TITLE: Randomized, Single-blinded, Controlled, Parallel-arm Study to Evaluate the Effect of Fast Bar™ on Physiological Fasting Condition

PROTOCOL NO.: None
WIRB® Protocol #20201920

SPONSOR: L-Nutra, Inc.

PRINCIPAL INVESTIGATOR: William C. Hsu, MD
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STUDY-RELATED PHONE NUMBER(S): 323-628-3158

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

You have been asked to participate as a subject in a medical experiment. Before you decide whether you want to participate in the experimental procedure, you have a right to the following information:

CALIFORNIA LAW REQUIRES THAT YOU MUST BE INFORMED ABOUT:

1. The nature and purpose of the study.
2. The procedures in the study and any drug or device to be used.
3. Discomforts and risks reasonably to be expected from the study.
4. Benefits reasonably to be expected from the study.
5. Alternative procedures, drugs, or devices that might be helpful and their risks and benefits.
6. Availability of medical treatment should complications occur.
7. The opportunity to ask questions about the study or the procedure.
8. The ability to withdraw from the study at any time and discontinue participation without affecting your future care at this institution.
9. Be given a copy of the signed and dated written consent form for the study.
10. The opportunity to consent freely to the study without the use of coercion.

I have carefully read the information contained above and I understand fully my rights as a potential subject in this study.

Date: _____ Time: _____

Signature: _____
(Research Participant)

INFORMED CONSENT

We invite you to take part in a research study. Please take as much time as you need to read the consent form. You may want to discuss it with your family, friends, and/or your personal doctor. If you find any of the language difficult to understand, please ask questions. If you decide to participate, you will be asked to sign this form.

This research study is sponsored by L-Nutra, Inc. They provide funding to cover the costs of conducting this study.

WHY IS THIS STUDY BEING DONE?

This study is about the effect of a specially formulated energy bar, the Fast Bar™, on people after an overnight fasting. We hope to learn how the Fast Bar™ affects the physiological fasting condition in generally healthy adults.

WHAT IS INVOLVED IN THE STUDY?

The study will be carried out at your home and last 2 days.

If you decide to take part, this is what will happen:

You will be asked to install Zoom (https://www.zoom.com), a teleconference App, on your phone or personal computer.

We will ask you about your medical history and assess whether you are eligible for the study.

We will evaluate whether you may have any conditions, medications or recent experiences that would affect the results of this study from study questionnaires.

You will be asked to consume a ready-to-eat dinner meal, followed by an approximate 15-hour overnight fasting.

You will be asked to take a sample of blood by picking your finger (a drop) to measure glucose and ketones levels before and after consuming a breakfast meal.

You will be asked about food allergies and whether you have special dietary needs.

If you qualify for participating in this study, you will be randomly assigned (like flipping a coin) to be in one of the following three groups. You will have an equal chance of being assigned to either group:

1) **Fast Group**: You will Fast overnight for a total of approximately 19 hours;
2) **Breakfast group**: You will fast overnight and, then, consume a breakfast bar;
3) **Fast Bar group**: You will fast overnight and, then, consume a Fast Bar.

Prescreening:
Before you to be enrolled in the study we will need to run a first screening phase via video conferencing (Zoom), to know whether you qualify for participating in this study.

During the screening phase, the following things will happen:

You will be asked to provide your identity documents and medical history.

You will be asked about the medications you are using and whether you recently changed your medications. This process is meant to determine that you do not have any conditions, medications or recent experiences that would affect the results of this study.

You will be asked about your dietary habit.

Treatment assignment
If you qualify for being enrolled in this study, you will be randomly assigned (like flipping a coin) to either the water-only Fast Group, the Breakfast Group, or the Fast Bar Group.

You will be sent a blood glucose/ketone monitor and other supplies for measuring blood sugar/ketones via finger sticks. If you are assigned to certain study groups, you will also be sent meals to consume.

You will be asked to take a sample of blood by picking your finger (a drop) to measure glucose and ketones levels before breakfast on day 1.

You will consume a ready-to-eat dinner meal by 5 PM followed by an approximate 15-hour water-only overnight fasting on day 1.

On day 2, you will be asked to take a sample of blood by picking your finger (a drop) to measure glucose and ketone levels around 8 AM (before consume a breakfast meal).

You will continue to water-only fast if you are in the water-only Fast Group and take a sample of blood by picking your finger (a drop) to measure glucose and ketones levels hourly for 4 times.

You will be asked to take a sample of blood by picking your finger (a drop) to measure glucose and ketones levels 1, 2, 3, and 4 hours after consume the study foods if you are in the Breakfast or Fast Bar groups.

You will be asked to complete questionnaires regarding the study foods consumed and how you feel.

Information about Samples and Data Collected as Part of This Research
You will submit your glucose and ketone readings before and after the dietary intervention.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

A 15-19 hours overnight fasting is a common practice. However, it is possible that some participants may feel fatigue, weakness, or other symptoms.

Although fingerstick is a common practice for checking blood glucose, you could experience pain, discomfort, bruising or infection (a slight risk any time the skin is broken).

Although you will be screened for food allergies and be able to review the ingredients, it is possible that an allergic reaction could occur upon ingestion of the study foods.

WILL YOUR INFORMATION BE KEPT PRIVATE?

The investigator and the Institutional Review Board (IRB) will keep your records private as far as the law allows. The IRB is a research review board that is made up of professionals and community members who review and monitor research studies to protect the rights and welfare of research participants. Your record will be kept confidential unless the law requires us to share these records. We may publish the information from this study in journal, present it at conferences, or share the data with other investigators. If we do, your identity will not be revealed.

Your information may be given to the following groups for the purpose to study the results and/or to see if the study was done right:

- The U.S. Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS) agencies,
- Western Institutional Review Board® (WIRB®)

You and your personal doctor will not learn the results of the research analysis.

The collected data and the resulting analysis may be included in research paper(s) for publication in peer-reviewed scientific journal(s) and may be entered into data repositories to be shared with other researchers.

Any information that is obtained in this study will be identified only by an identification number, not your name. When results of the research are published or discussed in conferences, no information will be included that would reveal your identity. Any identifying information will remain confidential and will be disclosed with your permission or as required by law.

Only members of the research team will have access to the data associated with this study. The data will be stored in our lab in a locked file cabinet/password protected computer. No personal information will be kept, to link your identity with our data. All the data will be store indefinitely or disposed at the investigator's discretion. Absolute confidentiality cannot be guaranteed because of the need to give information that identifies you to these parties.

By participating in this study, you agree to allow the researchers to use the data for future research studies. Your permission to use the data in future studies will not be obtained, since data will not contain any identifiers.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART IN THIS STUDY?

You may not receive any benefit from taking part in this study, but your participation will help us understand physiological and biochemical changes in the human body associated with consuming the Fast Bar during a physiological fasting condition.

WHAT OTHER OPTIONS ARE THERE?

An alternative would be to not take part in this study.

ARE THERE ANY PAYMENTS TO YOU FOR TAKING PART IN THE STUDY?

There is no payment for participation.

WHAT ARE THE COSTS?

The study will pay for all research tests and procedures. You and/or your health plan/insurance will not be billed for tests and procedures that are done in this research.

WHAT HAPPENS IF YOU GET INJURED OR NEED EMERGENCY CARE?

If you think you have been hurt by taking part in this study, tell the study personnel immediately. If you require treatment because you were injured from participating in this study, you should seek for treatment immediately. You and/or your health plan/insurance will be billed for this treatment. The study sponsor will not pay for this treatment. There are no plans to offer any type of payment for injury. However, by signing this form you have not given up any of your legal rights.

WHAT ARE YOUR RIGHTS AS A PARTICIPANT, AND WHAT WILL HAPPEN IF YOU DECIDE NOT TO PARTICIPATE?

Your participation in this study is voluntary. You may decide not to participate or you may withdraw your consent at any time. You are not waiving any legal claims or rights. You are not giving up any legal claims or rights. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

CAN YOU BE REMOVED FROM THE STUDY?

You may be removed from this study without your consent for any of the following reasons: you do not follow the investigator's or study doctor's instructions, at the discretion of the investigator or study doctor, or the study ends. If this happens, the investigator or study coordinator will discuss other options with you.

DO THE INVESTIGATORS OR THE INSTITUTION HAVE A CONFLICT OF INTEREST?

This study will use special food products developed by L-Nutra, Inc.

L-Nutra may develop products that can be sold. If they make money from the products, you will not receive any money.

Dr. Hsu has a leadership role in the sponsor company. Please feel free to ask any questions that you might have about this matter**.**

WHOM DO YOU CALL IF YOU HAVE QUESTIONS OR CONCERNS?

You may contact Angie Huang, at (323) 628-3158 or awu@l-nutra.com, with any questions, concerns, or complaints about the research or your participation in this study, or if you feel you were injured by your participation in the study.

If you have questions, concerns, or complaints about the research, contact the Institutional Review Board (IRB) Office at (800) 562-4789 between the hours of 5:00 AM and 5:00 PM (PST), Monday to Friday. (Email at help@wirb.com)

If you have any questions about your rights as a research participant, or want to talk to someone independent of the research team, you may contact the Institutional Review Board Office at the numbers above.

You will get a copy of this consent form.

AGREEMENT:

I have read (or someone has read to me) the information provided above. I have been given a chance to ask questions. All my questions have been answered. I have decided to sign this for in order to take part in this study.

Name of Research Participant	Signature	Date Signed (and Time*)

I have personally explained the research to the participant using non-technical language. I have answered all the participant's questions. I believe that he/she understands the information described in this informed consent and freely consents to participate.

Name of Person Obtaining Informed Consent	Signature	Date Signed (and Time*)

A witness is required when: (1) the participant cannot see, read, write, or physically sign the consent form, or (2) the Short Form method is used to obtain consent. In these situations, the witness must sign and date the consent form. If no witness is needed, leave this signature line blank.

Name of Witness	Signature	Date Signed