadan, the ratio was 48% NPH and 52% regular insulin. Other studies that used long-acting insulin such as glargine or human ultralente insulin have suggested that long-acting insulin be 60–70% of the TDD and that regular or ultra-short-acting insulin be 30–40% (17,18). Some have suggested that 75% of the usual dose of rapid-acting insulin and 25% of the usual dose of long-acting insulin may be given before the *Eftar* meal (20).

In an attempt to study the characteristics of people with diabetes who are more prone to experience hypoglycemia during Ramadan fasting, we further subgrouped our subjects into those who did not experience hypoglycemia (group 1) and those who did (group 2). The groups were matched for age, sex, and weight, and did not differ significantly with regard to duration of diabetes, serum fructosamine before or after Ramadan, A1C, or insulin TDD.

We found that the rate of hypoglycemia decreased in both groups during Ramadan from 5.33 to 3.30 in group 2 and from 1.25 to 0.00 in group 1, although the difference before and during Ramadan did not reach significance within each group. The rate of hypoglycemic events during Ramadan differed significantly between the two groups, with group 2 (the hypoglycemic group) decreasing its insulin TDD by ~17% by the end of Ramadan. Similarly, Al-Khawari et al. (10) reported that patients corrected for hypoglycemia by decreasing their insulin dose by about 8–16% during Ramadan.

In our study, we were obliged to use NPH as basal insulin because it is the only form of basal insulin available to patients receiving treatment through the Egyptian Ministry of Health's insurance program. The morning insulin dose was split into two doses with a mean of 6.25 units administered at 9:00 a.m. and 7.16 units administered at 4:00 p.m. The smaller doses delivered at two times benefited patients because a larger

single morning dose would have had a stronger and more lasting effect, which could have caused hypoglycemia during fasting hours (21,22). This modification adequately covered the long (16-hour) fasting period without a waning effect toward the end of the daily fast.

Good metabolic control is often related to a higher risk of hypoglycemia, as shown in the Diabetes Control and Complications Trial (23) in which A1C was identified as a predictor of future hypoglycemic events. However, some experimental evidence has failed to confirm such a relationship. In a recent study by Blasetti et al. (24), acceptable metabolic control (A1C <7%) was accompanied by a lower incidence of severe hypoglycemia. Other studies also have not found an increased risk of hypoglycemia in people with well-controlled diabetes and low A1C levels (25–27). In our study, an A1C <7% was associated with fewer hypoglycemic events, suggesting that optimal metabolic control with less hypoglycemia was achieved within the context of the educational program. Furthermore, the increase in hypoglycemic events in group 2 (the hypoglycemic group) could be attributed to variation among individuals in terms of the acquisition of knowledge and skills and the integration of these inputs into daily behavior.

The variability of body weight before and after Ramadan and other metabolic parameters that could affect the lipid profile were not assessed in our study. We recommend that future studies include other metabolic variables and explore the effect of the same educational program on weight.

### **Strengths and Limitations**

The primary strength of this study is the presentation of evidence on the impact of empowerment-based DSME in helping people with diabetes meet their needs to safely fast during Ramadan. This is especially ap-

plicable to those using intermediate-acting insulin such as NPH and regular insulin due to their limited resources.

The primary limitation is the small sample size. A larger cohort would have been ideal, but this was the number of patients who were recruited and complied with the study protocol in its entirety: those who both completed the EPPWD and were willing to fast during Ramadan. Also, the questionnaire that was used to evaluate patients' understanding of diabetes care had not yet been validated. Although this questionnaire has been in use for our educational programs for some time, an opportunity exists for external validation to be evaluated using a larger sample of patients representing multiple diabetes clinics throughout Egypt.

### Conclusion

We can deduce from this study that Ramadan fasting is feasible in people with type 1 or type 2 diabetes on an MDI insulin regimen. However, a proper diabetes educational program before Ramadan, strengthened by Ramadan-specific education reinforcement sessions, should be the mainstay to help ensure stable glycaemic control during Ramadan.

### Duality of Interest

No potential conflicts of interest relevant to this article were reported.

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