

Effect of a two-only-meals-a-day and exercise lifestyle on HbA1c and anti-diabetic medication in a follow-up study of subjects with type 2 diabetes attending a free clinic in a north Maharashtra city

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ABSTRACT

Background: Type 2 Diabetes (T2D) is a global challenge with rising prevalence, inadequate compliance, and poor outcomes. **Aims:** Assess the effect of a 2-only-daily-meals with exercise lifestyle (2-OMEX) on (a) HbA1c, (b) anti-diabetic medication count (ADMC), (c) Kcal intakes, body weight, fasting insulin, and subjective well-being. **Materials and Methods:** This is a single-arm follow-up study conducted in a free 2-OMEX clinic in 2019–2020. Information for two meals and exercise compliance was obtained during the clinic visit. HbA1c was tested by HPLC and fasting insulin by the CLIA/CMIA method in private laboratories. **Results:** Eligible subjects (f = 49, m = 116) completing two or more visits and 60 days of follow-up had a mean age of 55.92 (10.43) years, a T2D duration of 8.20 (6.28) years, and a median observation period of 140 days. Statistically significant changes included HbA1c decline from 7.69 (1.70) to 7.00 (1.20) gm% (equivalent by the LogNormal method to 1.088 gm%), average weight loss at 5%(m), and 2%(f). ADCM declined from 2.32 to 2.14, the difference being significant with the WSR test (z = 2.0087, P = 0.0223). Subjects attaining anti-diabetic medication-free and normoglycemic status (HbA1c < 6.5 gm%) were 20 (12%). The number attaining HbA1c ≤ 7 gm% significantly rose from 73 (44%) to 101 (61%) with an ADCM of 1.9 (chi-square = 9.531, df1, P = 0.0020203). Participants reported 'feeling energetic' (79%), feeling lighter (50%), and better sleep (35%). Average energy intakes dropped by 120 Kcal to 1580/day. Fasting insulin remained unchanged, from 12.61 (11.06) to 12.34 (11.78) mlU/L. The dropout rate was 35%. **Conclusions:** The 2-OMEX lifestyle showed a sizeable, favorable, and significant change in HbA1c, body weight, ADCM use in five months, and subjective benefits. Studies are necessary for remission impact and pathways.

Keywords: Anti-diabetic medication, BMI < 2-OMEX, HbA1c, meal frequency, type 2 diabetes, weight loss

Introduction

The rising tide of type 2 diabetes (T2D) is a global challenge, with an estimated prevalence of 6.28%.^[1] Further, the poor outcomes of the prevailing T2D management pose serious challenges.^[2,3] India, with prevalence rates of T2D at 7.3% and

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10.3% pre-diabetes, also has a 47% undiagnosed caseload.^[4] High estimates of the Indian diabetes risk score (IDRS) forecast an impending T2D rise.^[5,6] Thus, prevention and rolling back T2D are essential besides better therapeutic management. Indian experts have argued for novel therapeutic agents to meet the challenge, besides lifestyle change.^[7] The remission of T2D through Caloric restriction is a new frontier.^[8,9] Vegan diets are believed to be protective against T2D.^[10] Bariatric surgery and a low or very low carbohydrate diet (VLCD) are the suggested ways for T2D remission.^[10,11] Intermittent fasting is another possible pathway to remission or as an adjuvant to medication.^[12,13] An ongoing popular campaign in western India for weight loss advocated daily meal frequency to just two, with moderate physical exercise (2-OMEX), popularly known as the *Dixit* lifestyle. Many T2D subjects in this campaign self-experimented with the 2-only-daily-meals with exercise lifestyle (2-OMEX) way for T2D mitigation, and many reported a lowering of HbA1c with case reports showing remission of diabetes and pre-diabetes.^[14,15] The 2-OMEX campaign offered patients free services at the weekly 'diabetes reversal centers' (DRC). This study aims to estimate changes in (a) Glycemic control with the HbA1c parameter; (b) Fasting insulin levels, Kcal intakes, body weight, and BMI; (c) anti-diabetic medication count (ADMC); and (d) subjective benefits of well-being.

Materials and Methods

Study design, settings, and subjects

This is a single-arm, quasi-experimental follow-up study of voluntary participants attending a free lifestyle change clinic in Nashik (India) with the voluntary help of five physicians. Written informed consent was obtained from all participants. The clinic was operational from December 2018 until the COVID disruption in February 2020. Patients were expected to visit once a month initially for the first three months, and thereafter once every three months.

Inclusion and exclusion criteria

T2D was defined as HbA1c ≥ 6.5 gm% and/or current use of anti-diabetic medication (ADM). Subjects following the 2-OMEX lifestyle for at least one week before enrollment were included and duly counseled. Exclusion criteria included renal impairment, hemoglobin disorders, and impending surgery. Participants with either pre-diabetes or normoglycemia (HbA1 < 6.5 gm%) and no ADM at the first visit (V1) were excluded. Subjects with poor compliance (defined as ≥ 2 weeks missing from the 2-OMEX regime in the past month) as judged by a DRC physician were subsequently deleted from the analysis.

Lifestyle change

The lifestyle change (2-OMEX) prescribed only two meals daily and no energy drinks or snacks in between. A daily walking/aerobic workout for a minimum of 45 minutes was advised; however, at the time of assessment, six days a week was treated as satisfactory compliance. The DRC participants kept a daily

diary to note meals and exercise. DRC volunteers supported the participants on cell phones and in clinics regarding adherence to 2-OMEX, HbA1c tests, and regular clinic attendance. Medication was managed by the respective physicians. Trained primary care assistants, maintained case records, and noted the good and bad effects of 2-OMEX at the second visit.

Independent variables

Adherence to the 2-OMEX lifestyle was assessed at the DRC by the attending physician as fair or poor based on last month's verbal information. Age, duration of diabetes in years, parental history of T2D, and socio-demographic factors were recorded. Height was measured barefoot with a stadiometer (model MCP-number 265M, 200 cm) and weight with usual clothes using a calibrated digital weight machine (model WI/05/2016/014/EI). For energy intake, the usual daily count of chapatis (pancakes) and rice bowls was noted. The dry weight of chapati measured on a kitchen scale (Venezia, SF 400-A) gave an average of 38 grams. The consumption of Bhakari (millet pancake) was scant, and its average dry weight was 83.7 gm. One wati (bowl) of cooked rice was found to be equivalent to 35 gm of raw milled rice. We used values of 3.5 Kcal/gm of whole wheat flour (after adjusting for 10% wheat flour moisture while drying) and for cooked rice (one bowl = 35 gm dry rice) as per the ICMR manual.^[16] Based on a recent ICMR survey, cereals and millets make up 45.6% of all energy intakes in urban western India.^[17] Hence, multiplying the cereal-energy intake by 2.2 yields the total Kcal intake.

Outcome variables

HbA1c is a three-month measure of glycemic status that is not affected by the day's meals.^[18,19] We used HbA1c in gm% units from NABL-accredited laboratories with the HPLC technique. Participants bore the test costs and chose their laboratories. Test reports obtained within the last 7 days were used. A fasting insulin test with CLIA/CMAI was taken by the participants.

Weight and ADM count (ADMC) are outcome variables and also effect modifiers for HbA1c. ADMC was deciphered after analyzing the prescriptions with the Tata 1 mg app for trade names. Any change in dosage was not considered for the ADMC assessment. Good Glycemic Control (GGC) was defined as HbA1c ≤ 7.00 gm%, and normoglycemia was defined as HbA1c < 6.5 gm%.^[18,19]

Sample size

We used a sample size estimation table for paired differences from the Statstodo website (<https://www.statstodo.com/SSizPairedDiff.php>). Effect size(es) = difference between means/within group SD. The SD of differences between HbA1c paired means was 1.2% from a previous study.^[20] The expected mean difference in HbA1c between before and after the experiment = 1 gm%, hence es = 0.833. For a two-tailed test assuming Power = $1 - \beta$ (0.8), and α = Probability of Type I Error 0.05, the estimated sample size is $n = 15$ pairs.

Sources of bias and efforts to overcome

For any missing data in records, participants were contacted by phone. The treatment of missing values from records was as follows: ADM was not mentioned in 17 out of 165 initial records, where we used ADMC from V1. HbA1c was missing in the V1 in three entries; here, we used recorded baseline values. The duration of T2D was missing in seven cases, and here we used an average of 6.5 years in five subjects with an age ≥ 50 years and 3.5 years in two subjects < 50 years. Parental T2D is difficult to ascertain; hence, non-mention of a history of parental T2D was treated as its absence ($n = 80$), along with those who clearly said none of their parents had T2D.

Case records and quality checks

A pre-tested physical case record sheet was used by volunteers and physicians. All forms were checked routinely and at the end by author number two.

Statistical methods

The continuous variables (age, duration of diabetes, follow-up time, HbA1c, and BMI) were tested for normality with an online KS test. Log transformation is advised for non-normal data.^[21] Hence, we used lognormal values for paired tests for V1 and LV for HbA1c and BMI. Wilcoxon's Rank sum test was used for ADMC changes. Trend analysis for HbA1c changes by visits was done with Excel. We used Excel for data management and paired t-tests. Epi-Info was used for other analyses.

Ethical approval

Ethical approval was initially obtained for a multicenter-two arm study, and we have obtained its extension for this study (SMBT/IEC/19/038 dated January 16th, 2019). All participants were advised to inform their usual physician about the change to the 2-meal lifestyle.

Results

Study subjects and visits

We analyzed 165 (29%) out of 567 listed subjects attending DRC, against the required sample size of 15. Table 1 shows the socio-demographic and risk profiles of the study subjects. The following cases were dropped from the list of 567: no second visit ($n = 188$), prediabetes ($n = 22$), subjects with HbA1c < 6.5 gm% and ADM-free at the V1 ($n = 24$), allocation to another ongoing comparative study ($n = 70$), and 98 with < 60 days' follow-up. The dropouts ($n = 188$) had an average weight of 70.70 kg and an HbA1c of 7.6 gm%, mostly similar to the study subjects. The participants making successive visits and median days of observation were as follows: visit 2 ($n = 165$, days 28), visit 3 ($n = 147$, 89.09%, days 63), visit 4 ($n = 86$, 52.44%, days 139), and visit 5 ($n = 49$, 29.70%, days 203). Visit 6 ($n = 9$, 5.8%) and visit 7 ($n = 5$, 3.11%) were rare.

Meals frequency and total Kcal intakes

The average meal frequency before the adoption of 2-OMEX was 5.7/day. Food intakes, pooled for men and women, declined

Table 1: Sociodemographic profile and risk factor information of subjects

Variables	Value	Value	Remark
Age in years Mean (sd) women ($n=49$)	54.38 (10.52)		$P=0.278$
Age in Years (M) ($n=116$)	56.56 (10.37)		
Education	College 133 (74.26%)	Up to school 31 (23.22%)	
Social category ('Others' include disadvantaged categories)	General 80 (48.48%)	Others 85 (50.52%)	
Diet type	Mixed 88 (53.33%)	Vegetarian 77 (46.67%)	
Economic Category by Ration Card type ($n=124$) 41 not mentioned	Upper class (white card) 60 (36.36%)	Lower class (other cards) 64 (38.80%)	
Parental Diabetes either or both parents) ($n=165$)	Yes, 50 (30.31%)	No, 115 (69.69%)	
Mean (sd) years of T2D duration	8.20 (6.80)		
Mean (sd) days Duration from starting 2-OMEX lifestyle to first visit at DRC	84.3 (101.5)		Median 45 days
Duration in days from Visit 1-Vlast, Mean (sd)	166.33 (102.40)		Median 140 days
Pre-2-OMEX daily meal frequency, ($n=165$)	Mean 5.71 (1.79)		Median 6, mode 5
Total Kcal intakes before and after the adoption of 2-OMEX (pooled for gender)	Before 2-OMEX 1701.5 (652.19), median 1463	After 2-OMEX, 1580.54 (613.78), median 1401	Diff=120.5 Kcal, $P(\alpha) \leq 0.0001$ (2- tail)
Total Calories intake, Mean (sd) before and 2-OMEX adoption for women ($n=49$)	Before 1500.55 (549.78)	After 1373.71 (571.31)	
Total Calories intake, Mean (sd) before and 2-OMEX adoption for men ($n=116$)	Before 1785.86 (675.46)	After 1667.98 (634.18)	
Weekly aerobic minutes ascertained at first visit Mean (sd) ($n=165$)	320.09 (141.72)		
Patients with one or more current reported comorbidities ^s out of ($n=165$)	One or more comorbidities 34 (20.61%)	No comorbidities 131 (79.39%)	Hypertension, cardiovascular disease, stroke, hypothyroidism, depression.
Last/Baseline HbA1c gms% in pre-visit period, Mean (sd) ($n=56$)	7.86 (1.70)		

by 120.5 Kcal. The results of the paired t-test are as follows: mean difference = 120.54 Kcal, SD = 219.52, SE = 17.1417, $t = 7.0323$, $P(\alpha) \leq 0.0001$ (2 tail), 95% CI (2 tail) = 86.699 to 154.3925.

Figure 1 shows the trend in HbA1c over follow-up. A polynomial trend line could be fitted to explain the trend. To determine the change in HbA1c prior to V1, available records ($n = 56$) brought by participants were analyzed. For HbA1c at V1 and LV, a paired t-test was used. From this, the difference in logNormal values was 0.022545, and the antilog is 1.088 gm% HbA1c. (LogN V1 0.929419, LV 0.906874), $t_{Stat} = 3.65$, $P(T \leq t)$ two-tailed = 0.0005.

Table 2 shows V1 to LV changes in HbA1c values, ADMC, weight, and BMI. Participants with GGC (HbA1c ≤ 7 gm%) were 40% (22 out of 55 cases) from available pre-DRC records. Subjects with GGC at V1 were 72 (43.6%) with an HbA1c average of 6.42 gm% and an ADMC of 2.02. This number rose to 100 (60.6%) by the LV, and with an HbA1c average of 6.32 gm% and a lower ADMC (1.65), the difference was highly significant (chi-square = 9.531, df_1 , $P = 0.0020203$). At the LV, 20 participants (12.12%) were both Normoglycemic and ADMC-free.

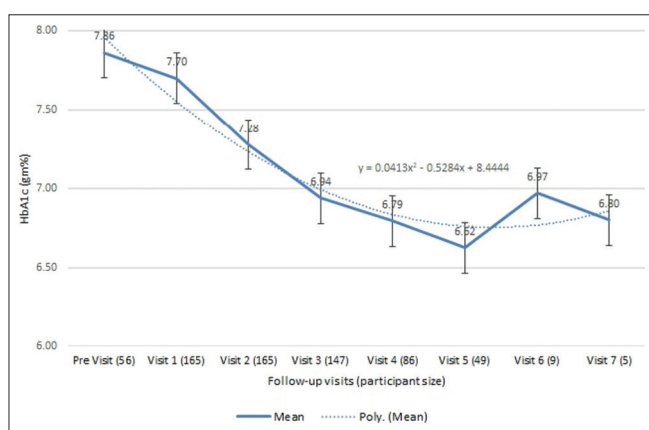


Figure 1: HbA1c trend during follow-up visits

The participant-reported benefits of 2-OMEX were better sleep (35%), clothes becoming lax due to weight loss (50%), and feeling energetic (79%). Two participants reported weight gain and ‘feeling hypoglycemic.’

Effect of age on HbA1c changes

Figure 2 shows the change in HbA1c from V1 to LV by age. The between-age-group differences are not significant (P for V1HbA1c = 0.1887, VLHbA1c $P = 0.5882$). However, paired differences in HbA1c within the same age group were significant: for 25–45 years, $P(T \leq t)$ two-tail 0.009; for 46–60 years, $P(T \leq t)$ two-tail 6.49181E-06; for >60 years, $P(T \leq t)$ two-tail 0.0019.

Discussion

Briefly, this study demonstrated that in a five-month period, 2-OMEX adopters had favorable and statistically significant changes in HbA1c, ADM use, GGC, body weight, and BMI. A trend of declining HbA1c is evident throughout follow-up. These changes are presumably linked to a two-meal frequency and exercise. Kcal intake declined in both sexes by an average of 120 Kcal, reaching a modest average intake of 1580 Kcal. By the LV, 12% of the participants had attained normoglycemia (≤ 7 gm%) and ADM-free status. The reported benefits of well-being (feeling energetic, laxity of clothes (implying weight loss), and improvement in sleep) should sustain compliance. These favorable results are seen despite the not-so-young mean age of 56 years, T2D duration of 8.2 years, and only a small BMI reduction of 1.04 kg/m² from 26.89 kg/m² at V1. Of the participants, 14 (8.5%) were on insulin at V1, hence this was not a biased sample. All these benefits have a clear edge over the stated outcomes of conventional or comprehensive management of T2D in good healthcare settings or Indian settings.^[2,3,20] Overall, the favorable changes in the 2-OMEX followers without drastic cuts in intakes indicate the feasibility of this lifestyle, with a caution raised by the 35% dropout rate. The 2-OMEX approach has demonstrated favorable results in

Table 2: Information on weight, medication, and HbA1c status in the first and last visits

Variables	First visit	Last visit	Remark
Weight (F) kg $n=49$	68.29 (11.88)	66.86 (11.88)	Paired t -test, $P=0.05945$
Weight (M) kg $n=116$	72.37 (10.79%)	68.78 (9.79)	Paired t -test, $P=0.0000$
BMI kg/m ² $n=165$	26.89 (4.40)	25.81 (4.27)	BMI difference by log is equivalent to 1.04 kg/m ² , tested with a paired t -test $P(T \leq t)$ two-tail 3.53443E-06
HbA1c gm% HPLC method $n=165$	7.69 (1.70)	7.00 (1.20)	Difference tested by paired t test by antilog 1.088 gm%, $Df=164$, $t_{Stat} 6.373431657$ $P(T \leq t)$ one-tail 8.98002E-10 t Critical one-tail 1.654197929 $P(T \leq t)$ two-tail 1.796E-09 t Critical two-tail 1.97453457
Fasting Insulin: Mean (sd) mIU/L	$n=133$ 12.61 (11.06)	$n=105$, 12.34 (11.78)	Pre-DRC $n=36$ 12.54 (7.57)
Good Glycemic Control (HbA1c ≤ 7 gm%)	72 (43.6%)	100 (60.6%).	Chi-square=9.531, df_1 , $P=0.0020203$
Median ADM count	2.32	2.14	WSR test shows that the difference between V1 ADMC and ADMC at the LV was significant, $z=2.02287$, $P=0.0223$. 14 subjects were on insulin at V1.
Subjects with ADMC=0	25 (15.15%)	37 (22.42%)	Difference NS, Chi-square test value=2.40 $df=1$, ($P=0.090$)
Subjects with normoglycemia and ADMC=0	0 (0.0%)	20 (12.12%)	

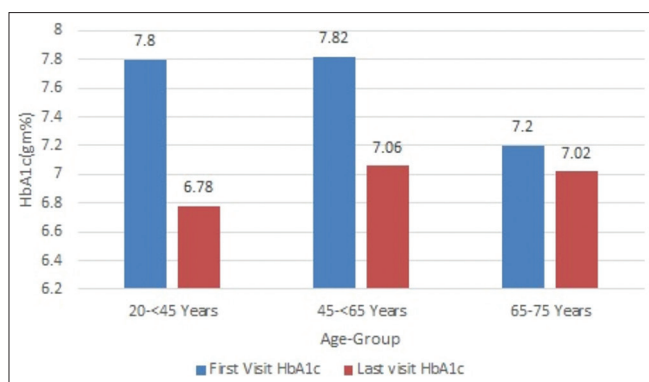


Figure 2: HbA1c Changes from the first to the last visit in age groups

case series, reports, and a recent quasi-experimental study.^[13,14,20] Attrition problems are common in both lifestyle approaches and conventional management.

The HbA1c and ADM change in the context of age

Most of the 20 participants who became ADM-free and normoglycemic were in the 45–65 age group, which is partly explained because this group has 63% representation in the study. Yet the steeper decline of HbA1c in the younger age group [Figure 2] is biologically more plausible because of less pancreatic dysfunction at lower ages. Thus, it is necessary to start lifestyle changes, 2-OMEX in this context, at younger ages, especially when corpulence indicators are adverse. This said, our study suggests that even 45–65 years subjects have experienced better control of T2D.

Plausible pathways for glycaemic changes with 2-OMEX lifestyle

How meal frequency affects glycaemic status is not well documented. Primarily, the 2-OMEX, in comparison to more meals, may cause fewer insulin spikes and less insulin quantum each day. Fasting insulin levels between V1 and LV remain nearly unchanged. Somewhat reduced weight (2% loss in women, 5% loss in men) should account partially for the observed change in HbA1c in this study. The relationship between body weight and glycaemic status is well known.^[22]

Limitations of conventional management of T2D

The conventional clinical management of T2D, with frequent small meals, coupled with ADMs, has obvious limitations as regards outcomes.^[2,3,20]

A Scottish study reported that conventional management could not attain GGC in 53% of subjects even after two years, and the average weight loss in 35% of subjects was only 2.5%.^[23] The NHANES study found that only 58% of subjects could achieve GGC even in good healthcare settings.^[2] Thus, conventional therapeutic management in T2D has both internal limitations and compliance problems. Indian experts have appealed for novel therapeutic agents because of the limitations of lifestyle changes.^[7]

Remission initiatives for T2D

The DiREct study banks on diet restriction to 800–850 Kcal.^[24] Restriction of calorie intake has shown strong links with remission.^[24,25] However, VLCD regimes are difficult to practice. Additionally, the problem of undetected T2D prevalence at 47% is massive.^[4] Even when T2D is detected, poor compliance with treatment is another problem. IDRS studies show the impending burden of T2D in India.^[5,6]

Thus, clearly, we need newer ways for primary and secondary prevention (early detection and management) of T2D, and 2-OMEX suggests a potential approach. A study shows that the two-meal frequency reduces BMI.^[25] A randomized two-arm cross-over Czech study showed that the two-meal option was better than a six-meal-a-day pattern for management outcomes in T2D with the same energy intakes.^[20] A recent quasi-experimental Indian study showed a sizeable (0.94 gm%) and significant reduction in HbA1c and medication in the two-meal-arm, while the conventional management arm showed no decline. Thus, the 2-OMEX is a window of opportunity. Since exercise is common to both conventional management of T2D and 2-OMEX, The 2-meal approach (and fasting) have some religious and cultural roots in Asian communities. Ramadan studies indicate HbA1c reductions in fasting months.^[27] But the 2-OMEX campaign intends to emphasize meal-frequency restriction, as fasting can be less popular and sustainable as a lifestyle. Since many physicians are still advocating small, frequent meals for managing T2D, a two-meal pattern is a potential candidate for T2D management trials.

Limitations of the study

A quasi-experimental study design, the intervention variables based on recall, and the assessment of the outcome variable HbA1c from diverse laboratories somewhat limit the rigor of this study. A large initial and subsequent dropout shows the limitations and challenges involved. Further, the COVID pandemic curtailed our study to a median period of 140 days, and hence remission outcomes were not tested. The cost of HbA1c in India (about 500 Rs, or 7 USD) is another reason for dropouts. For a large popular movement without research funds, we had to accept the cost as a limiting factor. Another limitation is that we have been able to capture the pre-first visit HbA1c change of only 56 (30%) of study subjects, while tracking from day 1 of the lifestyle change would have been better.

Generalizability and implications

Despite the limitations stated, the 2-OMEX lifestyle change showed a notable reduction in HbA1c, ADM use, and body weight. By the last visit, 12% of participants had freedom from ADM and HbA1c below 6.5 gm%, which is unlikely in conventional management of T2D. We had a robust sample size of 165, against the requirement of 15. Meal frequency restrictions are culturally acceptable. Total Kcal intake was reduced only by 120 to a pooled mean level of 1580, which makes it sustainable.

Reported benefits included feeling energetic, feeling light, and getting better sleep, which helps acceptability and sustainability. The study also shows that many patients can accept 2-OMEX, but ADM needs to be readjusted to meal timing by physicians to avoid hypoglycemia. Finally, this is the study of a real-life campaign. We feel that 2-OMEX is a window of opportunity against the tide of diabetes for primary prevention as well as secondary prevention.

Summary

This quasi-experimental study suggests partial success of the 2-meal and exercise (2-OMEX) lifestyle in mitigating T2 diabetes, with a significant decline of 1.088 gm% (log-normal value) in HbA1c and anti-diabetic medication. The changes occurred at a small weight loss (Men by 5%, women by 2%), with BMI still above 25. Further, 12.12% of participants attained ADM-free status with normoglycemia. GGC improved to 61%, compared to the V1 level of 44%. Kcal intakes declined only by 120 Kcal after to 1580 Kcal. Many subjects reported improved sleep, feeling energetic, and weight loss. Hence, 2-OMEX appears to be a feasible, safe, culturally acceptable, and promising strategy for T2D rollback.

Recommendations

This study suggests a new paradigm for prevention, rollback, and management of T2D, with two-meal frequency as a major area for research, especially because it's culturally relevant for Asian communities and works at modest energy intakes, hence sustainable as a long-term lifestyle change.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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