Attachment C

INFORMED CONSENT STATEMENT

RESEARCH TITLE

Effects of Time Restricted Low Carbohydrate Diet Feeding Combined with Exercise Training in Normoxia or Moderate Hypoxia on Health Outcomes

RESEARCH PURPOSE

You are cordially invited to participate in a research study, whose purpose is to examine the changes in health outcomes after short-term time-restricted feeding (TRF) combining with low carbohydrate diet (LC) with or without exercise training (high-intensity interval training, HIT or moderate-intensity interval continuous training, MICT) in normal or low oxygen.

STUDY INFORMATION

Participants

Enrollment criteria for the study include inactive healthy colleague students aged 18-35 years old, body mass index $\geq$ 23 kg/m^2, no participation in any structured exercise program in the past 6 months, non-smoker and no history of cardiovascular disease and osteoarthrosis. The recruited participants will be randomly assigned into control group with no exercise or dietary intervention (CON), TRF and LC with no-exercise (TCON), TRF and LC with HIT (10 sets of 6 s all-out cycling interspersed with 9 s of rest) in normoxia (TNH) or in moderate hypoxia (THH) and TRF and LC with MICT in normoxia (TNM) or in moderate hypoxia (THM), respectively.

Procedure

The interested students will come to the Kinesiology Laboratory of FED located at Rm 3014, N8, and an introduction of research content and procedures will be explained in detail. Then, the potential participates will have a try to do high-intensity interval exercise and moderate-intensity continuous exercise to familiarize the equipment and exercise format. Before participating in the study, the informed consent should be voluntarily signed by each of all the participants and the Principle Investigator.

Measures and exercise protocols

Exercise Tests

All exercise tests will be conducted before and after the exercise intervention, which include a graded exercise, an exhausted high-intensity exercise, and a moderate intensity exercise.

Blood sampling

To examine the changes of endocrine function, 5 ml venous blood samples at fasting state will be taken by a professional nurse before and after the intervention.

Training Protocols

The participants in exercise HIT group will be trained around 5 minutes per day and five days per week for four weeks and the participants in MICT group will be trained around 30 minutes per day and five days per week for four weeks. The participants in CON group have no exercise training. Three graduate assistants majored in Sports Science will be in service during the whole course of training.

Requirements

(1) No other physical activities besides this training program and Physical Education class.
(2) Refrain from any heavy exercise before and on experimental days.
(3) Keep regular schedule and dietary habit during the whole course of study.

QUIT AND STOP

Participation in this study is completely voluntary. If you decide to join this study, you may withdraw from the study at any time without any reasons. If you withdraw from the study before the completion of data collection, all the data will be destroyed. We will terminate your further participation in the study and/or destroy any data that has not been analysed. Yet, once the results of the study were incorporated after the completion of data collection, it will not be possible to remove your individual data from the research. Moreover, you are fully aware of the researchers have the right to stop this study when necessary.

_____

Participant's initials

RISKS

Risks / Discomforts

Low carbohydrate diet may result in side effects such as constipation, fatigue, weakness and skin inflammation (i.e. keto rash or Prurigo pigmentosa) due to ketosis. Normal human physiological responses including high ventilatory demand induced-sensation of breathlessness, locomotor muscle fatigue and soreness may be elicited during exercise. The sensation of breathlessness and perceived fatigue will be disappeared around 30 min after termination of the exercise while the muscle soreness may remain for few hours after the exercise. The discomfort and risk associated with taking blood samples are limited. Doing exercise under moderate hypoxia simulated at an altitude (15.2-12.0% O_2, corresponding 2000-4000m altitude) may result in mild headache and more significant responses of breathlessness and muscle fatigue.

Measures to minimize the Risks / Discomforts

All attempts will be made to minimize the risks & discomforts. Generally speaking, reintroduction of carbohydrates into the diet is sufficient to cure all the side effects caused by low carbohydrate diet. Participates are also encouraged to eat more vegetables to reduce any potential side effects.

In order to minimize the hard feeling elicited from the acute change from rest to vigorous physical activity, participates will be instructed to do a standard warm-up exercise before exercise. During exercise, participates will be closely supervised throughout the testing period and there is always a valid communication between participants and the test administrator. After the termination of the exercise, participants will be instructed to continue cycling for several minutes at light intensity immediately after the exercise test for avoiding the blood pooling in locomotor muscles. Blood oxygen saturation levels, heart rate and the diagnosis of acute mountain sickness (AMS) assessed by Lake Louise Score will be measured through the testing stage. Once AMS occurs, the researchers will remove the mask with low oxygen and stop the test immediately.

EMERGENCY MEDICAL TREATMENT

In the unlikely event of physical injury resulting from your participation in this research, emergency medical treatment will be provided at no cost to you. Be certain that you immediately notify the researcher if you're injured. If you require additional medical treatment, you have to be responsible for the cost. No other compensation will be provided in this research.

BENEFITS

When you complete the protocol, you will get a report including body composition, blood pressure, aerobic fitness and blood lipids. All parameters involved in this study will be explained in detail. You will receive an individual exercise program to improve your physical fitness. Also, long-term exercise instruction will be freely available. If you do not complete the protocol, you will still have the benefit of preliminary testing results.

CONFIDENTIALITY

Information collected for this study will be kept confidential. In case of a lawful investigation, your privacy will be carefully protected by the researchers Blood samples during the study well be stored for in freezers of the Kinesiology Lab for use in this research. If you agree, your blood samples will be stored up to 5 years. If you do not agree, your sample(s) will be destroyed in an appropriate way after the study has completed. The original paper copies of all identifiable data will be kept in locked storage cabinets and rooms, and electronic copies of all identifiable data will be kept on a secure cloud storage (i.e. UMDrive) with access limited to the Principal Investigator and authorised personnel only. After the completion of the study, we will keep the anonymised data (i.e. paper and electronic copies) for 5 years.

By signing the Informed Consent Form attached, you can get the result of the study published in scientific journals and presented at conferences. In such events relevant to this study, your identity will remain confidential.

CONTACT

If you have any questions about this research project or any discomforts due to participating in this study, please feel free to contact the Investigator of the study, Dr. Zhaowei Kong at 8822 8730 or zwkong@um.edu.mo.

STATEMENT

I solemnly and sincerely declare, A. having consulted with a medical professional, I am healthy and can do strenuous exercise. B. the Investigator completely addressed the purpose, procedures, and possible participation risks-benefits, and additionally, he answered me all the questions involved. Also, I clearly understood I could quit this study at any time.

CONSENT

I have read and understand the above information and I □agree / □ disagree to be taken blood samples from cubital vein.

Participate: _____ Signature: _____

Regarding the storage of blood samples, I □agree / □ disagree to be stored for 5 years after the completion of the study.

Participate: _____ Signature: _____

I have read and understand the above information and also have received a copy of this form. Hereby, I agree to participate in this study voluntarily.

Participate: _____ Signature: _____ Date: _____

PI: _____ Signature: _____ Date: _____

知情同意聲明

研究專案

限時飲食低碳輔助常氧/低氧運動訓練對身心健康的影響

研究目的

觀察短期限時低碳飲食、是否輔助常氧/低氧高強度間歇運動或中等強度持續運動對身心健康功能改善。

研究方法

研究參與者	身體健康肥胖大學生（18-35 歲，BMI 指數≥23 $kg \cdot m^{-2}$），過去半年無系統訓練史，不吸烟，無心血管疾病及骨關節疾病。經過 2-4 星期常規飲食及生活習慣記錄後，隨機將參與者分組。
分組	請勾選您的組別 □常規飲無運動之對照組 (CON) □低碳限食組 (TCON) □低碳限食+高强度間歇運動組（TNH） □低碳限食+低氧高强度間歇運動組（THH） □低碳限食+中等强度持續運動組（TNM） □低碳限食+低氧中等强度持續運動組（THM）
實驗流程	
簽署同意書：	時間約 30 分鐘，主要為詳細介紹研究內容、篩選合乎資格的被試、簽署同意書及熟悉運動方式。
運動測驗（訓練前後）：	**GXT 測驗**：遞增功率車評價心肺耐力。 **無氧能力測驗**： 30 秒全力蹬車，在運動過程中，記錄參與者的心率、血壓、主觀疲勞感覺。
血液採集：	特邀護士在訓練前及訓練後各取一次安靜態靜脈血 5 毫升。
訓練計畫：	訓練每週 5 次，共 4 週；HIT 組進行兩分半鐘 10 組 6s/9s 間歇性衝刺訓練，MICT 組進行 30 分鐘的低强度有氧運動；運動科學專業的研究助理將全程監控。
研究要求	(1) 除參加本訓練計畫和常規體育課外，不進行其它任何方式鍛煉。 (2) 實驗前一天及實驗當天且不做劇烈運動。 (3) 保持規律作息和日常的膳食習慣。

潛在危險性及不舒適感

低碳飲食可能會造成便秘、肌肉乏力感，有些人甚至會出現皮疹。

在運動中會出現人體生理反應包括不同程度的氣喘、疲勞及肌肉酸痛等不舒適感。氣喘及疲勞感會在運動結束後十分鐘至半小時內消失，而肌肉酸痛可能會持續幾天。受試者在取血過程中可能會感不適，但並無危險性。研究負責人及研究助理學生均具有急救經驗。

減少潛在危險性及不舒適感的措施：研究工作人員將全力採用力所能及的措施以減少受試者的危險性及不適感。低碳飲食肌肉乏力感是供能物質轉換的可能結果，期間需多進食綠葉蔬菜以避免便秘，低碳生酮可能引起的皮疹一般會隨著恢復常規飲食而消除。

每次運動前後研究工作人員將分別指導受試者進行標準的熱身及冷卻活動以減少安靜狀態與運動狀態之間轉換的不適感。在運動中，研究工作人員會密切觀察受試者的生理狀況及主觀反應。血氧含量、心率和鹽湖城問卷所測的急性高山症反應將被監控，若出現急性高山症反應，研究者將去除低氧面罩，立刻中斷實驗測試。

受試者簽署：_____

退出與中止

您可決定是否參加本實驗，實驗過程中可隨時撤銷同意，退出實驗，不須任何理由。若您在數據收集完成前推出，您的所有資料將不用於分析並被銷毀，下一步實驗參與亦將停止；若您的數據收集已完成且計入數據分析，您的個人資料將被保留於研究中。另外，您也已充份瞭解研究負責人亦可能於必要時中止該實驗之進行。

利益

1. 完成全部實驗後，可獲得一份詳盡的健康報告，包括身體成分、血壓、有氧能力等，並可得到一對一面談以詳盡瞭解所測定結果的意義；可獲得依據實驗結果而制定的個體化增進健康的運動及營養方案，並可獲得長期的免費指導。
2. 若未完成實驗，您也可獲得實驗人員對所測試結果的初步解讀。

緊急醫療處理

對於研究中可能造成的運動損傷，課題組將提供無需花費的醫療救助。在研究中受傷時，請立刻通知研究負責人。若需要額外醫療處理，課題組並不承擔參與者的費用。

個人隱私

對於您的所有資料，研究人員將絕對遵守保密之倫理，每位參與者的姓名將會由一個研究號碼代替。除了有關機構依法調查外，研究人員會小心維護您的私隱。受試者的血液樣本將貯存於研究用實驗室冰箱內。如果您同意，所收集血液樣本將在實驗結束後保存五年，若您不同意，您的血液樣本將以恰當方式銷毀。含有個人資料的紙質資料將被鎖入資料櫃儲存，電子資料將被儲存於有安全保障的雲端（即 UMDrive），僅研究負責人或其授權人可接觸到。研究結束後，紙質和電子資料將會以匿名方式保存五年。當您簽署知情同意書後，你便可獲得所發表科技期刊論文及會議論文報告資料。在此類資料中，您的身份資料將隱藏。

聯繫

如果您對本研究計畫有任何問題或因為參與本研究而發生任何不適或疑問，可隨時與研究負責人孔兆偉博士聯絡（電話：88228730，電郵：zwkong@um.edu.mo）。

聲明

受試者本人聲明：

1. 我已經諮詢過專業醫生意見，本人身體健康，可進行健身運動鍛煉；
2. 專案研究負責人已完整地向我說明本研究之性質、目的、方法與參加本研究可能的相關危險性和效益，且已回答我有關研究實驗的相關問題，並已解釋我有權隨時退出研究工作。我是自願參與本研究。

同意

我已經仔細閱讀並理解了上面的資訊，我 □同意/□不同意 抽取靜血。

受試者簽署：_____

關於血液樣本貯存，我 □同意/□不同意 所收集血液樣本在實驗結束後保存五年。

受試者簽署：_____

我已經仔細閱讀並理解了上面的資訊，並持有一份已簽署之受試者同意書。我同意參加此項研究實驗。

受試者：_____簽署_____日期 _____

研究負責人：_____簽署_____日期 _____