Cover letter:

Official project title:
Effectiveness of Low-Calorie MIND-HK Diet and Very Low-Calorie Diet on Glycemic Control and Cardiovascular Outcomes in Adults With Type 2 Diabetes: A 12-Week Randomized Controlled Trial

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Information Sheet

TITLE OF THE STUDY
Effectiveness of Low-Calorie MIND-HK Diet and Very Low-Calorie MIND-HK Diet on Glycemic Control and Cardiovascular Outcomes in Adults with Type 2 Diabetes: A 12-Week Randomized Controlled Trial

INTRODUCTORY SENTENCE
You are invited to participate in a research study conducted by Associate Professor, Dr. Law Pui Sze Queenie from the School of Nursing and Health Sciences of Hong Kong Metropolitan University (HKMU).

PURPOSE OF THE STUDY
This study aims to evaluate whether low-calorie and very low-calorie versions of the Mediterranean-DASH Intervention for Neurodegenerative Delay (MIND-HK) diet can improve blood sugar control and heart health in adults with T2DM.

PROCEDURES
The study would be last for twelve weeks. You are invited to screen for the inclusion criteria and sign a consent form before participation in this study. You are invited to measure fasting blood glucose (HbA1C, blood test that shows your average blood sugar level over the past 2 to 3 months), with secondary outcomes including cardiovascular factors such as a point-of-care test lipid profile, fasting blood glucose, blood pressure, waist circumference, breath ketone, and body mass index respectively. Additionally, you will complete some psychometric questionnaires, which will take about 45 minutes, before the intervention. The baseline measurements (T0), and measurements at the 12th week after the completion of the intervention (T1) will be assessed to determine their short-term effects.

The interventions are referring to either low-calorie MIND-HK diet group, very low-calorie MIND-HK diet group or attention control group. If you are assigned to low-calorie MIND-HK diet group and very low-calorie MIND-HK diet group, you will receive four in-person nutrition counselling sessions (one session per week, 60 minutes per session, and 30 minutes question and answer session). If you are in attention control group, you will receive four sessions of in-person infectious disease counselling sessions (one session per week, 60 minutes per session, and 30 minutes question and answer session).

The primary distinction between low-calorie and very low-calorie food menus lies in the total caloric intake, with a difference of approximately 200 calories between the two. This difference is attributed to the proportion of calories derived from carbohydrates, which is significantly lower in a very low-calorie diet (VLCD). While both diets include a balanced composition of carbohydrates, proteins, and fats, a VLCD drastically reduces carbohydrate intake, forcing the body to rely more heavily on fat stores for energy and promoting the production of ketones.

POTENTIAL RISKS/STRESS/PAIN/DISCOMFORTS/OTHER FACTORS AND THEIR MINIMIZATION

All tests will be conducted by trained personnel. The testing should not result in any undue discomfort. The possible minor pain is the finger-prink blood test. Please be aware of the risk of falling, as all point-of-care tests require participants to fast, which may lead to dizziness or weakness.

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When starting a very low-calorie diet (VLCD), some individuals may experience a temporary set of symptoms similar to the "keto flu." This occurs as the body adjusts to a significant reduction in calorie and carbohydrate intake, leading to a shift in energy metabolism from glucose to fat stores, which produces ketones. Symptoms may include fatigue, headache, nausea, dizziness, irritability, muscle cramps, difficulty sleeping, and brain fog. These symptoms are often caused by electrolyte imbalances, dehydration, and the body's adaptation to a lower energy intake. These symptoms are typically temporary and tend to phase out within one week as the body adapts to the VLCD. To minimize discomfort, gradually reducing calorie and carbohydrate intake over several days, rather than abruptly, can also ease the transition and reduce the severity of symptoms. Ensuring adequate protein intake, getting enough sleep, engaging in light physical activity, and consuming sufficient fluids can further support the body during this adjustment period. To monitor ketosis and support dietary adherence, participants will receive the KetoMetrics Breath Ketone System and its companion mobile app, donated by AusMed Global. The device connects via Bluetooth and automatically records breath ketone levels, macronutrients, micronutrients, and calorie intake. These data will help participants and the research team track compliance and detect early signs of ketosis that may lead to diabetic ketoacidosis (DKA). To manage adverse effects of a very low-calorie diet (VLCD), participants should undergo regular monitoring of ketone levels to detect early signs of hypoglycemia or ketoacidosis. For signs of hypoglycemia (e.g., nausea, vomiting) or symptoms of ketoacidosis (e.g., fruity breath), participants should increase carbohydrate intake, hydrate with water or electrolyte solutions, and seek medical attention if symptoms persist or worsen. Participants should be educated on emergency protocols, including the use of glucagon for severe hypoglycemia, and encouraged to contact research team or seek medical advice promptly for any concerning symptoms. Regular phone call follow-ups by research team will be provided.

POTENTIAL BENEFITS

Participation in this research project is free of charge including nutrition counselling sessions or infectious disease counselling sessions, cardiovascular tests, breath ketone, blood glucose, and body measurement tests. Upon completing all research activities, including measurements at weeks 12, each participant will receive a total of HK$100 supermarket vouchers.

PARTICIPATION AND WITHDRAWAL

Your participation is voluntary and that you can choose to withdraw from the study at any time you want without any penalty or negative consequences.

CONFIDENTIALITY

All information related to you will remain confidential and will be identifiable by codes only known to the researchers. The information you provide as part of the project is the research data. Any research data from which you can be identified is known as personal data. Personal data does not include data where the identity has been removed (anonymous data). We will minimize our use of personal data in the study as much as possible. The researcher team will have access to personal data and research data for the purposes of the study. Responsible members of HKMU may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

QUESTIONS AND CONCERNS

If you have any questions or concerns about the research study, please feel free to contact Associate Professor, Dr. Queenie Law of HKMU at 3970 2974 or via email: qlaw@hkmu.edu.hk. If you have questions about your rights as a participant of this research study, please contact the Research Ethics Committee of HKMU at 27686251.

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Consent Form

HONG KONG METROPOLITAN UNIVERSITY

School of Nursing & Health Sciences

Consent form for research project "Effectiveness of Low-Calorie MIND-HK Diet and Very Low-Calorie Diet on Glycaemic Control and Cardiovascular Outcomes in Adults with Type 2 Diabetes: A 12-Week Randomized Controlled Trial"

☐ I have read and understand the information provided on the above named study. I agree to participate in this study and authorise the use of the data generated from this study, and the indefinite storage of biological samples for future research.

Name of participant	Signature	Date
Name of investigator	Signature of investigator	Date

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