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Efficacy of time-restricted eating and behavioural economic interventions in reducing fasting plasma glucose, HbA1c and cardiometabolic risk factors compared with time-restricted eating alone or usual care in patients with impaired fasting glucose: protocol for an open-label randomised controlled trial

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ABSTRACT

Introduction Impaired fasting glucose (IFG) is a significant risk factor for diabetes mellitus. Time-restricted eating (TRE) is one type of diet showing positive effects on metabolic signal pathways. However, effects of TRE on cardiometabolic risk factors in humans are limited. Additionally, compliance with TRE remains problematic despite having intention to follow the diet control. Therefore, this study aims to investigate the efficacy of TRE with behavioural economic interventions or TRE alone relative to usual care, in reducing fasting plasma glucose (FPG), haemoglobin A1c (HbA1c) and other cardiometabolic risk factors in patients with IFG.

Methods and analysis This parallel-group, open-label randomised controlled trial will be conducted at the outpatient clinic of the Department of Family Medicine, Faculty of Medicine, Ramathibodi Hospital, Bangkok, Thailand. Patients aged 18–65 years with IFG defined as FPG 100–125 mg/dL and body mass index ≥25 kg/m^2 will be recruited between October 2021 and October 2022. Patients will be randomly allocated to three groups (1:1:1 ratio) as (1) TRE with behavioural economic interventions including financial incentives and text reminders, (2) TRE alone or (3) usual care. The number of participants will be 38 per group (a total of 114). The duration of the intervention will be 12 weeks. Primary outcome is FPG levels measured at 12 weeks after randomisation. Secondary outcomes are HbA1c, body weight, systolic and diastolic blood pressure, fasting insulin, serum triglyceride, total cholesterol, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol and high-sensitivity C reactive protein. P value of <0.05 of two-sided test will be considered as statistical significance.

Ethics and dissemination The study protocol has been approved by the Ethics Committee of the Faculty of Medicine, Ramathibodi Hospital, Mahidol University (MURA2021/389). All patients will be informed about the details of the study and sign written informed consent before enrollment in the study. Results from this study will be published in a peer-reviewed journal.

Trial registration number TCTR20210520002.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The study uses a randomised controlled trial design to assess the efficacy of time-restricted eating on blood sugar levels and other cardiometabolic risk factors in patients with impaired fasting glucose.
⇒ The study has longer-term follow-up than previous studies.
⇒ The interventions cannot be blinded; hence, the results may be affected by observer and information bias.
⇒ Contamination of time-restricted eating in the usual care group might occur due to the promotion of time-restricted eating on some social media platforms in Thailand.

INTRODUCTION

Diabetes mellitus (DM) is one of the important health problems in Thailand. The results from the National Health Examination Survey reported that the prevalence of DM in the Thai population has increased from 7.7% in 2004 to 9.9% in 2014.[1] Diabetes is a risk factor for cardiovascular diseases and also the cause of microvascular complications such as

chronic kidney disease and diabetic retinopathy. Moreover, around 4% of mortality in the Thai population is caused by DM.[2] Hence, the prevention of DM in the Thai population is critical to decreasing further morbidity and mortality in the future.

Impaired fasting glucose (IFG) or intermediate hyperglycaemia is the condition in which blood sugar level is higher than normal but does not reach the DM threshold. A person with IFG has a higher risk of DM, about 13 times than a person with a normal blood glucose level.[3] Evidence from a previous umbrella review found that lifestyle modifications by diet control and exercise significantly decreased the risk of DM in persons with IFG.[4] Most diet interventions including low and very low-calorie diets are mainly focused on caloric restriction with the main objective of body weight reduction. Although the efficacy of these diet interventions in decreasing DM risk is well established, most patients could not sustain their healthy behaviours or maintain their healthy lifestyle permanently.[5] As a result, other methods of diet control such as time-restricted eating (TRE) have been introduced as an alternative, which may help patients permanently maintain their behaviours.

TRE is one type of dietary approach that limits the daily eating window to commonly lower than 10 hours/day and prolongs fasting time.[6–8] Previous literature found that increased fasting time has positive effects on many metabolic signal pathways, that is, prolonged fasting stimulated autophagy and cell repair including mitochondria biogenesis resulting in better metabolic signal pathways in animals. In a human study, the TRE could significantly lower body weight but could not decline fasting plasma glucose (FPG), fasting insulin and haemoglobin A1c (HbA1c) when compared with the normal eating style in patients with metabolic syndrome.[9] Likewise, a study in patients with obesity also found that TRE could reduce body weight, blood pressure, low-density lipoprotein cholesterol (LDL-C) and non-high-density lipoprotein cholesterol (HDL-C), but could not reduce FPG, fasting insulin and HbA1c.[10] On the other hand, the study of Schroder *et al* found the significant reduction of body mass index (BMI), body fat percentage, and waist circumference in middle-aged women with obesity receiving TRE, but FPG, HbA1c, fasting insulin, LDL-C, HDL-C, serum uric acid, and blood pressure were not significantly different between TRE and control groups.[11] Contrastingly, meta-analyses found the benefits of TRE in lowering not only body weight but also FPG, blood pressure and triglyceride levels.[12 13] Until now, there are few small randomised controlled trials (RCTs) that examined the effect of TRE in patients with IFG. A cross-over RCT assessing the effects of early or delayed TRE in 15 men at risk of type 2 DM found that both early and delayed TRE improved glycaemic response, but only early TRE could lower mean FPG in men with a high risk of DM.[14] Another RCT assessed the effect of early TRE in eight men with pre-diabetes and found that early TRE could reduce insulin level, blood pressure and food appetite, increase insulin sensitivity and beta-cell responsiveness but could not reduce FPG.[15] However, these RCTs focused on only men with very short follow-up times (ie, 7 days and 5 weeks). Therefore, further RCTs investigating the longer-term effect of TRE in both male and female patients are still needed.

Although several studies found that TRE was well accepted by study participants[16] and well tolerated even in older adults,[17] the long-term adherence to TRE is still questionable in the real-life situation of some people. Such a gap occurs because the benefits of reducing cardiometabolic risks are intangible and will occur in the far future, whereas the cost of adherence to this diet control, namely being disciplined on diet time instead of eating freely whenever desired, happens immediately. Thus, some people who place much greater weight on the present than on the future will be less likely to adhere to diet control. This is called present bias from behavioural economics perspective.[18 19] Behavioural economics is a field that integrates insights and methods from psychology and economics to understand human decision-making.[20–22]

A few behavioural economics tools have been used to deal with a present bias to promote adherence to diet control, that is, financial incentives and text reminder.[23] Previous studies show that financial incentive was an effective tool to promote a healthy lifestyle such as smoking cessation, physical activity[24] and weight loss.[25] Text reminders about an individual commitment, performance or goal can immediately remind them of the priority. Such reminders have been proven effective in many domains, such as for the promotion of savings,[26] weight loss[27 28] and medication adherence.[29] As a result, using behavioural economics might help increase compliance with lifestyle modification such as TRE or even maintaining behavioural change and finally improve the efficacy of lifestyle intervention in people with IFG who require a lifelong healthy lifestyle to prevent DM conversion.

Nevertheless, there has been no study that assesses the efficacy of combined TRE with behavioural economic interventions in patients with IFG. Therefore, this RCT protocol is developed which aims to determine the efficacy of TRE plus behavioural economic interventions or TRE alone, when compared with usual care in patients with IFG with the following objectives. First, to investigate whether providing TRE plus behavioural economic interventions or TRE alone for patients with IFG will provide additional benefit in reducing FPG when compared with usual care. Second, to compare HbA1c, body weight, systolic blood pressure (SBP), diastolic blood pressure (DBP), fasting insulin, serum triglyceride, total cholesterol, LDL-C, HDL-C and high-sensitivity C reactive protein (hs-CRP) between TRE plus behavioural economic interventions or TRE alone with usual care.

METHODS AND ANALYSIS

Study design

This study is a parallel-group, open label RCT, which will be conducted at the outpatient clinic of the Department

of Family Medicine (OFM), Faculty of Medicine, Ramathibodi Hospital, during October 2021–October 2022. This research method complies with the Consolidated Standards of Reporting Trials statement extension for multiarm trials. The trial protocol has been registered at the Thai Clinical Trials Registry (TCTR20210520002).

Participants

Patients and staffs of Ramathibodi Hospital who are diagnosed with IFG will be recruited from October 2021 to October 2022, and they will be followed up until the 12th week after randomisation. Trained investigators and research assistants will approach and inform patients about the study protocol, randomisation process, and details of interventions and comparator. Participants will sign informed consent before participating the study.

Patients will be included in this study, if they meet all of the following criteria: (1) age 18–65 years, (2) having FPG of 100–125 mg/dL with HbA1c less than 6.5% and (3) BMI ≥25 kg/m^2. The patients will be ineligible if they are (1) currently on ketogenic or vegetarian diets, (2) doing night shift work at least ≥3 hours during 22:00–05:00 more than 1 day/week, (3) having more than 5 kg body weight changes during the 3 months before enrolment to the study, (4) taking medicines that must be taken with food in the early morning (ie, before 08:00) or late evening (ie, after 17:00), (5) pregnant or breast feeding, (6) having psychiatric disorders such as eating disorder or mood disorder but not including depression, (7) taking corticosteroid or anti-diabetic drugs, (8) having a history of bariatric surgery and (9) having impaired nutrients absorption.

Randomisation

Patients will be randomly assigned to any of three interventions including TRE plus behavioural economic interventions, TRE alone and usual care with a ratio of 1:1:1. Block randomisation with varying block sizes of 6 and 9 will be generated by a biostatistician who is not involved in the trial using STATA program V.16. Randomisation will be stratified according to age groups (ie, 18–59 years and 60–65 years). A random sequence list will then be concealed using sequential opaque sealed envelopes, which will be kept at the OFM. A research assistant will administer and open the sealed envelope once patients are eligible.

Blinding

The study is open label as participants and clinicians cannot be blinded due to the nature of interventions. However, data collectors and a biostatistician will be blinded about the intervention allocation. In addition, the outcomes of this study will be objectively measured that will not be affected by the unblinded interventions.

Study interventions

Interested interventions are TRE and behavioural economic interventions. TRE is a limitation of the daily time of food intake to 9 hours with prolonged fasting in the night-time of 15 hours. Participants will be requested to limit their periods of food intake from 08:00 to 17:00 without restriction on types of food and beverages. Participants will be asked to comply with TRE as much as they can.

Behavioural economic interventions will consist of financial incentive and text reminder. For financial incentive, the participant will receive monetary compensation of 1000 bahts per month (£23) if they self-report that they can adhere to TRE at least 5 days/week for 4 weeks. TRE adherence will be evaluated every week by asking participants to record their first and last mealtime every day via a log book, and financial incentive will be provided on 4th, 8th and 12th week after randomisation. In addition, text reminder will be sent to participants every 2 days to remind them about their commitment (your goal is to stick to the TRE plan for at least 5 days a week.), performance (last week you have successfully stuck to the TRE plan for 5 days) and also about the TRE interval. The TRE alone group will be advised about the benefit of TRE without any additional supports. However, participants in the TRE alone group will be asked to record their adherence to TRE via a log book.

Comparator of the study is usual care according to the current practice guideline of diabetes prevention. Patients will be educated about their conditions and DM progression, dietary control and exercise to prevent DM progression. Participants in TRE plus behavioural economic interventions and TRE alone groups will also receive education about dietary control and exercise similar to patients in the usual care group. In addition, patients in usual care group will be asked to record their first and last mealtime every day, which will be the same as the patients in the other two interventions to evaluate protocol violation. All patients in three groups will receive a leaflet that provides knowledge about healthy food and lifestyle modification to control their weight and reduce the risk of progression to DM.

Outcomes

The primary outcome of this study is FPG which will be measured at the end of the study, that is, 3 months (12 weeks) after randomisation. FPG will be measured by hexokinase glucose-6 phosphate dehydrogenase.

Secondary outcomes are HbA1c, body weight, SBP, DBP, fasting insulin, serum triglyceride, total cholesterol, LDL-C, HDL-C and hs-CRP. HbA1c will be measured by turbid metric inhibition immunoassay certified by the National Glycohemoglobin Standardization Program. Body weight and blood pressure measurement will be taken by trained research assistants. Body weight will be measured without shoes to the nearest 100 g. Blood pressure will measured after resting for at least 15 min with an automatic blood pressure monitoring. Fasting insulin, serum triglyceride, total cholesterol, LDL-C, HDL-C, and hs-CRP will be measured by chemiluminescent microparticle immunoassay, glycerol phosphate oxidase, enzymatic

method, liquid selective detergent, accelerator selective detergent, and immunonephelometry, respectively.

All primary and secondary outcomes will be measured at baseline, 1, 2 and 3 months after randomisation.

Adverse events

Adverse events such as syncope, dizziness and lightheadedness will be measured during all study periods.

Covariables

Other covariables will be collected as follows:

1. Demographic data including age, sex, educational level and marital status.
2. Underlying diseases such as hypertension, dyslipidaemia, fatty liver disease and history of gestational DM.
3. Health risk behaviours including smoking and alcohol intake.
4. Family history of DM in the first-degree relatives.
5. Sleep factors including sleep duration, sleep quality measured by the Thai version of the Pittsburgh Sleep Quality Index,[30] and morningness and eveningness preference using the validated Thai version of the Composite Scale of Morningness.[31]
6. Physical activity level measured by Global Physical Activity Questionnaire.[32]
7. Details of food and caloric intake assessed by 24-hour food recall and food frequency questionnaires.
8. Time and risk preference assessed by multiple price list method.[33–38]

Study protocol and data collection

A schedule matrix consisting of data collections and time at measurements is presented in table 1. At the first visit, trained investigators and research assistants will recruit the patient by screening FPG and other inclusion criteria (ie, age, HbA1c, and BMI). If the patient meets all the inclusion criteria, the research assistants will explain about the study protocol, process of data collection, and detail of TRE, behavioural economic interventions, and comparator. The patient will be asked to sign the informed consent if they are willing to participate in the study.

At 1 week after enrolment (second visit), participants will be interviewed by research assistants about demographic data, underlying diseases, health risk behaviours, 24-hour food recall, sleep factors, physical activity level, and time and risk preference questionnaire. Physical examination including blood pressure, body weight and height will be measured by trained research assistants. Laboratory measurements (ie, FPG, HbA1c, serum triglyceride, total cholesterol, LDL-C, HDL-C, fasting insulin and hs-CRP) will be performed after fasting at least 8 hours or longer. After that, participants will be randomly assigned to any of three groups as TRE plus behavioural economic intervention, TRE alone or usual care.

Physical activity level, sleep factors, 24-hour food recall, body weight, SBP, DBP and laboratory measurements will be obtained at third visit (4th week after randomisation), fourth visit (8th week after randomisation) and fifth visit (12th week after randomisation or the end of the study). The 24-hour food recall will be collected using a food diary for 7 days at each visit. INMUCAL-nutrients V.4.0 (https://inmu2.mahidol.ac.th/inmucal/index.php) will be used to calculate the dietary data to nutrient intake. This program was developed by the Institute of Nutrition, Mahidol University, Thailand.

Data management

All data will be collected and filled in paper-based case record forms (CRFs). All CRFs will be checked by investigators (US and TA) for completeness and correction before data entry. Hard-copy CRFs will be independently computerised by two research assistants using Epidata V.3.1 software. Data will be cleaned and checked every month by investigators (US and TA). Any unclear or missing information will be cross-checked against the source documents of CRFs and medical records if required. Hospital numbers will be encrypted and kept confidential; a unique identification (ID) number will be assigned instead to each patient. All data will be backed up using Google Drive to prevent data loss.

Data monitoring

A formal data and safety monitoring board is not required because of no expected major adverse event from the study's interventions. If adverse events occur, these will be managed by the trial committee, including all authors of this protocol. Recruitment and retention rates, and any protocol violations will be monitored by the trial committee via regular meeting every month.

Sample size calculation

Sample size is calculated based on a superiority trial using one way analysis of variance method in STATA V.17.0. Baseline mean and SD of FPG in patients of pre-diabetes cohort conducted in the OFM were 105 and 9 mg/dL. We expected that receiving TRE plus behavioural economic interventions and TRE alone should be able to decrease FPG around 7% and 5% relative to the control, that is, the FPGs were about 98 and 100 mg/dL, respectively. Type I error, power, and follow-up are set at 0.05, 0.8, and 20%; a total of 114 participants with 38 per group will be required to detect these differences.

Statistical analysis

Baseline characteristics and outcomes among three groups will be described using mean (SD) or median (range) where appropriate for continuous data, and frequency (percentage) for categorical data. Means of primary and secondary outcomes will be compared among three groups using a mixed-effect linear regression model by regress outcome on intervention and time considering patients as a random effect (ie, repeated measures at 4, 8 and 12 weeks) and the intervention arms (TRE with behavioural economic interventions and TRE alone vs usual care) as a fixed effect. Marginal means and differences between any pair of the three interventions

Table 1 Study assessment schedule

Activity	Time point				
	Screening visit	**Visit 1 (baseline)**	**Visit 2 (4 weeks)**	**Visit 3 (8 weeks)**	**Visit 4 (12 weeks)**
Enrolment					
Eligibility screen including assessment of age, FPG, BMI and HbA1c	√				
Informed consent		√			
Allocation		√			
Intervention					
TRE with behavioural economic intervention		√	√	√	√
TRE		√	√	√	√
Usual care		√	√	√	√
Assessment					
Demographic data		√			
Underlying diseases		√			
Health risk behaviour		√			
Family history of DM		√			
Physical activity		√	√	√	√
Sleep factors		√	√	√	√
24-hour food recall		√	√	√	√
Time and risk preference		√			√
Outcomes					
FPG		√	√	√	√
HbA1c		√	√	√	√
Body weight		√	√	√	√
Blood pressure		√	√	√	√
Fasting insulin		√	√	√	√
Serum triglyceride		√	√	√	√
Serum cholesterol		√	√	√	√
LDL-cholesterol		√	√	√	√
HDL-cholesterol		√	√	√	√
hs-CRP		√	√	√	√

BMI, body mass index; DM, diabetes mellitus; FPG, fasting plasma glucose; HbA1c, haemoglobin A1c; HDL, high-density lipoprotein; hs-CRP, high-sensitivity C reactive protein; LDL, low-density lipoprotein.

will then be estimated accordingly. Sensitivity analysis will be performed to check the robustness of the primary analyses. Independent t-test will be applied to compare means of primary and secondary outcomes at the end of the study between TRE plus behavioural economic interventions and usual care groups and to compare mean of primary and secondary outcomes between TRE and usual care groups. Last observation carried forward will be applied to impute the missing outcome data for patients who are loss to follow-up.

Protocol violation will be dealt with using an intention-to-treat analysis (ITT) and per-protocol analysis (PPA). For the PPA, patients in the TRE plus behavioural economic interventions and TRE alone who do not comply with TRE (ie, comply <5 days per week) throughout the study or patients in the usual care group who take TRE 5 days of more per week will be excluded from the analysis. Multivariate regression analysis will be applied, if there is a difference in baseline characteristics between three groups.

All analyses will be performed using STATA V.17.0. P value less than 0.05 of two-sided test will be considered as statistical significance.

Patient and public involvement

None.

Ethics and dissemination

The study protocol is approved by the Ethics Committee of Ramathibodi Hospital, Mahidol University, (MURA 2021/389) and will be conducted in agreement with the Helsinki Declaration. All participants will sign informed consent at the baseline of the study (online supplemental appendix). Protocol amendments will be reported to the institutional ethics committee. ID numbers will be used instead of hospital numbers to maintain the confidentiality of the study's participants. All data will be stored in a database with password protection and can be accessed only by authorised staff.

Results of this study will be presented at national or international conferences and will be published in a peer-reviewed journal. We plan to disseminate the results to participants, endocrinologists and primary care physicians.

DISCUSSION

Patients with IFG have a significant increased risk of DM. Diet interventions that focused mainly on caloric restriction have been proven to decrease DM risk in this population. TRE is one type of diet intervention that has positive effects on many metabolic signal pathways from animal studies but evidence in human is limited especially in patients with IFG. Therefore, this RCT is the first study that evaluates the effect of TRE on blood sugar levels and other cardiometabolic risk factors in patients with IFG. In addition, this is the first study that assesses the impact of behavioural economic interventions such as financial incentive and text reminder on adherence to TRE intervention.

Our study design has some critical issues. First, our interventions cannot be blinded; hence, the results may be affected by observer and information bias. However, most of our outcomes are laboratory values that are objectively measured and are blinded from the outcome assessors, thus measurement error or ascertainment bias should be reduced. Second, although our study has longer-term follow-up than previous studies, 3-month assessment is still considered as a short-term follow-up. Therefore, only surrogate outcomes as FPG, HbA1c, body weight and other laboratory tests will be assessed; either a long-term effect of TRE on cardiometabolic risk factors or permanent change of the participant's behaviour cannot be evaluated. Third, adherence to TRE will be measured through a self-reported log book which can be upwardly biased. However, concerning study outcomes, we consider only biological measures which will be objectively measured, for example, FPG, HbA1c, body weight, etc. Fourth, there may be contamination of TRE in patients randomised to usual care group because TRE has been promoted in some social media platforms in Thailand. Therefore, patients in the usual care group can adopt TRE by themselves. In contrast, patients randomised to the TRE group may not comply to the TRE protocol due to intolerance to the long fasting period and will drop out from the study. These drawbacks may dilute the effect of TRE in our study. However, we hope that the contamination should be minimised because we will carefully assess patients who may have already performed TRE before the beginning of this study; but once it occurs, this protocol violation will be dealt with ITT/PPA.

In conclusion, we will conduct an RCT to evaluate the efficacy of TRE plus behavioural economic interventions, TRE alone, and usual care in improving FPG, HbA1c, and other cardiometabolic risk factors in patients with IFG. The findings from this study will be applied for the recommendation of lifestyle modification used for diabetes prevention in patients with IFG. Findings about the efficacy of behavioural economic intervention will inform policymakers about the novel method to help people change and maintain their healthy behaviour.

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Contributors US and TA are the principal investigators. US, TA, SB, SP, AC, SR and AT designed the study. US and TA drafted the manuscript. US, TA, SB, SP, AC, SR and AT critically revised the study protocol and the manuscript. The entire project will be supervised by TA, SR and AT.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

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