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The impact of specialised meal replacements on weight loss, blood sugar control, and gene activity health in obese and overweight people with type 2 diabetes: a study

Submission date
06/09/2024

Recruitment status
Recruiting

Registration date
20/11/2024

Overall study status
Ongoing

Last Edited
18/12/2025

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Uncontrolled type 2 diabetes mellitus (T2DM) is linked to increased healthcare expenditures, which pose a potential global public health burden. In Malaysia, 15.6% of adults have been diagnosed with diabetes, while only 48% of them have their blood sugar under control. The increased risk of developing T2DM among overweight or obese people, coupled with the high co-occurrence of both, often represents a combined pathological condition called "diabesity," which is purported to be mediated by the chronic inflammatory response observed in obese individuals. To date, in Malaysia, 64% of those who have diabetes are obese or overweight. This can lead to an increase in the prevalence of T2DM because excess body weight and obesity are significant risk factors for the disease.
A balanced and well-structured diet plays a critical role in managing T2DM in order to achieve glycaemic and weight control. Meal replacement (MR) therapy has been recognized as one of the strategies to control weight and blood sugar levels among T2DM patients. MR is a term that refers to pre-packaged or commercially available food products or drinks used to replace one or more meals. Studies have found that partial or complete MR can be an effective extended strategy of medical nutrition therapy in T2DM management. However, there were inconsistencies in its impact. The aim of this study is to find out how well a diabetes-specific MR product works at helping overweight and obese T2DM patients lose weight, control their blood sugar, and change the way their genes work.

Who can participate?
Overweight and obese T2DM patients who are Malaysian and have a BMI of less than 25 kg/m2, between the ages of 30 and 59 years, male or female

What does the study involve?
Participants are randomly allocated to either the intervention group or the control group. All participants will receive dietary consultation, but only the intervention group will receive the MR product for 12 weeks. The researchers will assess dietary intake, physical activity, satiety level,

cost-effectiveness, quality of life, blood profile (sugar, lipid, renal, and liver), and metabolic gene expression at the start of the study and they will follow up at weeks 6 and 12 of the intervention. To assess compliance, they will ask the participants in the intervention group to bring their MR containers. Those who take less than 80% of the MR will be considered non-compliant.

What are the possible benefits and risks of participating?
The benefits of this study may not be direct. However, the study's MR has the potential to reduce the weight and blood sugar levels of the participants who received it. Besides, all of the participants will receive standard nutrition counselling that can help them gain more knowledge on T2DM management. Meanwhile, for the risk, the participants may or may not experience side effects. The side effects may include diarrhea and if it happens, participants should notify the researcher immediately of any side effects that they experienced by calling the phone number in the information sheet given and can come to the Klinik Primer and Poliklinik Warga for treatment.

Where is the study run from?
Klinik Primer and Poliklinik Warga, Hospital Canselor Tuanku Muhriz (HCTM), Universiti Kebangsaan Malaysia (UKM) (Malaysia)

When is the study starting and how long is it expected to run for?
March 2024 to September 2026

Who is funding the study?
Quantum Upstream Sdn Bhd

Who is the main contact?
Dr Munirah Ismail, munirahismail@ukm.edu.my

Contact information

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Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
NN-2023-019

Study information

Scientific Title
Efficacy of partial diabetes-specific meal replacement on weight reduction, glycaemic control and metabolic gene expression among overweight and obese type 2 diabetes mellitus: a randomized controlled trial

Study objectives
1. Partial diabetes-specific meal replacement can improve on weight reduction and glycaemic control (HbA1c, fasting blood glucose) among overweight and obese type 2 diabetes mellitus (T2DM) patients.
2. Partial diabetes-specific meal replacement can increase satiety levels among overweight and obese T2DM patients.
3. There is an effect of partial diabetes-specific meal replacement on metabolic-associated gene expression profile among overweight and obese T2DM patients.
4. Partial diabetes-specific meal replacement can improve quality of life among overweight and obese T2DM patients.
5. Partial diabetes-specific meal replacement is more cost-effective compared to standard of care among overweight and obese T2DM patients

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 24/10/2024, Medical Research Ethics Committee National University of Malaysia (Sekretariat Etika Penyelidikan Universiti Kebangsaan Malaysia, Tingkat 1, Blok Klinikal, Hospital Canselor Tuanku Muhriz, Pusat Perubatan UKM, Jalan Yaacob Latif, Bandar Tun Razak, Kuala Lumpur, 56000, Malaysia; +60 (0)3 9145 5046; sepukm@ukm.edu.my), ref: JEP-2024-695

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Weight loss and glycaemic control in overweight and obese type 2 diabetes mellitus patients

Interventions
This is a two-armed randomised controlled clinical trial (RCT). Participants will be selected using purposive sampling based on the inclusion and exclusion criteria. Data collection will be conducted at primary clinics, where patients will be screened through a digital medical records database for their eligibility to be potentially recruited into the study. In this randomized controlled trial there are two groups: the intervention group and the control group. The intervention group will be administered a meal replacement product with one session of dietary consultation, whereas the control group will only receive the same dietary consultation as the intervention group. The group allocation for participants will be conducted via block randomisation by gender and ethnicity, using an online randomizer software.

The oral nutrition supplementation used in the intervention group of this study is sponsored by Quantum Upstream Sdn Bhd. The product is known as Resurge DM and it provides complete nutrition specialized for diabetic patients which is low GI and contains 100 mg of chromium per serving.

Participants in the intervention group are asked to replace 1-2 meals with one serving of Resurge DM at each meal for 6 days per week for 12 weeks. Each serving (five scoops) of Resurge DM contains 53 g of milk powder and is diluted with 200 ml of room-temperature water. Additionally, participants are also provided with one serving of oats and chia seeds daily for the first 2 weeks of intervention in order to increase satiety during the transition period and increase adherence to the intervention.

All of the participants will receive one-to-one sessions of dietary consultation by a dietitian as well as other routine of medical care. During dietary consultation, participants will be prescribed with individualised calorie based on BMI. The counselling will follow a guideline from medical nutrition therapy for T2DM by the Malaysian Dietetic Association (MDA).

The researchers will follow up at weeks 6 and 12 of the intervention. They will only measure the participants' anthropometry, physical activity, and satiety levels in week 6. To assess their compliance, they will ask the participants in the intervention group to bring their MR containers. In week 12, they will measure the same parameter at the baseline level. Those who take less than 80% of the MR will be considered non-compliant. The researchers will compare and record the changes in body weight, body composition, physical activity, satiety level, cost-effectiveness, quality of life, blood profile, and metabolic gene expression profile.

Intervention Type
Supplement

Primary outcome(s)
1. Bodyweight and body composition will be measured by using the InBody 270 machine at baseline, weeks 6 and 12
2. Height will be measured using a SECA 217 stadiometer at baseline, weeks 6 and 12
3. Waist and hip circumference will be measured using SECA measuring tape at baseline, weeks 6 and 12
4. BMI will be calculated using a formula (weight in kilograms divided by height in meters squared) and the WHO cut-off point at baseline, weeks 6 and 12
5. Glycaemic control will be measured by HbA1c and fasting blood sugar at baseline and week 12

Key secondary outcome(s))
1. Lipid profile will be measured by taking blood samples at baseline and week 12
2. Renal profile will be measured by taking blood samples at baseline and week 12
3. Liver profile will be measured by taking blood samples at baseline and week 12
4. Dietary intake will be measured using a 3-day diet history questionnaire at baseline, weeks 6 and 12
5. Physical activity will be measured by using a global physical activity questionnaire (GPAQ) Malay at baseline, weeks 6 and 12
6. Satiety level will be assessed by using a visual analogue scale (VAS) at specified intervals of 30, 60, 120, 180 and 240 minutes after consumption at baseline, weeks 6 and 12
7. Quality of life will be assessed using a diabetes-dependent quality of life questionnaire at baseline and week 12
8. Cost analysis will be calculated based on the Net Present Value formula at week 12
9. Metabolic gene expression profile will be measured using nCounter from NanoString at baseline and week 12

Completion date
30/09/2026

Eligibility

Key inclusion criteria
Current key inclusion criteria as of 18/12/2025:

1. Malaysian
2. Aged 20-65 years old
3. Diagnosed with T2DM for at least 6 months with baseline HbA1c levels above 6.5–12 % for the

past 6 months
4. Overweight or obese with BMI ≥25 kg/m²
5. Able to communicate and understand in English or Malay language

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Previous inclusion criteria as of 09/04/2025:

1. Malaysian
2. Aged 30-65 years old
3. Diagnosed with T2DM for at least 6 months with baseline HbA1c levels above 7.5–12 % for the past 6 months
4. Overweight or obese with BMI ≥25 kg/m²
5. Able to communicate and understand in English or Malay language

_____

Previous inclusion criteria:

1. Malaysian
2. Aged 30-59 years old
3. Diagnosed with T2DM for at least 6 months with baseline HbA1c levels above 7.5–12 % for the past 6 months
4. Overweight or obese with BMI ≥25 kg/m²
5. Able to communicate and understand in English or Malay language

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
20 years

Upper age limit
65 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. On insulin treatment
2. With hepatic disease (ALT >120 IU/L)
3. With chronic kidney disease (GFR <30 M1/min/1.73 m2)

4. Pregnant and lactating women
5. Currently consuming any weight reduction products or any slimming prescriptions or any meal replacement
6. Currently on hormone replacement therapy (HRT)
7. Cancer on treatment
8. Currently involved in weight loss programs or any clinical trial

Date of first enrolment
25/11/2024

Date of final enrolment
30/06/2026

Locations

Countries of recruitment
Malaysia

Study participating centre
Klinik Primer Hospital Canselor Tuanku Muhriz
Jalan Dwitasik, Bandar Sri Permaisuri
Wilayah Persekutuan Kuala Lumpur
Kuala Lumpur
Malaysia
56000

Study participating centre
Poliklinik Warga Hospital Canselor Tuanku Muhriz
Tingkat 1, Blok Klinikal
Hospital Canselor Tuanku Muhriz
Jalan Yaacob Latif, Bandar Tun Razak
Kuala Lumpur
Malaysia
56000

Sponsor information

Organisation
Quantum Upstream Sdn Bhd

Funder(s)

Funder type
Industry

Funder Name
Quantum Upstream Sdn Bhd

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Munirah Ismail (munirahismail@ukm.edu.my). Only statistical data will be provided after obtaining consent from the participants. The type of data that will be shared is the data in the manuscript.
Dates of availability: August 2025
Consent will be obtained from all of the participants. All patient data will be confidential. Ethics approval will be obtained from Sekretariat Penyelidikan UKM.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		10/10/2025	20/10/2025	Yes	No
Participant information sheet			18/09/2024	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes