



## Effectiveness of Managing Diabetes During Ramadan Conversation Map intervention: A difference-in-differences (self-comparison) design

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### ABSTRACT

**Background:** Some individuals with diabetes fast during Ramadan despite medical concerns for risk of adverse outcomes. The Managing Diabetes During Ramadan Conversation Map is a self-management education group-based intervention for Muslim individuals with type 2 diabetes, specifically addressing diabetes management during Ramadan.

**Objective:** The aim of this study was to evaluate the effectiveness of the Managing Diabetes During Ramadan Conversation Map intervention in improving short-term clinical outcomes and reducing healthcare utilization following Ramadan.

**Design:** This was a retrospective rolling cohort study.

**Settings:** Participants were Clalit Health Services members with type 2 diabetes who participated in the intervention between 2014 and 2017 across Israel.

**Participants:** This study included 1732 participants who enrolled in the intervention over the five-year study period. The cohort was mainly between the ages of 45 and 74 years (83.3%), female (71.9%), of lower socioeconomic status (92.1%), with a diabetes duration of 10 years or more (51.7%), obese (64.0%), and had never smoked (73.8%).

**Methods:** The data used in this study came from Clalit Health Services' electronic health records, which are integrated in a central data warehouse. We used a difference-in-differences (self-comparison) design to examine the effect of the intervention on changes in laboratory results and healthcare utilization over a six month baseline and follow-up. Mixed model linear regressions and Poisson regressions were used to estimate continuous and count outcomes, respectively.

**Results:** Post intervention, participants experienced a reduction of 8.61 mg/dL in their glucose levels ( $p = 0.005$ ) and 0.34% in their HbA1c levels ( $p < 0.001$ ). In a sub-group analysis of participants with HbA1c > 7%, larger reductions in glucose (17.02 mg/dL [ $p < 0.001$ ]) and HbA1c (0.63% [ $p < 0.001$ ]) levels were recorded. This sub-group also experienced a reduction of 4.83 mg/dL in LDL level ( $p = 0.007$ ) and had 0.2 fewer primary care visits ( $p < 0.001$ ).

**Conclusions:** Participation in the Managing Diabetes During Ramadan Conversation Map improved patient glucose and HbA1c levels. A greater benefit was reported in those individuals with HbA1c > 7%. These findings hold important global health implications for the millions of individuals with type 2 diabetes for whom Ramadan can pose a challenge in disease control.

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## What is already known about the topic?

- Managing diabetes during Ramadan fasting requires individuals to modify their routine diabetes maintenance strategies in order to minimize the development of adverse events.
- Only a few studies have reported the relationship between non-medical intervention (e.g., self-management education program) and diabetes control during and after the Ramadan fasting month.
- These studies were comprised of small samples (less than 100 participants), with a short duration of follow up (i.e., immediately after the Ramadan fasting month), and mainly focused on clinical outcomes.

## What this paper adds

- Participation in the Managing Diabetes During Ramadan Conversation Map intervention, a self-management education program, is associated statistically and clinically with lower glucose and HbA1c levels compared to their change in levels over the Ramadan fasting month a year prior.
- Participants whose diabetes was uncontrolled (HbA1c > 7%) demonstrated a substantial benefit in multiple outcomes (lower glucose, HbA1c, and low-density lipoprotein levels and a reduction in primary care visits).
- Participants who were younger than 75 years old, were diagnosed with diabetes more than 10 years ago, had low oral medication adherence, and who used insulin treatment to manage their diabetes were at high-risk, as their glucose levels did not decline post-intervention.

## 1. Introduction

Despite medical recommendations against fasting, there are observant individuals with type 2 diabetes who at least partially fast during the month of Ramadan (Babineaux et al., 2015; Jabbar et al., 2017; Salti et al., 2004), with as many as two-thirds fasting for the full month (Babineaux et al., 2015). Long periods of fasting can increase risk of hypoglycemia, hyperglycemia, and dehydration for all individuals, and is associated with increased risk of negative outcomes in those with diabetes (Alabbood et al., 2017; Jabbar et al., 2017; Sadikot et al., 2017; Salti et al., 2004). One study found that those with type 2 diabetes who fast during Ramadan have a 7.5-fold increased risk of developing severe hypoglycemia during Ramadan compared to the risk during the non-fasting months (Salti et al., 2004). Consequently, managing diabetes during Ramadan fasting requires individuals to modify their routine diabetes maintenance strategies in order to minimize the development of adverse events (Sadikot et al., 2017). However, the cultural role of food, which needs to be consumed at particular times, impacts this population's ability to manage diabetes successfully (Jones & Crowe, 2017).

The guidance that currently exists for healthcare professionals includes individualized assessment of the patient's glycemic control, self-management capabilities, providing dietary guidance relevant to fasting periods, and the use of medications to help in regulation (Al-Arouj et al., 2005; Hassanein et al., 2017; Ibrahim et al., 2015; International Diabetes Federation & The DAR International Alliance, 2016). A recent meta-analysis concluded that the most common strategy used to prevent hypoglycemia while fasting during Ramadan was drug class changes (Lee et al., 2016). It has been suggested that healthcare providers need to preemptively provide relevant patients with appropriate training on how to effectively change their diabetes regimen during this

period (Ibrahim et al., 2015; International Diabetes Federation & The DAR International Alliance, 2016; Salti et al., 2004; Susilparat et al., 2014; Yaqub, 2014). Specifically, they need to educate patients with strategies such as consuming small portions of high-fiber food during the non-fasting interval and limiting physical exercise to nighttime. However, due to scarce resources in the healthcare system, physicians are limited in their ability to provide one-on-one personalized strategies for controlling diabetes during the Ramadan period. Specifically, only 30% (Al-Musally et al., 2017) to 54% (Almalki et al., 2018) of patients reported that they received education about fasting during Ramadan in two studies, which were conducted in Saudi Arabia. Thus, a group-based education intervention may be an effective and efficient strategy to target this need (Bravis et al., 2010).

Diabetes Conversation Map™ (Healthy Interactions, Inc.) engages patients with diabetes in group-based discussions about diabetes-related topics and educates them on effective self-management (Reaney et al., 2012). Although a recent systematic review reported limited evidence to support the effectiveness of the Diabetes Conversation Map™ program on improvements in patient outcomes (Srulovici et al., 2017), a meta-analysis reported its positive impact on reducing fasting blood glucose, post prandial blood glucose, and hemoglobin A1c (HbA1c) levels up to 12 months post intervention (Yang & Fang, 2016).

In 2013, a new Map was introduced, the "Managing Diabetes During Ramadan Conversation Map", which is already being implemented in many countries such as Egypt, Morocco, Algeria, Lebanon, South Africa, Malaysia, Pakistan, Israel, etc. (Adnan et al., 2016). However, no study to date has evaluated the effect of participation in the Managing Diabetes During Ramadan Conversation Map intervention on subsequent health outcomes and healthcare utilization. The aim of the current study was to evaluate the short-term clinical outcomes and healthcare utilization following Ramadan in terms of hospitalizations, length of hospital stays, and primary care visits among intervention participants.

## 2. Methods

### 2.1. Study design and participants

This was a retrospective rolling cohort study of members of Clalit Health Services aged 25 years and older with type 2 diabetes who participated in the Managing Diabetes During Ramadan Conversation Map intervention, which took place the month preceding Ramadan. The study period covered five years between 1 January 2013 to 31 August 2017 (Fig. 1) with the participation dates based on the Ramadan fasting month each year. Over the five year study period, each individual who enrolled in the Managing Diabetes During Ramadan Conversation Map intervention session during the one month prior to Ramadan (enrollment date = index date) was followed from the last day of the Ramadan fasting month to six months later. A pre-intervention period was also assessed during the six months previous to the index date to determine baseline health status. Furthermore, a self-comparison period was created for each individual during the Ramadan fasting month that occurred one year prior to the index date, where measurements were taken six months before and six months after the Ramadan month of that year. This approach was taken in order to estimate if the changes observed in the index year were due to factors beyond the intervention or could be attributed to the intervention.

An ethics approval was obtained from Clalit Health Services' Institutional Review Board.

Muslim patients, especially (but not limited to) those with an HbA1c level above 7%, were referred by their primary care physician or primary clinic nurse to participate in the intervention. All patients enrolled in the intervention during the study period

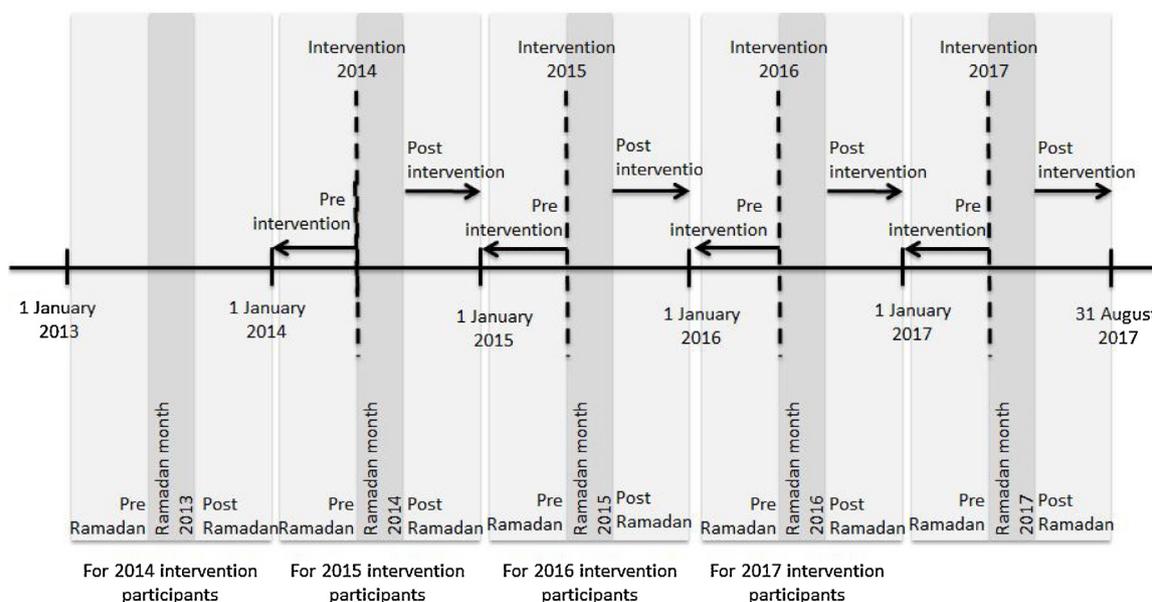


Fig. 1. Study design: A repetition of design yearly over the five year study period.

were included in the study unless they were younger than 25 years of age, were actively being treated for cancer during the study period, or if they were not members of Clalit Health Services for at least 12 months prior to the index date through to the end of the study period (Appendix A).

## 2.2. Data

Clalit Health Services is the largest payer/provider healthcare organization in Israel, with approximately 4.5 million current members, whose medical records were converted to electronic health records in the mid-1990s. The data used in this study came from Clalit Health Services' electronic health records, which are integrated in a central data warehouse and include diagnostic information on all members' outpatient and inpatient visits, as well as demographic, laboratory, pharmacy, clinical, and administrative (healthcare utilization) information.

### 2.2.1. The Managing Diabetes During Ramadan Conversation Map intervention

The intervention was designed to provide education to patients and their caregivers on strategies to manage diabetes during Ramadan. Intervention participants generally completed a 4-session Diabetes Conversation Map program prior to attending the one-time intervention, which took place 1–2 months before Ramadan fasting month starts. Each participant experienced only one Managing Diabetes During Ramadan Conversation Map Intervention, thus there were no overlapping participants between the cohorts.

The key topics discussed in the group intervention included understanding the risks of fasting during Ramadan; pathophysiological changes while fasting; managing the day during the Ramadan month; diet, physical activity, and medication schedule during Ramadan; and finally, creating a 'Diabetes and Ramadan Management Plan' together with both healthcare providers and a support network of patients (Healthy Interactions, 2015).

Clalit Health Services nurses from primary care and nurses who are diabetes specialists were certified by Eli Lilly Company in clinical competencies and knowledge in order to provide appropriate medical care during Ramadan. These certified nurses also supported participants with individualized meal planning,

medication adjustments, coping, and symptom management strategies.

## 2.3. Variables

### 2.3.1. Outcomes

The study's outcomes included four laboratory values: HbA1c, glucose, low density lipoprotein (LDL) cholesterol, and triglyceride levels, and two healthcare utilization variables: the number of primary care clinic visits and the number of any type of hospital admission. All outcomes were extracted at four time points for each participant: before the index date, during the follow-up period, and six months before and after the Ramadan fasting month in the previous year.

### 2.3.2. Independent variables

Independent variables included socio-demographic characteristics: age group (25–34, 35–44, 45–54, 55–64, 65–74, 75+ years), sex (male, female), and socioeconomic status (low, medium, high). Clinical characteristics included body mass index (underweight [ $<18.5 \text{ kg/m}^2$ ], normal weight [ $18.5\text{--}24.99 \text{ kg/m}^2$ ], overweight [ $25\text{--}29.99 \text{ kg/m}^2$ ], and obese [ $\geq 30 \text{ kg/m}^2$ ]), duration of type 2 diabetes (<5 years, 5–10 years, 10+ years), insulin use (yes/no), and smoking status (never, current, past). Oral medication adherence was measured using proportion of days covered. The proportion of days covered was calculated as the number of days over the six months prior to the intervention and over the follow-up for which a patient was "covered" (purchased medication) by a diabetes-related oral medication, divided by the number of days in this period. This variable was divided into groups of low (<50%), medium (50–80%), or high (>80%) proportion of days covered.

## 2.4. Statistical analysis

Baseline characteristics of intervention participants at index date (demographic, clinical, and healthcare utilization) are expressed as means ( $\pm$  standard deviation [SD]) for continuous variables and as percentages for categorical variables. Differences in these characteristics between pre- and post-Ramadan

were tested for statistical significance, using t-tests, Wilcoxon tests, and chi-square tests, as appropriate. The differences in outcomes associated with the intervention were calculated by the value of a given outcome  $Y$  under four scenarios (six month period pre- and post-intervention, and the six month period pre- and post-Ramadan month the year prior to the intervention as the self-comparison period) and taking the difference-in-differences:  $[(Y_{\text{intervention,post}} - Y_{\text{intervention,pre}}) - (Y_{\text{prior,post}} - Y_{\text{prior,pre}})]$  (Goldman et al., 2006).

Adjusted mixed model linear regression models were conducted for HbA1c, glucose, LDL cholesterol, and triglyceride levels, after the normality assumption was approved. An adjusted mixed model linear regression with square root transformation regression was conducted for primary care visits and an adjusted Poisson regression model was conducted for hospital admissions visits. A sub-group analysis of participants who had pre-Ramadan HbA1c levels above 7.0%, who were likely to be at a greater risk for developing adverse outcomes for all outcomes was conducted. No missing values of independent variables were observed, and only participants with full values of dependent variables were entered into the analyses. Variable significance was set at p-values (two-tailed) < 0.05. All analyses were conducted using SPSS version 21 (IBM, 2012).

### 3. Findings

#### 3.1. Baseline characteristics

A total of 1732 individuals enrolled in the intervention over the five-year study period. Specifically, the 2014 cohort included 325 participants, the 2015 cohort included 398 participants, the 2016 cohort included 524 participants, and the 2017 cohort included 485 participants. The cohort was mainly between the ages of 45 and 74 years (83.3%), female (71.9%), of lower socioeconomic status (92.1%), with a diabetes duration of 10 years or more (51.7%), obese (64.0%), and had never smoked (73.8%) (Appendix B). Prior to their intervention participation, the participants' mean laboratory results included glucose levels of 167.4 ( $\pm 66.2$ ), HbA1c levels of 8.5% ( $\pm 1.9$ ), and LDL cholesterol levels of 92.9 ( $\pm 32.1$ ). Additionally, 40.7% of the participants had low medication adherence and, on average, they visited their primary care provider 3.2 ( $\pm 2.8$ ) times during the six months prior to participation in the intervention (Table 1). No significant differences in laboratory values or healthcare utilization at index date were observed among the different cohort years.

#### 3.2. Difference in clinical lab measures before and after intervention

Table 1 presents the clinical outcomes that were assessed pre- and post- intervention participation and the five year mean of the

unadjusted differences that were assessed both in the intervention year and in the year prior to the interventions over the five year study period. In the year of the intervention participation there were significant changes pre- and post-Ramadan in mean glucose levels ( $-7.1$  mg/dL), HbA1c ( $-0.4\%$ ), and LDL cholesterol (3.8 mg/dL), while mean triglyceride levels increased by 9.1 mg/dL. In the year prior to the intervention, there were no changes in mean glucose, HbA1c, or LDL cholesterol levels between pre- and post- Ramadan, though the mean triglyceride levels increased significantly by 9.6 mg/dL (Table 1).

In the sub-group analysis (see Appendix B for the associated socio-demographic and clinical characteristics) of participants with baseline HbA1c levels greater than 7%, the glucose, HbA1c, and LDL cholesterol mean levels all significantly changed between the pre- and post-period of the intervention, and the mean triglyceride levels increased by 11.3 mg/dL. In the year prior to the intervention, the mean glucose and triglyceride levels significantly increased by 6.5 and 9.2 mg/dL, respectively (Table 2).

#### 3.3. Healthcare utilization pre- and post-intervention

There was no significant change in hospital admissions pre- and post- intervention year, while there was a significant decrease in primary care visits ( $p < 0.001$ ). In the year prior to the intervention, there was also a decrease in primary care visits ( $p = 0.024$ ), though its magnitude was lower (Table 1). In the sub-group analysis, primary care visits decreased by a mean of 0.4 visits ( $p < 0.001$ ), but there was no change in hospital admissions between pre- and post-intervention year. However, there were no significant changes in these types of healthcare utilization in the year prior to the intervention (Table 2).

#### 3.4. Managing Diabetes During Ramadan Conversation Map intervention effectiveness

The unadjusted difference-in-differences analyses between pre- and post- intervention year and their self-comparison period in the year prior to the intervention presented significant improvement in three clinical measures (Table 3). On average, participants' glucose levels decreased by 12.2 mg/dL, HbA1c levels decreased by 0.3%, and LDL cholesterol levels lowered by 5.0 mg/dL. In the sub-group analysis of participants with HbA1c > 7%, glucose levels decreased by 17.6 mg/dL, HbA1c levels decreased by 0.5%, and LDL cholesterol levels were lower by 5.7 mg/dL. Moreover, the number of primary care visits significantly decreased by 0.3 visits.

In the adjusted difference-in-differences models (Table 4) participants experienced a significant reduction of 8.6 mg/dL and 0.3% in their glucose and HbA1c levels, respectively, but not in

**Table 1**  
Unadjusted comparison of patients' outcomes pre- and post-Ramadan fasting month, by the year of and prior to the Managing Diabetes During Ramadan Conversation Map intervention.

Characteristics (Mean $\pm$ SD or Median [IQR])	Year of Intervention Participation					One year Prior to Intervention Participation				
	n	Pre	Post	Difference	p-value	n	Pre	Post	Difference	p-value
Glucose (mg/dL)	970	168.4 $\pm$ 66.0	161.3 $\pm$ 66.8	-7.1	0.002	1007	167.5 $\pm$ 67.4	170.1 $\pm$ 71.3	2.6	0.233
HbA1c (%)	950	8.6 $\pm$ 1.8	8.2 $\pm$ 1.7	-0.4	<0.001	969	8.6 $\pm$ 1.8	8.5 $\pm$ 1.8	-0.0	0.331
LDL cholesterol (mg/dL)	757	93.5 $\pm$ 31.9	89.8 $\pm$ 29.7	-3.8	<0.001	800	94.7 $\pm$ 29.9	94.9 $\pm$ 30.3	0.1	0.888
Triglycerides (mg/dL)	860	161.2 $\pm$ 103.4	175.0 $\pm$ 120.3	9.1	0.006	908	172.0 $\pm$ 138.0	181.6 $\pm$ 128.9	9.6	0.006
Primary care visits <sup>a</sup>	1247	3.2 $\pm$ 2.7	2.9 $\pm$ 2.7	-0.3	<0.001	1247	3.0 $\pm$ 2.6	2.8 $\pm$ 2.6	-0.2	0.024
Hospital admissions <sup>a</sup>	1247	0.1 $\pm$ 0.3 0 [0]	0.1 $\pm$ 0.3 0 [0]	0.0	0.212	1247	0.1 $\pm$ 0.2 0 [0]	0.1 $\pm$ 0.2 0 [0]	0.0	0.939

Abbreviations: SD, standard deviation; HbA1c, glycated hemoglobin; LDL cholesterol, low-density lipoprotein cholesterol.

<sup>a</sup> During 6-month intervals prior to and following the Ramadan fasting month.

**Table 2**

A sub-group analysis of unadjusted comparison outcomes pre- and post-Ramadan fasting month, by the year of and prior to the Managing Diabetes During Ramadan Conversation Map intervention, among patients with HbA1c levels of 7% or above.

Characteristics (Mean, $\pm$ SD or Median [IQR])	Year of Intervention Participation					One Year Prior Intervention Participation				
	N	Pre	Post	Difference	p-value	N	Pre	Post	Difference	p-value
Glucose (mg/dL)	737	181.8 $\pm$ 67.3	171.6 $\pm$ 70.6	-10.1	<0.001	666	179.0 $\pm$ 66.8	185.5 $\pm$ 73.8	6.5	0.021
HbA1c (%)	758	9.2 $\pm$ 1.6	8.7 $\pm$ 1.6	-0.5	<0.001	658	9.0 $\pm$ 1.7	9.1 $\pm$ 1.7	0.1	0.234
LDL cholesterol (mg/dL)	561	93.7 $\pm$ 32.5	89.0 $\pm$ 30.0	-4.7	<0.001	526	94.3 $\pm$ 28.9	95.1 $\pm$ 30.5	0.8	0.512
Triglycerides (mg/dL)	646	171.3 $\pm$ 101.2	182.6 $\pm$ 130.6	11.3	0.005	603	179.3 $\pm$ 156.4	188.5 $\pm$ 137.3	9.2	0.047
Primary care visits <sup>a</sup>	785	3.4 $\pm$ 2.6	3.0 $\pm$ 2.7	-0.4	<0.001	785	3.0 $\pm$ 2.6	2.9 $\pm$ 2.5	-0.1	0.441
Hospital admissions <sup>a</sup>	785	0.1 $\pm$ 0.3 0 [0]	0.1 $\pm$ 0.3 0 [0]	0.0	0.292	785	0.1 $\pm$ 0.2 0 [0]	0.1 $\pm$ 0.2 0 [0]	0.0	0.667

Abbreviations: HbA1c, glycated hemoglobin; SD, standard deviation; LDL cholesterol, low-density lipoprotein cholesterol.

<sup>a</sup> During 6-month intervals prior to and following the Ramadan fasting month.

**Table 3**

Unadjusted Difference-in-Differences Analyses Comparing Differences Pre-And Post- Ramadan In The Intervention Year and The Year Prior.

Characteristics (Mean, $\pm$ SD)	Entire sample					Sub-group of participants with HbA1c > 7.0%				
	N	Previous year difference	Intervention year difference	DID	p-value	N	Previous year difference	Intervention year difference	DID	p-value
Glucose (mg/dL)	657	5.5	-6.7	-12.2	0.002	495	7.9	-9.7	-17.6	<0.001
HbA1c (%)	614	0.0	-0.3	-0.3	<0.001	497	0.1	-0.4	-0.5	<0.001
LDL cholesterol (mg/dL)	461	2.1	-3.0	-5.0	0.014	338	1.4	-4.3	-5.7	0.025
Triglycerides (mg/dL)	549	14.3	9.2	-5.1	0.435	409	15.4	11.9	-3.5	0.634
Primary care visits <sup>a</sup>	1247	-0.2	-0.3	-0.1	0.429	785	-0.1	-0.4	-0.3	0.029
Hospital admissions <sup>a</sup>	1247	0.0	0.0	0.0	0.362	785	0.0	0.0	0.0	0.571

Abbreviations: DID, difference-in-differences; HbA1c, glycated hemoglobin; SD, standard deviation; LDL cholesterol, low-density lipoprotein cholesterol.

<sup>a</sup> During 6-month intervals prior to and following the Ramadan fasting month.

**Table 4**

Difference-in-Differences Analysis of Multivariable Mixed Linear Regression Models Comparing Differences Pre-And Post- Ramadan In The Intervention Year To The Year Prior.

Characteristics	Entire sample			Sub-group of participants with HbA1c > 7.0%		
	Estimate	Std. Error	p-value	Estimate	Std. Error	p-value
<b>Glucose levels</b>						
Intervention (ref- a year prior)	7.90	2.25	<0.001	14.03	2.99	<0.001
Time (ref- pre)	4.44	2.19	0.043	9.17	2.81	0.001
Intervention*Time	-8.61	3.08	0.005	-17.02	4.03	<0.001
<b>HbA1c levels</b>						
Intervention (ref- a year prior)	0.28	0.05	<0.001	0.43	0.06	<0.001
Time (ref- pre)	0.32	0.05	<0.001	0.49	0.06	<0.001
Intervention*Time	-0.34	0.06	<0.001	-0.63	0.08	<0.001
<b>LDL levels</b>						
Intervention (ref- a year prior)	4.48	1.07	<0.001	6.26	1.36	<0.001
Time (ref- pre)	2.92	1.02	0.004	4.39	1.26	0.001
Intervention*Time	-2.69	1.43	0.060	-4.83	1.80	0.007
<b>Primary care visits</b>						
Intervention (ref- a year prior)				0.20	0.04	<0.001
Time (ref- pre)				-0.05	0.04	0.266
Intervention*Time				-0.20	0.06	<0.001

All regression models are adjusted for sex, age group, socio-economic status, diabetes duration, body mass index, smoking status, insulin use, and medication adherence. Abbreviations: DID, difference-in-differences; LDL cholesterol, low-density lipoprotein cholesterol.

their LDL cholesterol levels ( $p = 0.060$ ). In the sub-group analysis among participants with HbA1c > 7% pre-intervention (Table 4), the reduction in glucose and HbA1c levels were 17.0 mg/dL and 0.6%, respectively. Additionally, there was a significant reduction in LDL cholesterol levels of 4.8 mg/dL and 0.2 less primary care visits.

The independent covariates that were positively associated with a reduction in glucose levels included being 75 years or older, having high oral medication adherence, having diabetes for less than 10 years, and not using insulin prior to the intervention. Independent covariates associated with a greater reduction in

HbA1c levels included having diabetes for less than 10 years and use of insulin prior to the intervention. Independent covariates associated with a greater reduction in LDL levels included male sex, being 75 years or older, and having high oral medication adherence. In the sub-group analysis, there were no independent covariates that were significantly associated with less primary care visits.

#### 4. Discussion

Our results suggest that participation in the Managing Diabetes During Ramadan Conversation Map intervention significantly

lowers glucose and HbA1c levels, not only compared to pre-intervention levels, but also compared to the change in levels over the Ramadan fasting month a year prior. This finding was strengthened by a sub-group analysis, which also found significant difference-in-differences in glucose and HbA1c levels in participants who, prior to Ramadan, had not achieved glycemic control (HbA1c > 7%), and found a reduction in primary care visits. These outcomes can be attributed to the attendance of one intervention educational session that was conducted by certified nurses that was an extension of the Diabetes Conversation Map 6-session program.

Findings in the literature are inconsistent regarding the health impact of the Ramadan fasting month on individuals with type 2 diabetes. Some have reported increased risk of hypoglycemia, hyperglycemia, and dehydration (Alabbood et al., 2017; Jabbar et al., 2017; Sadikot et al., 2017; Salti et al., 2004), while other studies found no significant change in glucose and HbA1c levels pre- and post-Ramadan (Karatoprak et al., 2013; Lessan et al., 2015; Sahin et al., 2013). Among the total study population, health outcomes improved between pre- and post-Ramadan in the year of the intervention (McEwen et al., 2015; Tourkmani et al., 2016). However, it is of interest that in the year prior, there were no changes observed pre- and post-Ramadan among any of the outcomes suggesting that the participants' health status did not deteriorate. This is likely due to a selection bias among the study population, where those who participated in the intervention might have been a motivated group in the first place with previous positive healthcare behaviour. Furthermore, the current study examined outcomes over a six month period in order to gather more observations and to also detect long-term impacts of the intervention, which may have attenuated the findings. Results from the sub-group analysis of participants with >7% HbA1c levels, however, indicated an increase in glucose levels pre- and post-Ramadan in the year prior, as anticipated. It seems that without the intervention in this sub-group, the probability of harm from fasting was higher (Hassanein et al., 2017), and the one-time group-based discussion about managing diabetes during Ramadan indeed had a positive impact on participants' clinical health outcomes.

The current study showed significant difference-in-differences estimates in glucose and HbA1c levels when comparing the changes in the intervention period to the changes in the self-comparison period a year prior. Only a few studies have conducted Ramadan specific interventions for Muslim patients with type 2 diabetes. Three studies from Pakistan, Thailand, and Malaysia compared post-Ramadan outcomes (up to four months post Ramadan) between participants and controls without baseline information (Ahmedani & Alvi, 2016; Lee et al., 2015; Susilparat et al., 2014), while another study reported outcomes throughout the Ramadan period without a control group (Ahmedani et al., 2012). Only one study by Bravis et al. conducted a rigorous evaluation applying a difference-in-differences design (Bravis et al., 2010) and found greater weight loss, fewer hypoglycemic events, and lower HbA1c levels in the intervention group compared to the controls. While the intervention described by Bravis et al. (2010) was a more extensive one with a large support staff and multiple sessions compared to the current intervention, which was a less resource intensive, one-session intervention, both evaluations found significant clinical findings.

The current study was the first to examine healthcare utilization as an outcome of intervention participation. While there were no significant differences between participants pre- and post-intervention among the entire sample, in a sub-population of patients with HbA1c levels greater than 7%, there was a significant decrease in primary care visits. This finding suggests that participation in the intervention may have also had an impact on decreasing healthcare utilization, particularly among

high risk individuals; this has an impact on both the individual and costs on the healthcare system.

#### 4.1. Limitations

Despite the strengths of the current study, including a large sample size, which was powered to see differences pre- and post-intervention, and a sub-analysis of a large sample of individuals with HbA1c levels greater than 7.0%, a few study limitations should be noted. The difference-in-differences analytic design simulated a counterfactual assessment by examining the change in outcomes both during the year of the intervention and a previous year, attempting to hold all other factors constant. However, a retrospective cohort design always has a compromised ability to determine causality between an intervention and the outcomes due to residual confounding. Second, although Managing Diabetes During Ramadan Conversation Map participants were expected to participate in the broader Diabetes Conversation Map program in the year surrounding their participation in intervention, we did not have the data to confirm who did and who did not attend the other sessions. Consequently, we cannot say that participation in the isolated Ramadan Diabetes Conversation Map was what influenced the outcomes. Finally, the hospitalization admission measure was not specific to diabetes-related admissions, thus the measure might lack specificity and not pick up hospitalizations due to the Ramadan fasting month, which might explain the insignificant association between participation and hospitalization outcomes.

#### 5. Conclusion

It can be suggested that in a group-based Ramadan-focused intervention, individuals with type 2 diabetes can gain tools to better control their glucose and HbA1c levels. It also has a substantial benefit in multiple outcomes for those individuals whose diabetes is uncontrolled (HbA1c > 7%). Moreover, glucose levels did not decline post-intervention for a high-risk group of individuals who were younger than 75 years, diagnosed with diabetes more than 10 years ago, had low oral medication adherence, and who used insulin treatment to manage their type 2 diabetes; this sub-group may benefit from a different education focus in the interventions. These findings hold important global health impact for the millions of people with type 2 diabetes for whom Ramadan can pose a challenge in disease control.

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#### Conflict of interest

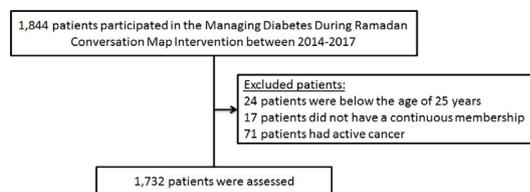
Clalit Research Institute received a partial funding for this research from Eli Lilly and company, however, Clalit Research Institute authors did not receive any fees or benefits from Eli Lilly and company. B.C, X.E, N.L.I, and A.S are all employees of Eli Lilly and company. Clalit Research Institute authors had full access to all of the data in this study and take complete responsibility for the integrity of the data and accuracy of the data analysis. Eli Lilly and company authors had full access to the aggregated data and study tables.

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## Appendix A. Flow chart



## Appendix B

Characteristics	Ramadan participants (n = 1732)	Ramadan participants with HbA1c > 7% (n = 1099)
Age (years; Mean, ± SD)	59.1 ± 10.8	58.9 ± 10.6
Age group (N, %)		
25–34	25 (1.4)	17 (1.5)
35–44	133 (7.6)	78 (7.1)
45–54	414 (23.9)	274 (24.9)
55–64	608 (35.1)	391 (35.6)
65–74	421 (24.3)	267 (24.3)
75+	131 (7.6)	72 (6.6)
Gender (N,%)		
Male	486 (28.1)	299 (27.2)
Female	1,246 (71.9)	800 (72.8)
Socioeconomic Status (N, %)		
Low	1,596 (92.1)	1016 (92.4)
Medium	115 (6.6)	71 (6.5)
High	21 (1.2)	12 (1.1)
Index date (N, %)		
2014	325 (18.8)	208 (18.9)
2015	398 (23.0)	264 (24.0)
2016	524 (30.3)	313 (28.5)
2017	485 (28.0)	314 (28.6)
Diabetes duration (N, %)		
<5 years	345 (19.9)	141 (12.8)
5–10 years	491 (28.3)	300 (27.3)
>10 years	896 (51.7)	658 (59.9)
Insulin use (N, %)		
Yes	838 (48.4)	679 (38.2)
No	894 (51.6)	679 (61.8)
BMI category (N, %)		
<18.5 (underweight)	2 (0.1)	1 (0.1)
18.5–24.99 (normal weight)	122 (7.0)	86 (7.8)
25–29.99 (overweight)	500 (28.9)	313 (28.5)
30 and greater (obese)	1,108 (64.0)	699 (63.6)
Smoking status (N, %)		
Never	1,278 (73.8)	812 (73.9)
Former	234 (13.5)	144 (13.1)
Current	220 (12.7)	143 (13.0)
Medication adherence A10B		
Low	698 (40.3)	432 (39.3)
Medium	317 (18.3)	205 (18.7)
High	717 (41.4)	462 (42.0)

Abbreviations: SD, standard deviation; BMI, body mass index.

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