A Cohort Study of Weight Loss and Gliosis

NCT0357887

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UNIVERSITY OF WASHINGTON
CONSENT FORM – Pandemic alternate
WEB Study – Weight Effects on Brain Health Study

[redacted] [redacted] [redacted] [redacted]

24-hour emergency telephone number: [redacted]

Researchers' statement

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent." We will give you a copy of this form for your records.

PURPOSE OF THE STUDY

A new, higher "set point" (the weight the body fights to maintain) seems to occur after people gain weight. In this study, we will study the brain's role in this "set point" and observe changes in the brain that may occur following obesity treatment. We will include three groups in the study: people undergoing weight loss surgery, people participating in a behavioral change and weight loss program and people who are not undergoing weight loss.

STUDY PROCEDURES

You will participate in the research study over about 18 months. We will contact you to schedule all study visits. All study visits will take place at UW South Lake Union (SLU). All study participants will participate in all of the visits described below. Not all procedures may be carried out due to pandemic related restrictions. Table 1 applies to Behavioral Weight Loss (BWL) participants and Healthy Weight Control (HWC) participants. Table 2 applies to Surgical Weight Loss (SWL) participants.

Table 1 (BWL and HWC)		

Visit type	Length of visit	Procedures
In-person screening *if we cannot successfully draw blood at this visit, we will ask if you are willing to return on a different day for a brief blood draw. People in surgical cohort do not have in-person screening visit.	1-2 hours	Sign consent/HIPAA if not completed remotely, body measurements, vitals, non-fasting blood draw. Questionnaires will be completed remotely. Physical exam or system review with study physician via phone or video call (Zoom) or in person if needed for BWL participants.
**Actigraph and ASA24 before or after Baseline visit	**	**
Baseline visit	About 6-8 hours	Fasting blood draw, body measurements, vitals, DXA, MRIs, snack and food served. Questionnaires will be completed remotely.
3-Month ASA-24	20-40 minutes	At approximately the 3-month time point (about 3-months after the Baseline visit), you will receive 3 unannounced 24-hour dietary recalls via email. Each dietary recall will take about 20-40 minutes to complete
Interim visit (BWL only if contacted to schedule. HWC will not have this visit.)	2-4 hours	Fasting blood draw, body measurements, DXA, MRI. Questionnaires will be completed remotely.
**Actigraph and ASA24 before or after 6-month visit	**	**
6-month visit	About 6-8 hours	Fasting blood draw, body measurements, vitals, DXA, MRIs, snack and food served. Questionnaires will be completed remotely.
12-month visit	2-4 hours	Fasting blood draw, body measurements, DXA, MRI. Questionnaires will be completed remotely.
18-month visit	2-4 hours	Fasting blood draw, body measurements, DXA, MRI. Questionnaires will be completed remotely.

wear activity monitor and complete dietary recall for 7 days before or after Baseline and 6-month visit

Table 2 (SWL)		
Visit type	**Length of visit**	**Procedures**
Baseline visit	2-4 hours	Sign consent/HIPAA if not completed remotely, body measurements, fasting blood draw, body measurements, vitals, DXA, MRI. Questionnaires will be completed remotely.
**Actigraph and ASA24 after Baseline visit	**	** These procedures may not occur if on surgical prep diet and/or if the baseline visit is too close to the date of surgery (for example, if surgery is only a few days after Baseline).
Interim visit	2-4 hours	Fasting blood draw, body measurements, DXA, MRI. Questionnaires will be completed remotely.
3-Month ASA-24	20-40 minutes	At approximately the 3-month time point (about 3-months after the Baseline visit), you will receive 3 unannounced 24-hour dietary recalls via email. Each dietary recall will take about 20-40 minutes to complete
**Actigraph and ASA24 before or after 6-month visit	**	**
6-month visit	2-4 hours	Fasting blood draw, body measurements, vitals, DXA, MRI. Questionnaires will be completed remotely.
12-month visit	2-4 hours	Fasting blood draw, body measurements, DXA, MRI. Questionnaires will be completed remotely.
18-month visit	2-4 hours	Fasting blood draw, body measurements, DXA, MRI. Questionnaires will be completed remotely.

wear activity monitor and complete dietary recall for 7 days before or after Baseline and 6-month visit

Visit types

Screening Visit: BWL and HWC participants only. You will come to the UW South Lake Union for a visit (about 1-2 hours) to meet with research staff. If you have not already signed the consent form, you will have the opportunity to ask questions and sign the consent form. Staff will measure vitals (blood pressure, heart rate and temperature), height and weight, and you will have a non-fasting blood draw. We may ask you to return on an additional day for the blood draw if we could not successfully draw blood at the screening visit after a few attempts. Only participants who could not have their blood drawn will be asked if they are willing to return. Eligibility for the study is in part based on results from this blood draw. We do not offer additional compensation for this brief visit. If you are unwilling to return for the screening blood draw, you will not be able to continue with the study.

Questionnaires will be administered by REDCap or email before or after this visit. We may view information from your medical record to determine if you are appropriate for the study and can participate safely in all study procedures (applies to participants undergoing bariatric surgery only). A study physician will conduct a review of systems by phone call or video call (Zoom) prior to your start in the intervention if you are in the intervention group. If further restrictions apply, some of these procedures may be omitted.

We may try to confirm how your body fits in the MRI scanner with a mock scanner at the screening visit. The MRI does not accommodate all body shapes/sizes. If having an MRI is not possible due to fit, or for other reasons, you will not continue with any further study procedures.

The following will occur as part of screening:

□ Sign consent (if have not already)

□ Non-fasting blood draw

□ Body measurements

□ Vitals

□ Questionnaires (remotely)

□ Physical exam or system review (remotely or in person, BWL only)

Actigraph and ASA24 before or after Baseline and 6-month visit:
If eligible, you will receive an Actigraph, a watch-like activity meter worn on the wrist, to wear for 7 days and then return it to the study staff. The Actigraph and associated materials will either be mailed or handed to you at your Baseline and 6-month visit. You will be asked to record some information on paper logs about activity. You will also receive 3 unannounced 24-hour dietary recalls via email. Each dietary recall will take about 20-40 minutes to complete. Some SWL participants may not complete these tasks around Baseline visit.

Baseline and 6-month Study Visit: Each visit lasts about 6-8 hours for BWL and HWC groups; these visits last 2-4 hours for SWL participants. Research procedures include DXA scan, fasting blood draw, measurements such as weight, waist and hip, neck (at Baseline visit only), vitals (blood pressure, heart rate and temperature), questionnaires, and an MRI. BWL and HWC will have a snack following the MRI, then a second MRI, followed by lunch. SWL participants have

one MRI and no food will be served. If further restrictions apply, some of these procedures may be omitted.

If you are in the Behavioral Weight Loss cohort or the Surgical Weight Loss cohort, you will receive a smart scale at the Baseline visit. You will get to keep the scale. You will be asked to weigh yourself daily in the morning after urinating and defecating, and before eating or drinking. Your weights will be transmitted to study staff. You will be notified by email or in person when we will no longer receive your weights (this will happen at some point before your last study visit).

The 6-month visit occurs after the Interim visit.

Procedures included in Baseline and 6-month visit:

□ Fasting blood draw

□ Body measurements

□ Vitals

□ Questionnaires (administered via REDCap or email before or after visits)

□ DXA scan

□ MRI

□ Snack and meal (BWL and HWC only)

□ Receive scale (Baseline Visit only, Behavioral Weight Loss or Weight Loss Surgery cohorts)

□ Receive Actigraph, logs (if mailed ahead of time, will return at visit)

At approximately the 3-month time point (about 3-months after the Baseline visit), you will receive 3 unannounced 24-hour dietary recalls via email. Each dietary recall will take about 20-40 minutes to complete.

□ ASA24/dietary recall (3 unannounced recalls sent via email)

Interim Visit: You may be asked to come for an additional visit at some point between the Baseline and 6-month visit if you are in the BWL group. SWL participants will have this visit. HWC participants will not have this visit. The visit lasts about 2-4 hours and includes measurements such as height, weight, waist, hip, a fasting blood draw, MRI and DXA scan. This visit will occur about 2 weeks to 3-5 months after baseline. If further restrictions apply, some of these procedures may be omitted.

Procedures that will occur as part of this study visit:

□ Fasting blood draw

□ Body measurements

□ Vitals

□ Questionnaires (administered via REDCap or email before or after visits)

□ DXA

□ MRI

12 and 18-month Study Visits: This visit is similar to Interim Visit in length and procedures. We will take waist and hip measurement and vitals at 18-month visit. At 18-month visit, vitals (blood pressure, heart rate and temperature) will be measured.

□ Fasting blood draw

□ Body measurements

□ Vitals

□ Questionnaires (administered via REDCap or email before or after visits)

□ DXA

□ MRI

Specific information about study procedures

Physical examination. Height, weight, waist and hip circumference, and vital signs (blood pressure, heart rate/pulse, temperature) will be obtained. A physical examination may be performed by study staff and/or physicians at the Baseline visit, or conducted by phone call/video call (Zoom) check-in before starting the intervention if you are in the intervention group.

Body composition.
You will change into scrubs for the DXA scan (special x-ray that gives information about density of your body tissues). DXA scan: Dual energy xray absorptiometry (or DXA) is a special x-ray that measures your percent body fat. You will be asked to remove all of your clothes except your undergarments and change into hospital pants and gown. If you are a woman who could become pregnant, you will have a pregnancy test before your DXA scan. Height and weight will be measured and then you will lie down on the DXA table. A total body scan will be performed which takes 5-10 minutes. The time to complete the DXA scan procedure should be about 30 minutes.

Questionnaires. You will be given questionnaires which will ask you questions about demographics, eating and weight, physical activity, sleep, your feelings and emotions, and your health history. We will ask questions such as “Do you go on eating binges though you are not hungry?” or “What is the most you have ever weighed?” You may refuse to answer any question or item in any test, inventory, questionnaire or interview if you do not wish to answer. Time to

complete questionnaires should be about 15-20 minutes. Questionnaires will be presented to you before or after study visits by a link to REDCap or emailed to you.

Fasting and Meals: You will fast for at least 10 hours overnight until the morning of your visit. You may drink water during this time. Between the MRIs you will be given a snack. You will have 15 minutes to finish it entirely. At the end of your visit, you will be allowed to eat freely from food we provide. SWL participants will not be served food.

Physical Activity. You will wear a watch-like device for 7 days (ActiGraph), day and night, for at least 10 hours per day. This will provide information about time spent being active.

Dietary Intake. You will be emailed links to a dietary recall on 3 separate occasions (leading up to or the week following the Baseline visit, at the 3-month time point, and leading up to or the week following the 6-Month visit). It can take 20-40 minutes to complete each recall. You will provide details about all food eaten.

MRI: For BWL and HWC participants, MRIs on Baseline and 6-month visit days will take about 90 minutes (two scans, with a break between). For SWL participants, there is only one MRI scan at Baseline and 6-month visits that lasts about 30-45 minutes. MRIs on other days will take about 30 minutes. You will change into scrubs before entering the scanner. No contrast will be administered to you. MRI screening will be repeated by study staff and MRI Technician. The MRI lab will retain the screening form for 2 years with name and date of birth. Then the form will be destroyed. Due to facility requirements, the MRI lab will collect your name and contact information for contact tracing purposes. This information will be collected and will be kept for about a month and then destroyed.

Blood draw: The screening visit blood draw is non-fasting. For all other visits, you will fast as instructed for about 10-12 hours overnight. The blood draw procedure takes a few minutes, but there is occasionally a short wait to see the phlebotomist, so the procedure including wait time could be about 30-45 minutes. Over the course of the study, about 157 mL (~ 32 teaspoons) of blood will be collected (see table below for amount drawn for each visit). The blood volume includes a tube of whole blood to be kept frozen for potential future use. This sample could be used to examine obesity related genetic markers that are known or emerge.

Visit type	**Blood volume drawn** *** an additional 30 mL may be drawn at any or all of the visits below.**
In-person screening *(BWL, HWC only)*	about 7 mL (~2 teaspoons)
Baseline visit	about 40 mL (~8 teaspoons)
Interim visit	about 25 mL (~5 teaspoons)
6-month visit	about 35 mL (~7 teaspoons)
12-month visit	about 25 mL (~5 teaspoons)
18-month visit	about 25 mL (~5 teaspoons)

Behavioral Weight Loss Group ONLY

Dietary Intervention: This applies only to subjects participating in the Behavioral Weight Loss group. The intervention will take place over 6 months at Fred Hutchinson with research staff. Due to the pandemic, the intervention will take place by videoconference (Zoom). If allowed, some sessions may take place in person. There will be a combination of about two one-on-one visits that will last 1 to 1.5 hours, between you and the interventionist, and about 20 weekly/every other week group meetings that will last about one hour, and monthly phone calls/emails with nutrition staff/interventionist, which will last about 15 minutes.

The interventionist will lead a class over a 6 month period. The course material will consist of a modified version of the Diabetes Prevention Program with energy restriction following clinical guidelines for obesity management. You will learn how to set personal goals for energy intake and physical activity. In weeks 2–12, you will meet weekly with the registered dietician/interventionist in groups of up to 15 participants. Groups will then meet approximately every other week to cover the remaining sessions (about 6 sessions). Your physical activity will increase to 2.5–3 hours per week of moderate intensity physical activity.

Session type	**# of sessions**	**Length of session**
Individual session	1-2 sessions	1-1.5 hours
Group sessions	10-12 weekly sessions followed by about 6 sessions, every other week.	About 1 hour
Individual phone, email, in-person meetings, if needed	Throughout 6-month intervention, if needed	About 15 minutes in length

Prior to starting the Behavioral Weight Loss program, you will have a brief physical exam or consult by phone or video call (Zoom) with a study physician. The physician will review health systems or check your heart, lungs, endocrine and neurological systems. If an abnormality is found, the physician will recommend you follow-up with your primary care physician. If the abnormality indicates a serious condition that would make it unsafe for you to participate in the Behavioral Weight Loss program, you would not participate any further in the study.

RISKS, STRESS, OR DISCOMFORT

1. *Risks of Participating in Behavioral Intervention*: You may experience embarrassment or discomfort from discussing personal information about food, eating habits, body image, or exercise. Dietary change, exercise, and weight loss may pose special risks for those with specific comorbid medical conditions. There is some risk to initiating an exercise program, including revealing unknown health or cardiac disease or becoming injured. Making lifestyle changes can be difficult and frustrating, and weight regain after an intervention can be discouraging.

2. *Study Procedures.* Potential risks include 1) anxiety and embarrassment as a result of completing the medical history, physical examination, or other self-reported measures; disappointment if

unable to undergo MRI; 2) pain, minor injury (bruising), or the development of a localized inflammation (thrombophlebitis) or risk of infection from obtaining blood samples. Occasionally people feel faint or nauseous during blood draw; 3) intake of a mandatory amount of a standardized snack that may in rare cases cause discomfort, nausea, vomiting, or a reaction from an unidentified food allergy or sensitivity (does not apply to SWL group); and 4) discomfort from hunger due to fasting or hypoglycemia due to fasting.

DXA scan: There are some risks from the DXA scan you will undergo during this study. This scan will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called "background radiation." A "millisievert" (mSv) is a unit used to measure doses of radiation. The radiation dose to your whole body from your DXA scan will be less than 0.01 mSv. The risk of harm from this amount of radiation is very low. If you have more procedures that expose you to radiation, this risk will go up. The radiation from x-rays and scans may be harmful to a fetus. If you are a woman who could become pregnant, you must have a pregnancy test done before your DXA scan. If you are pregnant you may not take part in this study.

3. *Symptomatic Hypotension:* Weight loss may reduce blood pressure.

4. *MRI scanning*. The risks associated with MRI are extremely low, and no invasive procedures or intravenous contrast agents are included in this procedure. Because the MRI machine uses a very strong magnet, you may not participate if you have any metal objects in your body or other conditions that would make you ineligible for an MRI scan. You must remove items like credit cards, watches, metallic jewelry, and hair clips. You may feel "closed in" or claustrophobic while in the scanner. Lying still for an hour may be uncomfortable. You could feel embarrassment if your body shape is a tight fit or not conducive to fitting in the MRI. Headphones and earplugs are provided to protect your hearing. There will be no cost to you or your insurance company for the MRI scans done specifically for this study. The scans will be paid for by the study. However, if an incidental finding occurs, you may experience anxiety, and additional procedures or costs could be incurred.

5. *Breach of confidentiality*. The potential risk of DNA analysis and financial risks associated with participating in this study are due to the potential of any health information being disclosed to health or life insurance companies or to current or potential employers. While this is a potentially serious risk, it is very unlikely, as we will keep all personally identifiable information physically separate from all health information. All information will be on password-protected computers or in locked file cabinets in locked offices.

ALTERNATIVES TO TAKING PART IN THIS STUDY

Participation in research studies is voluntary. You do not have to participate in this study. You could participate in a weight loss program independent of the study.

BENEFITS OF THE STUDY

Your participation could lead to advances in understanding why set points occur and what makes treating obesity a challenge. If you are participating in our weight loss intervention, you may have health benefits as a result of your participation.

SOURCE OF FUNDING

The study team and the University of Washington is receiving financial support from the National Institutes of Health (NIH).

CONFIDENTIALITY OF RESEARCH INFORMATION

All of the information you provide will be confidential. However, if we learn that you intend to harm yourself or others, we must report that to the authorities.

Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

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.

We have a Certificate of Confidentiality from the federal National Institutes of Health. This helps us protect your privacy. The Certificate means that we do not have to give out information, documents, or samples that could identify you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- a member of the federal government who needs it in order to audit or evaluate the research;
- individuals at the institution(s) conducting the research, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
- the federal Food and Drug Administration (FDA), if required by the FDA;
- individuals who want to conduct secondary research if allowed by federal regulations and according to your consent for future research use as described in this form;
- state or local authorities, if we learn of child abuse, elder abuse, or the intent to harm yourself or others.

The Certificate expires when the NIH funding for this study ends. Currently this is 6/30/2023. Any data collected after expiration is not protected as described above. Data collected prior to expiration will continue to be protected.

OTHER INFORMATION

You may refuse to participate and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled. If you wish to withdraw, please contact the researcher listed on page 1 of this consent form.

If a screening x-ray is required prior to the MRI you could pay up to several hundred dollars. The study cannot pay for this procedure.

If an abnormality in labs or MRI is discovered the Principal Investigator/study physician will contact you and advise you to see a physician to follow up on the abnormal finding.

For subjects participating in Behavioral Weight Loss Program: we will likely contact your primary care physician in writing to inform them you are participating in a weight loss program. Study physicians will be available to your physician to answer questions or provide information about the program if needed.

We will store your data and blood samples for future use with the study ID assigned to you. We may obtain your DNA from your stored blood sample.

You may be paid up to $500 in gift cards or checks for your participation in the study: $25 for the screening visit and up to $475 for completing study visits. You will receive $150 after completing the Baseline visit, $50 for Interim visit (not all participants have this visit), $150 after completing the 6-month visit, $50 for completing the 12-month visit, and $75 after completing the 18-month visit. For SWL participants, screening visit payment will be added to your Baseline payment and you will receive payment after the Baseline visit.

Visit Type	Payment
Screening	$25
Baseline Visit	$150
Interim Visit (SWL, BWL if contacted to schedule, not HWC)	$50
6-Month Visit	$150
12-Month Visit	$50
18-Month Visit	$75

We will collect your Social Security Number as required by the University of Washington for payments greater than $50 made to research participants. This will be reported to the financial administration at the University of Washington at the end of the year for tax purposes.

A copy of the consent form will be emailed to you at an email address that you provide. It will be a “PDF” document. Most computers already have PDF viewer software installed, which will allow you to open, read, or print the consent form. The email we send you will include a link to PDF viewer software (such as Adobe Acrobat Reader) in case your computer doesn’t already have it. If you would prefer to receive a paper copy of the consent form at no cost to you, please contact the researcher listed on page 1 of this consent form.

RESEARCH-RELATED INJURY

If you think you have a medical problem or illness related to this research, contact [redacted] right away. She will treat you or refer you for treatment.

If you are injured as a result of being in this study, necessary medical treatment will be offered at a UW Medicine facility.

The costs of the treatment may be billed to you or your health insurance just like other medical costs, or it may be covered by the UW's discretionary Human Subjects Assistance Program (HSAP), depending on a number of factors. The researcher may request HSAP coverage by following established procedures. If you wish to request HSAP coverage yourself, contact the researcher or the UW Human Subjects Division at [redacted] or 2[redacted]. You may also call collect to the UW Human Subjects Division at [redacted] if you do not otherwise have access to a telephone. Ask the researcher if you would like information about the limits and conditions of the HSAP. The UW does not normally provide any other form of compensation for injury. However, the law may allow you to seek payment for injury-related expenses if they are caused by malpractice or the fault of the researchers. You do not waive any right to seek payment by signing this consent form.

Printed name of study staff obtaining consent Signature Date

Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. If I have questions about my rights as a research subject, I can call the Human Subjects Division at [redacted] or call collect at [redacted]. I give permission to the researchers to use my medical records as described in this consent form. I will receive a copy of this consent form.

I give permission to be contacted in the future to ask for additional information.

□ Yes

□ No

I give permission to have my DNA saved and used in current and future research.

□ Yes

□ No

Printed name of subject Signature of subject Date

Copies to: Researcher
Subject