

Informed consent forms

Research Information

Research Title:

A Randomized Controlled Trial on the Effectiveness and Adherence of Modified Alternate-day Calorie Restriction (MACR) in Improving Activity of Non-Alcoholic Fatty Liver Disease

Researcher's Name:

Professor Dr Lee Yeong Yeh

Dr Juhara Haron

Dr Chandran Nadarajan

Dr Wan Nor Ariffin

Dr Muhammad Izzad bin Johari

Dr Khairiah Mat Yusoff

Mdm Khairun Nisah Ibrahim

Dr Zheng Feei Ma

Mdm Nurhazwani Hamid

SN Bee Eng Chua

INTRODUCTION

You are invited to take part voluntarily in the research of study of evaluation effect of MACR as intervention in radiological and biochemical changes in non-alcoholic fatty liver disease (NAFLD). Duration of the study started from 2 week prior to calorie restriction, 8 weeks of calorie restriction and 1 week after calorie restriction. Calorie restriction will be done alternate day in a week where participant will be informed amount of calorie/food that allowed on that day.

During the baseline control period for 2 weeks, each participant is requiring to keep their body weight stable by maintaining their usual eating and activity habits, then, during 8-week MACR period, all participant consumed only 30 % energy needs for 24 hours then follow with consumed ad libitum (at participant pleasure) on each alternate "feed" day (24 h). Calorie restriction begins at 9 am until 9 am on the next day and followed with Ad libitum starts at 9 am until 9 am. During the calorie restriction (9 am to 9 am- 24 hours) participant only allowed to take food by calorie specified. Participants are advised to take the prescribed amount of calorie at 2 pm and 8 pm. No control over intake of plain water or unsweetened water such as Chinese tea or free calories food during this calorie control. Participants will also be given an appointment to meet with officials dietition related foods and cooking methods according to this calorie control period. If participants tolerate with calorie restriction as example because of certain health problems, participants should record the matter in the diary.Appointment every 2 weekly will be given to you.

Before agreeing to participate in this research study, it is important that you read and understand this form. If you participate, you will receive a copy of this form to keep for your records.Your participation in this study is expected to last up to 8 weeks.

PURPOSE OF THE STUDY

The purpose of this study is to determine favourable effects of MACR on changes in liver steatosis and fibrosis and also biochemical changes in non-alcoholic fatty liver disease (NAFLD) patiens after 8 weeks of MACR. It is possible that information collected during this study will be analyzed by the sponsor in the future to evaluate the effect of MACR for other possible uses or other medical or scientific purposes other than those currently proposed.

QUALIFICATION TO PARTICIPATE

The doctor in charge of this study or a member of the study staff has discussed with you the requirements for participation in this study. It is important that you are completely truthful with the doctor and staff about your health history. You should not participate in this study if you do not meet all qualifications.

Some of the requirements to be in this study are:

- ✓ Age ranges 18 to 70 years old
- ✓ Baselines Ultrasound show evidence of fatty liver
- ✓ Elevated alanine aminotransferase (ALT) or aspartate aminotransferase (AST) values (ALT41 or AST34U/L)

You cannot participate in this study if:

Exclusion criteria

- × Medically or surgically ill patients who cannot consent
- × Complicated chronic liver disease with portal hypertension
- × Significant alcohol consumption (1 standard drink per day)
- × Contraindications to calorie restriction
- × Pregnancy
- × Engagement in an active weight loss program
- × Taking weight-loss medication, substance abuse
- × Significant psychiatric problems

Withdrawal criteria

- × Subject who unable to tolerate alternate daily fasting intervention during the trial
- × Patient own choice

STUDY PROCEDURES

You will undergo screening and physical examination if needed. First visit will be 2 weeks prior to MACR where weight, height, blood pressure, waist circumferences will be measured with the use of a standardized calibrated balance throughout the study. Besides that, baseline blood parameters will be taken which are ALT, AST, triglycerides, HDL cholesterol, cholesterol and fasting plasma blood glucose. Ultrasound of liver will be performed by a specific radiologist trainer.

Second visit will be within 1 week after 8 weeks of MACR; we will repeat the anthropometric measurement, blood pressure, blood parameters and Ultrasound of liver.

You can be allowed home after the visit or for those who prefer to stay in the hospital because of distance from their house, and then we can arrange for admission.

RISKS

There may be risks to you if you participate in this study. These tests are fairly safe with little risk involved. For most people, needle puncture for blood draws will cause discomfort but do not cause any serious problems.

If any important new information is found during this study that may affect you wanting to continue to be part of this study, you will be told about it right away.

REPORTING HEALTH EXPERIENCES

If you have any injury, bad effect, or any other unusual health experience during this study, make sure that you immediately tell the nurse or Dr. Lee Yeong Yeh [MMC Registration No.36810] at 09-7663917 or 017-9028147 or Dr Muhammad Izzad Bin Johari [MMC Registration No.50603] at 016-9066530. You can call at anytime, day or night, to report such health experiences.

PARTICIPATION IN THE STUDY

Your taking part in this study is entirely voluntary. You may refuse to take part in the study or you may stop participation in the study at anytime, without a penalty or loss of benefits to which you are otherwise entitled. Your participation also may be stopped by the study doctor or sponsor without your consent.

POSSIBLE BENEFITS [Benefit to Individual, Community, University]

Study procedures will be provided at no cost to you. You may receive information about your health from any physical examination and laboratory tests to be done in this study. We hope that the outcome and information regarding this research will be beneficial to future patients.

QUESTIONS

If you have any question about this study or your rights, please contact;

Dr. Lee Yeong Yeh (MMC No.: 36810)
Department of Internal Medicine
PPSP, USM Health Campus
Tel :09-7676576/017-9028147

Dr. Muhammad Izzad Bin Johari (MMC No.: 50903)
Department of Internal Medicine
PPSP, USM Health Campus
Tel :016-9066530

If you have any questions regarding the Ethical Approval or any issue / problem related to this study, please contact;

Mr. Mohd Bazlan Hafidz Mukrim
Secretary of Human Research Ethics Committee USM
Centre for Research Initiatives, Clinical & Health Sciences
USM Health Campus
Tel. No. : 09-767 2354 / 09-767 2362
Email : bazlan@usm.my/jepem@usm.my

CONFIDENTIALITY

Your medical information will be kept confidential by the study doctor and staff and will not be made publicly available unless disclosure is required by law.

Data obtained from this study that does not identify you individually will be published for knowledge purposes.

Your original medical records may be reviewed by the researcher, the Ethical Review Board for this study, and regulatory authorities for the purpose of verifying clinical trial procedures and/or data. Your medical information may be held and processed on a computer.

By signing this consent form, you authorize the record review, information storage and data transfer described above.

SIGNATURES

To be entered into the study, you or a legal representative must sign and date the signature page.

Patient/Subject Information and Consent Form
(Signature Page)

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To become a part this study, you or your legal representative must sign this page. By signing this page, I am confirming the following:

- I have read all of the information in this Patient Information and Consent Form including any information regarding the risk in this study and I have had time to think about it.
- All of my questions have been answered to my satisfaction.
- I voluntarily agree to be part of this research study, to follow the study procedures, and to provide necessary information to the doctor, nurses, or other staff members, as requested.
- I may freely choose to stop being a part of this study at anytime.
- I have received a copy of this Patient Information and Consent Form to keep for myself.

Patient Name (Print or type)

Patient Initials

Patient I.C No. (New)

Patient I.C No. (Old)

Signature of Patient or Legal Representative

Date (dd/MM/yy)

Name of Individual Conducting Consent Discussion

Date (dd/MM/yy)

Signature of Individual onducting Consent Discussion

Date (dd/MM/yy)

Name & Signature of Witness

Date (dd/MM/yy)

Note: i) All subject/patients who are involved in this study will not be covered by insurance.

Patient's Material Publication Consent Form
Signature Page

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To become a part this study, you or your legal representative must sign this page.

By signing this page, I am confirming the following:

- I understood that my name will not appear on the materials published and there have been efforts to make sure that the privacy of my name is kept confidential although the confidentiality is not completely guaranteed due to unexpected circumstances.
- I have read the materials or general description of what the material contains and reviewed all photographs and figures in which I am included that could be published.
- I have been offered the opportunity to read the manuscript and to see all materials in which I am included, but have waived my right to do so.
- All the published materials will be shared among the medical practitioners, scientists and journalist worldwide.
- The materials will also be used in local publications, book publications and accessed by many local and international doctors worldwide.
- I hereby agree and allow the materials to be used in other publications required by other publishers with these conditions:
- The materials will not be used as advertisement purposes nor as packaging materials.
- The materials will not be used out of context – i.e.: Sample pictures will not be used in an article which is unrelated subject to the picture.

Patient Name (Print or type)

Patient Initials or Number

Patient I.C No.

Patient's Signature

Date (dd/MM/yy)

**Name and Signature of Individual
Conducting Consent Discussion**

Date (dd/MM/yy)

Note: i) All subject/patients who are involved in this study will not be covered by insurance.