Diabetes, Obesity and Metabolism

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LETTER TO THE EDITOR

Feasibility and Preliminary Effects of a 5-Day Fasting-Mimicking Diet in Asian Americans With Prediabetes: A Pilot Study

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1 | Introduction

Asian Americans have disproportionately high rates of prediabetes (37.0%) and type 2 diabetes mellitus (T2DM) (19.1%) compared to non-Hispanic white individuals [1, 2], despite having lower body mass index (BMI) [2, 3]. Hyperglycaemia in Asian individuals is more commonly driven by beta cell dysfunction, characterised by impaired insulin secretion, rather than insulin resistance [4]. This hyperglycaemia can trigger further beta cell dysfunction and insulin resistance, leading to T2DM [5].

Recommendations for reversing prediabetes typically centre around losing weight and exercising more, which is helpful for addressing obesity and insulin sensitivity but less so for insulin deficiency caused by beta cell dysfunction [6]. A 5-day fasting-mimicking diet (FMD) once a month for several months has been shown to improve metabolic health in T2DM patients [7] and promote the generation of stable beta cells and reverse insulin deficiency in mice [8]. However, prior FMD trials were conducted in largely non-Hispanic white populations [9]. Given the differences in pathophysiology of prediabetes in Asian individuals, it is unknown whether FMD could reverse prediabetes in this subpopulation. We therefore conducted a pilot study to assess the feasibility and preliminary metabolic effects of FMD in Asian Americans with prediabetes, as a foundation for a future, longer-term randomised trial.

2 | Materials and Methods

2.1 | Study Design

This study was conducted as a pragmatic, intent-to-treat, single-armed pilot intervention study (NCT06518798). The University of California Irvine (UCI) Office of Research Institutional Review Board approved the protocol (UCI IRB #4223) before study recruitment began.

2.2 | Participant Recruitment and Intervention

Eligibility and exclusion criteria, and confirmation of eligibility are described in the Supporting Information: Methods. Briefly, participants were recruited primarily by emails sent to the UCI community, including faculty, staff and patients. Potential participants completed an online pre-screening eligibility survey. Eligible individuals were contacted by email or phone and completed an online informed consent form with a study coordinator over zoom.

Participants were asked to come to a UCI clinic in a fasting state (no food or drink other than water for ≥ 12 h) for a pre- and post-FMD study visit. At their baseline visit, each participant was given a 5-day FMD kit (L-Nutra Inc.) [7] and asked to eat only the kit's contents for 5 days (water ad libitum), then return to the

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clinic on Day 6. Support for study participants is described in the Supporting Information: Methods.

2.3 | Data Collection and Outcome Measures

A fuller description is provided in the Supporting Information: Methods. Briefly, demographic information was collected in the pre-screening survey. HbA1c levels were obtained from participants' most recent clinical lab report. Blood samples to assess fasting blood glucose and ketone levels were obtained by finger-prick. Dietary non-compliance (i.e., consumption of non-FMD kit food items or beverages) and adverse events [10] were logged by participants and reported at their follow-up appointment. Participants also completed a feedback survey.

Feasibility was assessed by three measures: study enrolment, study adherence and protocol compliance rates. Study acceptability, likelihood of future trial engagement and changes in fasting glucose, ketone and body composition measures were also assessed.

2.4 | Statistical Analysis

Participant characteristics and study outcomes were analysed using descriptive statistics (Supporting Information: Methods). Pre- vs. post- FMD measurements were compared overall and stratified by BMI category using the Asian-specific cut-offs of < 23 for normal weight and ≥ 23 for overweight/obese [3].

3 | Results

3.1 | Study Recruitment Workflow, Feasibility and Baseline Characteristics

Over 7 months, 117 individuals completed the pre-screening survey and were contacted (Figure 1A). Thirty-four individuals completed the online consent form via Zoom (29% enrolment rate). Of these, 29 completed all 5 days of the FMD and returned for their post-FMD visit (85.3% adherence rate). Most adherent participants were female. The mean age was 51.5 ± 6.6 years. Most were overweight or obese (BMI ≥ 23). Additional baseline characteristics of the cohort are in Table S1.

Among the 29 participants who adhered to the 5-day protocol, eight drank beverages and four consumed foods outside the kit. Since the beverages had no appreciable nutritional value (e.g., black coffee/tea), they did not affect protocol compliance status. Of the four participants who consumed food outside of the kit,

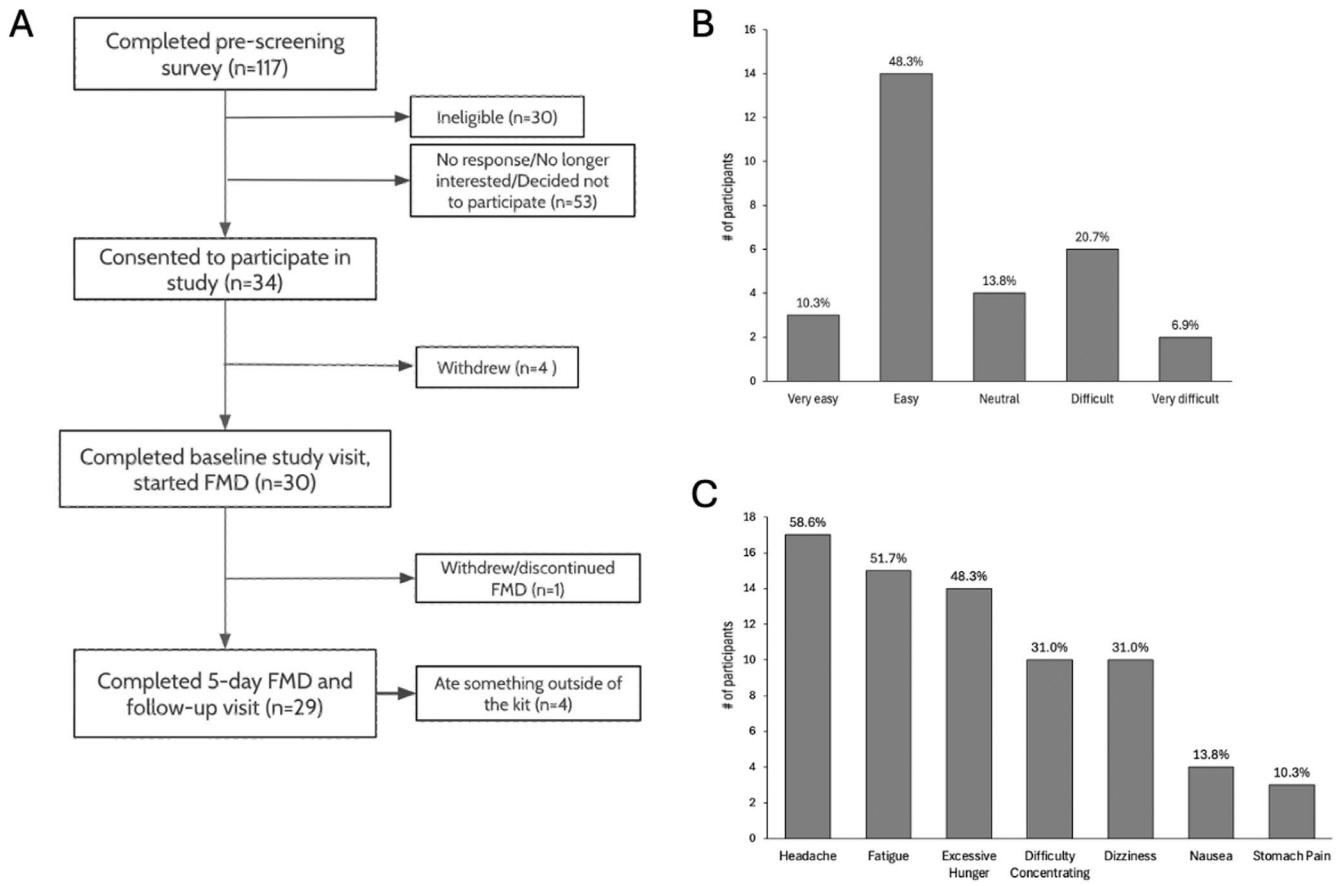


FIGURE 1 | Feasibility and acceptability of a 5-day FMD study in Asian Americans with prediabetes. (A) Participant enrolment, adherence and compliance workflow. Reasons for ineligibility included having other medical conditions, could not provide a lab result confirming their prediabetes status, contraindicated medication use and food allergies. Reasons for no longer being interested included scheduling conflicts, long commute to in-person study appointments and concern about potential muscle loss. (B) Reported ease of compliance to the 5-day FMD; (C) Reported negative symptoms and adverse events.

TABLE 1 | Pre- versus post-FMD measures of metabolic health in overall cohort.

	Pre-FMD	Post-FMD	Overall cohort ($n = 29$)		% who changed (direction)
	Measures, mean ± SD (95% CI)		Difference	p	
Fasting blood glucose (mg/dL)	107.1 ± 13.3 (102.0, 112.2)	89.1 ± 11.8 (84.6, 93.5)	−18.0 ± 17.5 (−24.7, −11.3)	< 0.001	96.6[a] (↓)
Body weight (kg)	71.4 ± 15.6 (65.5, 77.4)	68.8 ± 15.0 (63.2, 74.5)	−2.6 ± 1.1 (−3.1, −2.2)	< 0.001	100 (↓)
Body mass index (kg/m^2)	26.7 ± 6.0 (24.4, 28.9)	25.7 ± 5.7 (23.5, 27.8)	−1.0 ± 0.5 (−1.2, −0.8)	< 0.001	100 (↓)
Waist circumference (cm)	90.0 ± 12.8 (85.1, 94.8)	87.4 ± 12.9 (82.5, 92.3)	−2.6 ± 3.2 (−3.8, −1.3)	< 0.001	86.2 (↓)
Hip circumference (cm)	99.1 ± 11.2 (94.9, 103.4)	97.7 ± 12.0 (93.2, 102.3)	−1.4 ± 3.3 (−2.6, −0.1)	0.03	65.5 (↓)
Waist: hip ratio	0.9 ± 0.1 (0.9, 0.9)	0.9 ± 0.1 (0.9, 0.9)	−0.01 ± 0.04 (−0.03, 0.01)	0.16	65.5 (↓)
Total fat mass (kg)	24.1 ± 12.1 (19.5, 28.7)	22.8 ± 11.9 (18.3, 27.4)	−1.3 ± 1.2 (−1.8, −0.8)	< 0.001	86.2 (↓)
Percent body fat (%)	32.6 ± 10.5 (28.6, 36.6)	32.0 ± 11.0 (27.8, 36.2)	−0.6 ± 1.3 (−1.1, −0.1)	0.03	65.5 (↓)
Visceral fat area (cm^2)	116.3 ± 62.7 (92.0, 140.6)	109.4 ± 65.8 (83.4, 135.4)	−4.1 ± 6.5 (−6.6, −1.5)	0.004	40.7 (↓)
Skeletal muscle mass (kg)	26.0 ± 5.5 (23.9, 28.2)	25.3 ± 5.6 (23.2, 27.5)	−0.7 ± 0.5 (−0.9, −0.5)	< 0.001	89.7 (↓)
Percent skeletal muscle mass (%)	37.0 ± 6.3 (34.6, 39.4)	37.4 ± 6.6 (34.9, 39.9)	0.4 ± 0.9 (0.04, 0.7)	0.05	69 (↑)
Basal metabolic rate (kcal)	1389.1 ± 196.8 (1312.8, 1465.5)	1347.2 ± 185.8 (1273.7, 1420.7)	−28.9 ± 15.8 (−35.2, −22.7)	< 0.001	96.3 (↓)
Blood ketone (mmol/L)	0.1 ± 0.1 (0.1, 0.2)	1.6 ± 1.6 (1.0, 2.2)	1.5 ± 1.6 (0.8, 2.1)	< 0.001	100[b] (↑)
Systolic blood pressure (mm Hg)	122.1 ± 15.1 (116.4, 127.9)	115.4 ± 11.9 (110.8, 119.9)	−6.7 ± 14.2 (−12.1, −1.3)	0.02	69 (↓)
Diastolic blood pressure (mm Hg)	79.5 ± 10.4 (75.5, 83.4)	76.7 ± 10.4 (72.7, 80.6)	−2.8 ± 8.7 (−6.1, 0.5)	0.07	62.1 (↓)

[a]The one participant whose fasting blood glucose level did not decrease reported that she ate a candy on Day 5.
[b]Baseline ketone levels for two participants were not available due to technical difficulties at the beginning of the study; these participants were not included in the ketone level analysis.

two consumed < 50 cal total throughout all 5 days, but all four participants were considered not compliant. Thus, 25 of 29 participants (86.2%) were considered compliant to the 5-day FMD protocol.

3.2 | FMD Protocol Acceptance, Negative Symptoms and Likelihood of Participating in Future FMD Studies

Most participants (58.6%) reported that compliance was 'easy' ($n = 14$) or 'very easy' ($n = 3$) (Figure 1B). While 25 participants (86.2%) reported at least one negative symptom, none were above a Grade 3 adverse event [10]. The most frequently reported negative symptoms were headache ($n = 17$), fatigue ($n = 15$) and excessive hunger ($n = 14$) (Figure 1C). Most participants reported they would be 'likely' or 'very likely' to participate in a future trial involving monthly FMD for 4 months (Figure S1).

3.3 | Pre- Versus Post- FMD Physical Measures

There were significant decreases in most physical measures post-FMD compared to baseline ($p < 0.05$, Wilcoxon signed-rank test). Blood ketone levels were significantly higher ($p < 0.001$). In the BMI-stratified analysis, there were no significant differences observed between the BMI groups except for ketone levels, which increased more in the BMI < 23 group post-FMD ($p < 0.05$) (Table S2).

Twenty-eight of 29 adherent participants (96.6%) exhibited a decrease in fasting blood glucose levels, with 23 participants

achieving a level <100 mg/dL compared to six participants before the intervention. All participants showed an increase in ketone levels, with post-FMD levels ranging from 0.4 to 6.5 mmol/L (Table 1). Pre- versus post- FMD physical measurements assessed using the InBody scanner, overall and stratified by BMI group, are displayed in Tables S3 and S4.

4 | Discussion

This pilot establishes the feasibility of conducting a 5-day FMD clinical trial in Asian Americans with prediabetes. Despite feedback from the four non-compliant participants regarding palatability, the FMD may still be a feasible dietary intervention among Asian individuals as it does not require consistent dietary changes. The observed decreases in fasting blood glucose and increases in ketone levels objectively support the high reported protocol compliance rate.

Our observations that one cycle of FMD resulted in significant improvements in common markers of metabolic health are consistent with previous FMD studies [7, 11]. Our observation that FMD resulted in decreased visceral fat area may be particularly significant for Asian American individuals since higher levels of visceral fat have been found to decrease the first and second phase of insulin secretion [12]. While total muscle mass decreased, % muscle mass marginally increased due to a concurrent and more substantial decrease in fat mass and % fat.

In conclusion, our study demonstrated for the first time the feasibility, recruitment, adherence and acceptability of an FMD intervention in Asian Americans with prediabetes, with one cycle producing significant improvements in fasting blood glucose, visceral fat and other metabolic markers. Future trials should enrol larger, more diverse cohorts to enable disaggregation by Asian subgroup, evaluate multiple FMD cycles and incorporate beta cell function assessment to better characterise mechanisms, supporting the long-term study of FMD's efficacy in reversing prediabetes in this high-risk population.

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Conflicts of Interest

Valter D. Longo has equity interest in L-Nutra Inc., the company that makes the FMD kits used in this study. Valter D. Longo does not receive consulting or patent royalty payments from L-Nutra, which have been or will be donated to the Create Cures Foundation or other non-profit organisations. The other authors declare no conflicts of interest.

Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Peer Review

The peer review history for this article is available at https://www.webofscience.com/api/gateway/wos/peer-review/10.1111/dom.71168.

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Supporting Information

Additional supporting information can be found online in the Supporting Information section. **Table S1:** Demographics and baseline characteristics of study cohort. **Figure S1:** Likelihood of participating in a future randomised controlled study. Participants were asked to report their likelihood of (A) participating in a future, longer-term randomised controlled trial that includes four consecutive monthly cycles of FMD; and (B) participating in a future FMD trial involving four in-person study visits over the course of a year (compensation would be provided for each visit). **Table S2:** Pre- and post-FMD measures of metabolic health stratified by BMI category. **Table S3:** Pre- versus post-FMD additional measurements of metabolic health in overall cohort. **Table S4:** Pre- versus post-FMD additional measurements of metabolic health stratified by BMI category.