Informed Consent Document for

Efficacy of Low-Frequency, High-Intensity Ultrasound for Reduction in Subdermal Adipose Layers

Device Investigated: Ultimate Contour Body Sculpting Device

Indication Studied: Application of ultrasound for non-invasive waist circumference reduction.

A randomized, blinded comparison of waist circumference reduction of an active test group vs. a placebo control in adults.

Sponsor: CAO Group, Inc.
Development Phase: Performance Validation

Protocol ID: 005-00036-8
NCT ID: Not Yet Assigned

Anticipated Initiation Date: 15 December 2019

Anticipated Completion Date: 1 May 2020

Document Date: 4 November 2019

Consent and Authorization Document

BACKGROUND

You are being asked to take part in a research study that explores a new way to reduce body fat that is present in the central area of the body - the stomach region and "love handles". This method will use a special type of ultrasound device that will send ultrasound waves through the skin to disrupt the fat cells. Your body then naturally removes this disrupted fat. The intended result is a reduction in measurement around your waist. This study will provide support so this device can be allowed onto the U.S. market by the FDA. This device offers the ability to achieve a rapid and noticeable reduction in waist size without surgery, painful procedures, or changes in eating habits. This study will be conducted by a licensed doctor and by trained staff who will use the device, and record measurements and information about you and your experience during this study.

Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you want to volunteer to take part in this study.

For your information, the device that will be used during this study is investigational and has not been approved or cleared by the U.S. FDA.

STUDY PROCEDURE

This study will evaluate the effectiveness of using ultrasound energy to disrupt fat cells below the skin in order for the cells to be removed by the body's natural processes. Other devices already exist that accomplish these results. This device uses a different ultrasound energy than these other units, and the purpose of this study is determine if this different type of ultrasound can do the same job. The ultrasound sensor is placed on the skin and transmits the ultrasound through the skin into the fat cells. There is no need for any needles or anything to poke through the skin.

Prior to beginning this study, you will be assessed to determine if you are eligible to participate. You will be asked a number of questions, in particular about your past and present health, and any medications that you currently take. You will also be asked about any medical procedures you are currently undergoing or have had in the recent past. It is important that you respond truthfully and provide as much information as you know about your health and the medications you take. If you are unsure, you may contact your doctor to get details. During the study, your height and weight will be measured at the beginning of the study, and your waist circumference (the distance around your belly) will be measured multiple times during the study.

We ask that you please participate in the full study. Results may vary from one person to another.

The study will consist of the following steps:

1) A pre-treatment visit will be made to determine if you are a good candidate for the treatment. During this visit, we will ask a number of questions about your overall health and medical history. Measurements will be made of your height, weight, and waist size. This visit is expected to take about 30 minutes.
2) If selected, you will be scheduled for the first of 3 treatment visits. Each visit will take about 45-60 minutes. Your waist size will be measured, and then you will be prepared to receive the treatment. The treatment is made by revealing the waist (belly) area of the body, after which a treatment gel is applied to the exposed skin. The ultrasound sensor is placed on the skin, and the treatment begins. The doctor will move the sensor back and forth over the belly area for 30 minutes. Afterwards, the gel is cleaned off and another waist size measurement is made. A few questions will be asked about any discomfort during the treatment, and then you will make an appointment for the next visit, which will be within the next 6-8 days.
3) A total of 3 visits will be made. Before the beginning of the second and third treatments, you will be asked questions about anything unusual that your felt or saw that you think is related to this study.
4) After the final visit, you will be asked to return 1 week, 4 weeks, and 12 weeks after the last treatment for follow-up evaluations, and discussion about you overall experience.

The part of this study that is considered experimental is that this product uses ultrasound at a lower frequency compared to other products already used by doctors for the same effect. A total of about 50 people will be recruited for this study.

RISKS

Conversation about a person's weight and body appearance can be difficult. Please understand that the doctors and staff in this study are trained in medical product studies and will consider any fears or embarrassment about this topic. Please talk with the study staff about any concerns you may have. Please know that all personal information, including your identity, weight and measurements, are well protected. Your identity will not be published or revealed, and measurements and weights will be listed just as numbers without any link to your identity.

In general, this procedure may involve risks to you which are currently unforeseeable.

For women who are pregnant, or may become pregnant during this study, the effects of this ultrasound on the developing embryo or fetus are not well known and may create risks that are currently unforeseeable. To keep you and unborn baby safe, you should not participate in this study if you are pregnant, think you might be pregnant, or are trying to become pregnant. If you are a woman of child-bearing age, you will be required to take a pregnancy test.

The use of this product may create some reactions or side-effects, some of which may currently be unforeseeable. These may not appear at all. Some might appear in different amounts from person to person. The study staff will ask about and look for any of these types of results. As always, please discuss any concerns with the staff at any time during the study.

These side effects include:

- Localized inflammation, swelling, numbness or tingling, blistering, redness or purple discoloring, bruising, and elevated temperature of the treatment area: Based on the proposed mechanism of action, the application of ultrasound and the disruption of cells could result in a localized increase in tissue temperature, accompanied by increased blood circulation through the affected tissue.
- Localized pain or discomfort: The action of ultrasound of this frequency and intensity on nerve cells is not well understood. The same mechanism of action could trigger nervous cell responses interpreted by the brain as a pain response. The disruption and cavitation of adjacent adipose cells could also trigger a pain response.
- Possible system disruption: The applied ultrasound energy is intended to provide localized energy at the typical depth of tissue where sub-dermal adipose cells are found. The ultrasound energy could continue to propagate further into the body, reaching gastro-intestinal organs beneath the treated area. In generalized terms, there could be disruptions to digestive processes resulting from exposure to the ultrasound energy.
- Possible elevation of blood glucose levels: The disruption and lysis of adipose cells may release an increased amount of glycogen into the blood stream. Patients who present with diabetes or pre-diabetes or who are susceptible to variations in blood glucose levels may experience side-effects consistent with elevated glucose levels wherein they are unable to metabolize and/or process the glucose products adequately.
- Changes in skin color such as lighter or darker spots or patches. There may also be bruising, bumps, burning, blisters, or scarring.

BENEFITS

Your help with this study could lead to an improved quality of life for many people through the use of this device. We cannot promise any benefits to you from your being in the study, however during the course of this study you may see some benefits that are expected from this product, including a reduced waist size and better body shape through your belly and mid-section.

Many people are concerned about their weight. Diet and exercise take a long time and can be hard to keep going. Other medical treatments can require extreme surgery that must be done at a hospital and can be expensive. This product seeks to provide an alternative to reducing your waist circumference in a way that will be safe and effective relative to other treatment options that are available.

ALTERNATIVE PROCEDURES

As explained in the Benefits, there are several alternatives to reducing waist circumference and improving your body shape around your belly. These can be used individually or in combination. They include:

- **Eating a balanced, low calorie diet.** This approach is usually safe and requires little cost, but results can take a long time, and you might not see any results at all.

- **Regular aerobic and conditioning exercise.** This approach can be effective, but requires consistent effort over a long period of time to see results. Some people may have other medical conditions that prevent effective exercise. For some people, exercise may actually increase other health problems.
- **Liposuction, ultrasonic cavitation, "freeze", or laser sculpting.** These approaches can achieve dramatic results in 1 or a few visits. Some procedures may require some small surgical openings. Often, these procedures can be expensive and require some rest or recovery time.
- **Bariatric surgery, such as "lap band".** This approach requires surgery. You can achieve dramatic results within a few months. These procedures force a change in how you eat and what you can eat. Sometimes, there are problems after the surgery that can last for a long time or require more surgery to fix. These procedures are usually expensive.

PERSON TO CONTACT

If you have questions, complaints or concerns about this study, or if you feel you have been harmed as a result of participation, please call [redacted] who may be reached at any hour in case of any injury related to this research. In the event that the injury requires immediate medical attention, you should seek immediate medical attention from either an urgent care facility or an emergency room, depending on the seriousness of the injury. If immediate medical attention is received, please contact [redacted] as soon as possible to inform him of the situation.

Institutional Review Board: Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

Research Participant Advocate: You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu.

VOLUNTARY PARTICIPATION

Research studies include only people who choose to take part. You can tell us that you don't want to be in this study. You can start the study and then choose to stop the study later at any time and without any penalty. This will not affect your relationship with the investigator. If you choose to do so, simply contact the investigator at [redacted] and indicate your intention to stop. There are not any expected problems or side-effects from this treatment should you choose to immediately stop.

The investigator may also choose to stop your participation in the study, even if you wish to continue. These reasons may include:

- Continued use may create long-lasting damage to your skin or to your overall health.

- You undergo other medical treatments or procedures after the study has started.
- You become ill or sick.
- The results collected so far suggest the device is not having the desired effect, or any useful effect.

COSTS AND COMPENSATION TO PARTICIPANTS

There will be no cost to you for participating in this study, other than the time spent and your travel to and from the study location. No payments will be made to you for being in this study. Compensation or medical treatments are not available from the study sponsor in the event that injury occurs associated with this study. If you need medical attention to address any injury or adverse effect resulting from this study, you may be responsible for medical costs related to office visits, emergency room visits if they happen, and cost for medications or treatment to address the issue. Medical insurance may not cover these costs your insurance provider has policies about participating in clinical research. You are advised to contact your insurance provider and ask about insurance coverage before you decide to participate in this study.

NEW INFORMATION

Sometimes during the course of a research project, new information becomes available about ways to reduce belly circumference. If this happens, your research doctor will tell you about it and discuss with you whether you want to continue in this study.
You may decide to withdraw at that time, and are free to do so. If you decide to continue in the study, you may be asked to sign an updated consent form. Also, on receiving new information your research doctor might consider it to be in your best interests to withdraw you from the study. He/she will explain the reasons if this happens.

AUTHORIZATION FOR USE OF YOUR PROTECTED HEALTH INFORMATION

Signing this document means you allow us, the researchers in this study, and others working with us to use some information about your health for this research study.

This is the information we will use and include in our research records:

- Demographic and identifying information like name, address, telephone number, and email address.
- Related medical information about you like personal and family medical history, allergies, current and past medications or therapies, and information from physical examinations, such as weight, height, blood pressure reading, and heart rate.
- All tests and procedures that will be done in the study

How we will protect and share your information:

- We will do everything we can to keep your information private but we cannot guarantee this. Study information will be kept in a secured manner and electronic records will be password protected. Study information may be stored with other information in your medical record. Other doctors, nurses, and third parties (like insurance companies) may be able to see this information as part of the regular treatment, payment, and health care operations of the hospital. We may also need to disclose information if required by law.

- However, if you disclose information that gives study staff a reason to believe that a child or disabled or elderly adult has been subjected to abuse or neglect, study staff will report that information to Child Protective Services, Adult Protective Services, or the nearest law enforcement agency to the extent required by law.

- There are some cases in which a researcher is obligated to report issues, such as serious threats to public health or safety, or to yourself. If such evidence is disclosed or obvious to the study staff, that information will be reported.

- In order to conduct this study and make sure it is conducted as described in this form, the research records may be used and reviewed by others who are working with us on this research:
    - Members of the research team;
    - The University of Utah Institutional Review Board (IRB), who reviews research involving people to make sure the study protects your rights;
    - The study sponsor: CAO Group, Inc.
    - The U.S. Food and Drug Administration

- If we share your identifying information with groups outside of [redacted], they may not be required to follow the same federal privacy laws that we follow. They may also share your information again with others not described in this form.

- A description of this clinical trial will be available on **http://www.ClinicalTrials.gov**, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

- If you do not want us to use information about your health, you should not be part of this research. If you choose not to participate, you can still receive health care services from your primary care physician.

What if I decide to Not Participate after I sign the Consent and Authorization Form?

You can tell us anytime that you do not want to be in this study and do not want us to use your health information. You can also tell us in writing. If you change your mind, we will not be able to collect new information about you, and you will be withdrawn from the research study. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research.

This authorization does not have an expiration date.

You have a right to information used to make decisions about your health care. However, your information from this study will not be available during the study; it will be available after the study is finished.

CONSENT:

I confirm that I have read this consent and authorization document and have had the opportunity to ask questions. I will be given a signed copy of the consent and authorization form to keep.

I agree to participate in this research study and authorize you to use and disclose health information about me for this study, as you have explained in this document.

_____
Participant's Name

_____ _____
Participant's Signature Date

_____
Name of Person Obtaining Authorization and Consent

_____ _____
Signature of Person Obtaining Authorization and Consent Date