# PUBLIC HEALTH RESEARCH

# The Effectiveness of Ramadan Focused Education on Awareness and Glycemic Control of Diabetic Muslims (Type 2 Diabetes) During Ramadan Fasting

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## ABSTRACT

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| **Introduction** | The majority of Muslim diabetic patients are unaware of complications during fasting, therefore diabetic patients who want to fast need a pre–Ramadan assessment and education to increase their awareness of the risks of fasting. This study examined the effectiveness of Ramadan focused education aimed at increasingself-awareness and glycemic control in Muslims with type 2 diabetes who fast during Ramadan. |
| **Methods** | A pre and post experiment with a randomized controlled trail was being conducted among 212 patients at Primary Care Units of Songkhla. To be eligible, patient participants must be fasting diabetic patients during Ramadan.The study is a two-centre randomized wait-list controlled trial. Subjects were 108 patients who were allocated to the intervention group (educated about meal planning, physical activity, medications, recognizing and managing complications before Ramadan) and 104 patients were in the control group or wait list control (The control group received conventional group counseling).The data were analyzed using descriptive statistics, ANCOVA, and t- test. |
| **Results** | After Ramadan, we observed no difference in FBS and HbA1c between intervention and control patients. On comparing the self-awareness score of realization of the diabetic patients between the intervention and the control groups after adjusting for baseline [adjusted difference1.10, 95% confidence interval (CI). 29, 1.71; P=0.005], the difference statistically significant (p<0.005). |
| **Conclusions** | The intervention significantly increased self-awareness. The role of structured education for patients is well established in the management of diabetes. This should be extended to Ramadan-focused diabetes education and drug modification program on awareness of self-care and glycemic control in Muslims with type 2 diabetes who fast during Ramadan in Thailand. |
| **Keywords** | Ramadan - education - awareness - Muslim - type 2 diabetes. |

## INTRODUCTION

The incidence of type 2 diabetes mellitus is increasing worldwide. Type 2 diabetes results from the interaction between a genetic predisposition and behavioral awareness. Although the genetic basis of type 2 diabetes has yet to be identified, there is strong evidence that such modifiable risk as unawareness physical inactivity are the main nongenetic determinant of the disease[1]. For Muslims, fasting in Ramadan is one of the five main practices and therefore has significant religious meaning and hence psychological connotations for the person undertaking it[2-6]. Fasting during Ramadan is prescribed for every healthy adult Muslim except those who are weak, sick or travelling. During this time, they have to abstain from food, water, beverages, smoking, oral medications and sexual intercourse[6-7].

In Thailand, most Muslim population live in the five Southern border provinces; in Songkhla Province one thirds of the population are Muslims[18]. The practice of fasting in Ramadan makes the way of life of fasting Muslim diabetic patients different from other months as they have to change their eating behavior and the time of their medication taking. They must change from eating three meals: morning, noon, and evening to eating two meals: after sunset and before sunrise. This behavior change can affect the glycemic control[11-13]. Medicine dosage schedule have to be altered during Ramadan. In fact the drugs can be taken only between sunset and dawn and the time span between two doses is sometimes shorter than usual non-Ramadan days[11, 14]. Many studies have found a significant increase in the risk of hypoglycemia and hyperglycemia during Ramadan[9,17,20], but the majority of Muslims diabetic patients are unaware of these complications during fasting[20]. Controlling the blood sugar levels to prevent complications from fasting by Muslim diabetic patients during Ramadan cannot be done by physicians and the health team alone. Therefore, building self-awareness by providing advice will help increase the patients' self-awareness. Self-awareness Theory states[29] that when we focus our attention on ourselves, we evaluate and compare our current behavior to our internal standards and values. We become self-conscious as objective evaluators of ourselves. Various emotional states are intensified by self-awareness. However, some people may seek to increase their self-awareness through these outlets. People are more likely to align their behavior with their standards when made self-awareness. People will be negatively affected if they don't live up to their personal standards. Various environmental cues and situations induce awareness of the self, such as mirrors, an audience, or being videotaped or recorded. These cues also increase accuracy of personal memory. From reviewing related literatures indicate that fasting in Ramadan is safe for the majority of diabetic patients with proper education and diabetic management[3,5,19-21]. Nevertheless, in Thailand studies have not been done extensively, therefore the aim of the study was to evaluate the effect of Ramadan focused education on self-awareness and glycemic control in Muslims with type 2 diabetes who fast during Ramadan to improve care for fasting Muslim diabetic patients.

## METHODOLOGY

*Study design*

This experimental design was conducted at the two Primary care units of Songkhla Hospital during June-September 2012. The study is a two-centre randomized wait-list controlled trial. We randomly allocated participants by using computer generated randomization sequence prepared before any participants (type 2diabetic) were randomized. All the subjects were informed about the procedures and signed a written term of informed consent that was approved by the ethic committee of Songkhla Hospital. Participants randomly allocated to a Ramadan focused education on awareness. The intervention group received a leaflet based educational intervention, new drug management and verbal instructions. Participants randomly allocated to the usual care group received standard care. Participants are assessed at the baseline after providing informed consent and then randomly allocated to either the awareness education intervention or usual care arm of trail. The subjects were selected by simple random sampling method. The inclusion criteria were all Muslim patients with a diagnosis of type 2 diabetes mellitus for more than 1 year who had decided to fasting Ramadan. The exclusion criteria were patients with acute seriously sick such as high grade fever, severe infection or sepsis, pregnant woman and those having serious complications such as unstable angina, severe liver or renal disease, elderly patients with alertness problems. Data were collected using a questionnaire that had been tested for its content validity by three experts (CVI was 0.80). In our study, the reliability coefficient (Cronbach's alpha coefficient was 0.83).

Enrolled subjects were randomly assigned to the intervention group or the control group by the study participants with the use of a randomization list (the study is a two-centre randomized wait-list controlled trial). This process was blinded to other staff members as well as to the subjects. The sample size needed for the study was determined based on information to detect the difference in primary end point with a significance level of 5%, power of 90% and medium effect size. Subjects were 108 patients who were allocated to the intervention group (educated about meal planning, physical activity, medications, recognizing and managing complications before

Ramadan) and 104 patients were in the control group or wait list control (The control group received conventional group counseling).Subjects who withdrew from the study and for whom there were no data on outcome measures were excluded from the main analysis.

*Statistical Analysis*
All data were entered and verified, and scores were calculated for multiple-item instruments. Summary statistics including frequency distributions, means and other descriptive analyses of variables were conducted to provide an overview of the characteristics of participants in both groups. We also examined statistics to ensure that data met statistical test assumptions. Difference between groups for baseline characteristics of the subjects who completed the trial were assessed by the Student's *t* test .Outcome measures were compared using ANCOVA by adjusting for baseline values (ANCOVA on study variables by normal). ANCOVA was used to test for the effects that pretest had on posttest scores, with age, sex and education as covariates. Hence, ANCOVAs for post-treatment change in each primary outcome measure were completed, using the baseline value of the outcome measure as a covariate. This approach controlled statistically for the baseline differences between groups, reducing the influence of correlations between baseline status and change scores. All reported p-values are for two-sided tests with effects considered statistically significant at p<0.05.

*Educational Intervention*
The management intervention being studied was related to fasting during Ramadan by people with diabetes. This was conducted by the educational team (a family physician, two specialists nurse practitioners and two village health volunteers) based on the experience of diabetes management and the literature recommendations at the time[2, 8, 10-12,15,16]. The steps in providing group-based diabetes self-care knowledge were divided into four phases in the intervention group.

*1) The first phase* of the intervention started 6 weeks before Ramadan and was directed towards the educational team who participated in the study. Every care providers was equipped with information on methods of providing group-based diabetes self-care and a comprehensive review of the management of diabetes in Ramadan. This was to ensure uniformity and consistency of the educational messages to be provided to the patients.

*2) The second phase* of the intervention started 2-4 weeks before Ramadan involved the recruited patients and included educational sessions with the

family doctor and the specialist nurse practitioner. There were 7 groups of patients, each with 15-16 patients and there were two educational sessions, one conducted by the same family doctor and the other by the same specialist nurse practitioner. In the session with the specialist nurse practitioner, the education program contained meal planning and physical activity lasted for 30-40 minutes. In the session with the family doctor, the patients' physical well being, glycemic control and risk stratification based on the published ADA model[15] that assessed risk of hypoglycemia, hyperglycemia and other diabetic complications during fasting were assessed, and recognizing and managing complications were emphasized. Hypoglycemic drugs adjustment were made regarding dosage, timing and the decision for altering the hypoglycemic drugs regimen was at the physician' discretion, depending on the glycemic control of individual patients, in addition to telephone counseling and support in response to patients' calls during Ramadan, a self-recorded diary for recording hypoglycemic, hyperglycemic symptoms and cause of break fasting or non-fasting during a day were also provided to all patients. This session lasted for 60-90 minutes. All patients were given the opportunity to discuss their individual's questions regarding their diabetes and fasting at the end of the sessions.

*3) The third phase* of the intervention started in the 1st-2nd week of Ramadan, every patient was re-assessed regarding diet, physical activity, hypoglycemic drug taking and need for dose readjustment, complications during fasting by active home visits service of the education team.

*4) The fourth phase* of the intervention started 2-4 weeks after Ramadan including follow up feedback of events during Ramadan. In addition, the therapeutic regimens were changed back to previous schedules. The control group was followed by a usual care. Patients received usual medications and advice without systematic and continuous advice, without medication adjustment, without home visits, and without follow-ups by officials. They also received a self-recorded diary for recording hypoglycemic, hyperglycemic symptoms and causes of break fasting or non-fasting during a day.

*Definition of term*
The effectiveness of Ramadan focused education intervention refers to the results of treatment with continuous knowledge provision about self-care for type 2 diabetic patients during Ramadan. The results of this study revealed changes in scores for realization of self-care in meal planning, physical activity, medications, recognizing and managing complications, and blood sugar level control.

*Outcome Measures*
Body weight, Fasting blood sugar (FBS), Hemoglobin A1c (HbA1c) were measured, and also self-awareness was assessed by a questionnaire consisting of 10 simple questions before and after Ramadan fasting. Usual care refers to treatment by giving patients usual medications and advice by physician without systematic and continuous advice, without medication adjustment, without home visits by officials and without follow-ups.

## RESULTS
When comparing the baseline characteristics of the intervention group with those of the control group, it was found that they were not statistically different at the level of 0.05 in their age, sex, duration of diabetes, education level, type of treatment, FBS, HbA1c, Body mass index (BMI) and self-awareness score (Table1).

**Table 1** Comparison of baseline characteristics, clinical data and self-awareness score between the control group and the intervention group.

| Baseline characteristics | Control group n = 104 | Intervention group n = 108 |
|---|---|---|
| Age (years) | 62.08 ± 9.15 | 61.05 ± 10.24 |
| Female, *n* (%) | 80 (76.92 %) | 89 (82.40 %) |
| Duration of diabetes (years) | 7.53 ± 4.80 | 6.96 ± 4.68 |
| No formal or primary education, *n* (%) | 101 (97.12 %) | 106 (98.15 %) |
| Comorbidity | | |
| • Hypertension, *n* (%) | 89 (85.58 %) | 97 (89.81 %) |
| • Dyslipidemia, *n* (%) | 87 (83.65 %) | 83 (76.85 %) |
| Type of treatment | | |
| • Lifestyle modification, *n* (%) | 3 (2.88 %) | 3 (2.78 %) |
| • Sulfonylurea, *n* (%) (Glibenclamide or Glipizide) | 84 (80.70 %) | 80 (74.10 %) |
| • Metformin, *n* (%) | 81 (77.88 %) | 91 (84.26 %) |
| • Pioglitazone, *n* (%) | 19 (18.26 %) | 17 (15.74 %) |
| • Insulin, n (%) | 4 (3.84 %) | 4 (3.70 %) |
| FBS (mg/dl) | 165.33 ± 62.13 | 178.62 ± 70.08 |
| HbA1c (%) | 9.12 ± 2.59 | 9.70 ± 2.74 |
| BMI (kg/m$^2$) | 26.64 ± 4.72 | 26.40 ± 5.19 |
| Awareness score of self - care | 5.65 ± 1.96 | 6.04 ± 1.15 |

Data are mean ± SD or n (%)
*Self-Awareness score, FBS, HbA1c, BMI*

When comparing the levels of FBS and HbA1c between the before and after Ramadan at the end of the program, it was found that the levels of FBS and HbA1c of the intervention group was significantly decreased (Table 2) For the BMI, there was a significant decrease in BMI after Ramadan in the intervention group, but when compared between the two groups, it was found that the BMI level of the intervention group was less than that of the control group but in the statistical test, the difference was not statistically significant (Table 3)

**Table 2** Comparison of clinical data on FBS, HbA1c and BMI between before and after completing a Ramadan focused education of the intervention group.

| Clinical Data | Before Ramadan | | After Ramadan | | t-value | p-value |
|---|---|---|---|---|---|---|
| | Mean | S.D. | Mean | S.D. | | |
| FBS | 178.62 | 70.08 | 160.13 | 55.04 | 1.62 | .020 |
| HbA1c | 9.70 | 2.74 | 9.11 | 1.10 | 2.33 | .021 |
| BMI | 26.40 | 5.19 | 25.99 | 5.26 | 2.85 | .005 |

**Table 3** Comparison of clinical data on FBS, HbA1c and BMI between the control group and the intervention group after completing a Ramadan focused education intervention.

| Clinical data | Control Group | | Intervention group | | t-value | p-value |
|---|---|---|---|---|---|---|
| | Mean | S.D. | Mean | S.D. | | |
| FBS (mg/dl) | 165.33 | 62.13 | 178.62 | 70.08 | -1.46 | 0.15 |
| HbA1c (%) | 9.12 | 2.59 | 9.70 | 2.74 | -1.59 | 0.113 |
| BMI (kg/m$^2$) | 26.64 | 4.72 | 26.40 | 5.19 | 0.341 | 0.74 |

After Ramadan, we observed no difference in FBS and HbA1c between intervention and control patients, after adjusting for baseline FBS [adjusted difference 0.70, 95% confidence interval (CI) -0.15, 0.0.22; P=0.78] and HbA1c [adjusted difference 0.10, 95% confidence interval (CI) -0.15, 0.0.33; P=0.90]. On comparing the self- awareness score of realization of the diabetic patients between the intervention and the control groups after Ramadan, after adjusting for baseline.[adjusted difference 1.10, 95% confidence interval (CI) .29, 1.71; P=0.005] there was a significant increase in the intervention group (p<0.005) (Table 4).

**Table 4** Adjust of Significance intervention effect; ANCOVA Analyses Controlling for Baseline Measures

| Comparison | Control | Intervention | Adjusted difference (95%) | P-value (ANCOVA) |
|---|---|---|---|---|
| FBS (mg/dl), mean (SE) | | | | |
| Base line | 165.33(4.56) | 168.62(4.78) | 0.70 (-1.5, 0.22) | 0.78 |
| | 164.63(4.46) | 160.13(5.14) | | |
| HbA1c (%), mean (SE) | | | | |
| Base line | 9.25 (.18) | 9.80 (.21) | 0.10 (-0.15, 0.33) | 0.90 |
| Post Ramadan | 9.12 (.20) | 9.70 (.14) | | |
| Awareness score of self – care, mean (SE) | | | | |
| Base line | 5.65 (2.3) | 6.04 (1.21) | 1.10 (.29, 1.71) | 0.005 |
| Post Ramadan | 5.27 (.38) | 9.20 (.14) | | |

After fasting in Ramadan, the research team followed up the complications during their fasting in Ramadan and found that 18.5 % of the patients in the intervention group had 62 times of hypoglycemic events while 25 % of the patients in the control group had 84 times of hypoglycemic events. Every case of hypoglycemia was mild. For hyperglycemia, it was found that 1.85 % of the patients in the intervention group had it 5 times compared with 8.65% of the patients in the control group that had it 36 times; every hyperglycemia case was mild. For hyperglycemia, it was found that 1.85 % of the patients in the intervention group had it 5 times**.**

## DISCUSSION

From the study, it was found that the FBS, HbA1c, BMI levels of the patients in the intervention group decreased while their self- awareness score increased significantly after using the Ramadan focused education intervention. The results of this intervention correspond with previous studies that have also shown that diabetic patients who attended Ramadan focused education have more self-awareness[19], lower FBS, HbA1c, and BMI levels than those patients in the other group that did not attend the education[20-22]. The patients in the intervention group had improved levels of FBS, HbA1c, BMI while their self- awareness increased significantly could be resulted from the patients participated in an intervention, in which a systematic review of randomized controlled trials of the effectiveness of self-management training in people with Type 2 diabetes, educational interventions that involved patient collaboration were more effective than didactic interventions in improving short-term glycemic control (<6 months),weight and lipid profiles[23]. The patients were provided small-group education where systematic review with meta-analysis of group based diabetes self-management education compared to routine treatment for 154 people with type 2 diabetes mellitus revealed that group based diabetes self-management education results in improvements in clinical, lifestyle and psychosocial outcomes[24]. There were home visits to assess complications that might take place from taking medication, diet, and doing daily routines. Dose adjustment and change of medication-taking time could be suggested if necessary. Discussions with the patient and family members also took place when they had questions. Previous studies

have found that home visits for type 2 diabetic patients could reduce problems that might be a result of medication and home visits also increased the quality of care for patients[25]. From this study, the control group was found to have higher levels of FBS and HbA1c in accordance with results of previous studies[5,12,13] that have found higher levels of FBS and HbA1c as a result of the type of food consumed by the patients such as food high in carbohydrate and sugar, excessive amount of food consumed in the sunset meal while doing less daily routines and usually slept or watched television because they might afraid of having hypoglycemia[13,27]. Other factors causing higher levels of FBS and HbA1c included the control of blood sugar level before fasting, difference in metabolism, and irregularity in taking anti-diabetic medication. Of all the factors, food consumption was most important[4,13]. The BMI levels that did not significantly change for the control group corresponded with previous studies[5,27,28] could be due to the total energy the patients received that was not different from what they had before fasting even though they consumed more in the sunset meal, they had only two meals a day. Many researchers have confirmed that lipid, carbohydrate, protein and hormone metabolism changes occur during the fasting. Diurnal fasting during Ramadan is counterbalanced by compensatory changes during the night, which preserves normal body weight[26,28]. The reasons why the patients in the intervention group had lower levels of FBS, HbA1c, and BMI while the level of their self-awareness was significantly higher than those of the control group could not be concluded clearly whether they were because of the use of the Ramadan focused education intervention or because of the dose adjustment or selection bias. This is because it could be that the patients on the Ramadan focused education intervention had more motivation than those in the control group, and wanted to effectively control their blood sugar level. It is recommended that further studies should run randomized controlled trials using multiple arms, each strategy per arm and one combination group.

## CONCLUSIONS

This intervention significantly increased self-awareness and the effects of this intervention on FBS, HbA1c and BMI were significant but with small reduction. The role of structured education for patients is well established in the management of diabetes. This should be extended to Ramadan-focused diabetes education and drug modification program on awareness of self-care and glycemic control in Muslims with type 2 diabetes who fast during Ramadan in Thailand. Many Muslims with diabetes are very passionate about fasting during Ramadan. This passion is a golden opportunity to empower people with diabetes for better management of their diabetes, not only during Ramadan but also throughout the year. However, many health care professionals find that they are unable to give the appropriate medical advice due to lack of knowledge about the optimum management of diabetes while fasting. Indeed, often people with diabetes feel that there is lack of harmony between the medical and the religious advice they receive. Hence, a Ramadan-focused diabetes educational program should ideally include three components: (1) An awareness campaign aimed at people with diabetes, health care professionals, the religious and community leaders as well as the general public, (2) Ramadan-focused structured education for health care professionals, and (3) Ramadan-focused structured education for people with diabetes.

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