Official Title of Study: Exercise and Nutritional Prehabilitation

NCT# Pending

IRB ID#: 2072911

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Attached is the most recent IRB approved informed consent form.

Sincerely,

Marianne Abouyared, M.D.

Department of Otolaryngology Head and Neck Surgery

University of California, Davis School of Medicine

Title of research study: Exercise and Nutritional Prehabilitation for head and neck cancer patients

Investigator: Marianne Abouyared MD

California Experimental Subjects Bill of Rights

- Someone will explain this research study to you, including:
  - The nature and purpose of the research study.
  - The procedures to be followed.
- Any common or important discomforts and risks.
- Any benefits you might expect.
- Whether or not you take part is up to you.
- You can choose without force, fraud, deceit, duress, coercion, or undue influence.
- You can choose not to take part.
- You can agree to take part now and later change your mind.
- Whatever you decide it will not be held against you.
- You can ask all the questions you want before you decide.
- If you agree to take part, you will be given a signed and dated copy of this document.
- If you agree to take part, you will be given a copy of this document.

Key Information about This Research Study

You are invited to take part in a research study. The purpose of this research is to access the safety and acceptability of using a prehabilitation program before head and neck cancer surgery. You are invited to be in this study because you have been recently diagnosed with head or neck cancer and may benefit from an exercise and nutrition program before surgery. Your participation in this research will include three study visits, two phone calls and will last about 3 months. We expect about 20 people at UC Davis to take part in this research.

Being in this study will involve signing an informed consent form, measuring your grip strength and skinfold thickness, measuring your ability to complete a 6-minute walk test, a timed test to stand up from a chair and walk 10 feet away and then return and sit back in the chair, complete questionnaires, complete a 2-week home based exercise and nutritional program prior to surgery. All research studies have some risk. Risks of this study are minimal. These risks are described in detail later in this document. There is the possibility that you may benefit from participation in this study.

Here are some reasons you may not want to be in this research: You may find the exercise protocol too difficult or time consuming. You may not have the time to complete the exercises daily as requested by the study protocol. You may have pain or discomfort related to the exercises that result in you not completing the exercises.

Your participation in this study is voluntary. You do not have to be in this study if you do not want to. While there currently is no other standardized prehabilitation program available to head and neck

cancer patients, you may choose to perform self-led exercise and strength-training prior to your surgery.

The rest of this form gives a more complete description of this study. Please read this form carefully. You can ask any questions you need to help you choose whether or not to join this study.

Information to help you understand research is online at https://research.ucdavis.edu/policiescompliance/irb-admin/for-research-participants/

What if I have Questions?

The person in charge of this study is Marianne Abouyared MD. If you have questions or concerns about this study, please contact the Lead Researcher, at (916) 734-2801.

For non-emergency issues you can call the UC Davis Health Hospital Operator (916-734-2011), tell the Operator you are in a research study and you wish to talk to Otolaryngology resident on-call. Someone is available to answer the operator line 24 hours a day. In the case of an emergency, dial 911 from any phone.

If you have any questions about your rights as a research subject or have complaints about the research study or study team, you may talk to a team member at the Institutional Review Board (IRB) by phone: (916) 703-9158, by email: hs-irbeducation@ucdavis.edu, or by mail: 2921 Stockton Blvd, Suite 1400, Room 1429, Sacramento, CA 95817. The IRB is a group of people who oversee research.

What happens if I say yes, I want to be in this research?

If you decide to join this research study, the researchers will ask you to complete the following procedures.

Visit 1: Baseline Screening

- You will sign the Informed Consent form
- Review study of Inclusion/Exclusion Criteria with study team
- Assessment of handgrip strength using a handgrip dynamometer on both hands
- Assessment of skinfold thickness using calipers on the back of your arm
- Weight & height measurement to calculate Body Mass Index (BMI)
- Baseline questionnaires about your physical, social, emotional, and functional well-being, assessing the physical function and quality of life after surgery and it will take you 10 minutes to complete them.
- Baseline physical assessment including Timed Up and Go and 6-Minute Walk Test (6MWT)
    - Timed Up and Go (TUG) is a 3 meter out-and-back walk (10 feet) beginning and returning to a seated position. This will be performed twice to obtain an average.

  - The 6MWT will be performed after a 10-minute rest period. You will walk between two marked areas for 6 minutes, study personnel recording time and number of "laps" and you will be informed of the time left after each minute passes.

- You will receive an exercise/nutritional log-book, exercise equipment (pedometer & resistance bands)
- You will receive instructional material for exercise prehabilitation and suggested nutritional macronutrient goals. Instruction will be provided either electronically or paper copy depending on your preference.

Once you are informed of you surgical date, you will be contacted and instructed by the study team of you exact "start" date for their prehabilitation 2-week program. Study exercise Physical Therapist will contact you to review the home based exercise program.

The study team will contact you briefly by phone 14 days and 7 days prior to surgery to review safety and compliance to the exercise program. Study team will also review standard of care laboratory reports.

Visit 2: Day of surgery

On the day of surgery, the following procedures will be done prior to surgery:

- Assessment of handgrip strength using a handgrip dynamometer
- Assessment of skinfold thickness using calipers on the back of your arm
- Weight measurement to calculate Body Mass Index (BMI)
- Complete a Day of Surgery Questionnaire
- Turn in exercise/nutritional log-book, exercise equipment (pedometer). You can keep the resistance bands provided.

Visit 3: End of Treatment 1 month after surgery (+/- 1 week)

- Assessment of handgrip strength using a handgrip dynamometer
- Assessment of skinfold thickness using calipers on the back of your arm
- Weight measurement to calculate Body Mass Index (BMI)
- Physical assessment including Timed Up and Go and 6-Minute Walk Test
- Questionnaires about your physical, social, emotional, and functional well-being, and quality of life after surgery and it will take 10 minutes to complete

Study Calendar

Metric	Visit 1 Pre-op Visit (Date of Head and Neck Cancer Diagnosis)	Begin Prehab (Surgery date minus 2 weeks)	Check-in Phone Call 14 days and 7 days prior to surgery by Study Team	Visit 2 Day of surgery	Visit 3 1-month post-op (± 1 week)
Informed Consent	X				
Review of Inclusion/Exclusion	X				
Handgrip strength	X			X	X
Skinfold thickness	X			X	X
Review of BMI	X			X	X
Review of labs[1]	X			X	
6 Minute Walk Test & Timed up & Go Test	X				X
Questionnaires	X			X	X
Compliance with program			X	X	
Adverse Events			X	X	X
Exercise & Nutritional Prehabilitation		X			

1. labs that are performed as standard of care will be reviewed by the study team.

How is being in this study different from my regular health care?

If you take part in this study, the main difference between your regular care and the study is that, if you take part in this study, you will participate in a 2-week exercise and nutrition program before the head and neck cancer surgery that you are receiving as part of your regular health care.

Do I have to be in this study? What if I say "yes" now and change my mind later?

No, you do not have to be in this study. Taking part in research is voluntary. You can choose to be in the study or not be in the study. If you decide to be in the study, you can choose to leave the study at any time.

If you decide not to take part in the study, or if you choose to leave the study, your choice will not affect any treatment relationship you have with healthcare providers at UC Davis Health or any services you receive from them. No matter what you decide, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

Please let the researchers know if you choose to leave the study. If you stop the exercise and nutritional program please contact the study team. We will ask you to come in for a final study visit to check your health.

Any data that is collected up to the point of withdrawal will not be used for research and it will be retained and destroyed at the end of the study.

What are my other choices if I do not take part in this study?

You do not have to be in this research study to get care for your head and neck cancer. You will still receive standard-of-care cancer treatment and surgery. There are currently no standard alternatives to achieve similar benefits of this prehabilitation program.

Can I be removed from the research without my OK?

The researchers may take you out of the study, even if you want to continue, if:

- your health changes and staying in the study is no longer in your best interest;
- you do not follow the study rules or you no longer meet the requirements to be in the study; or
- the study is stopped by the sponsor or researchers.

Is there any way being in this study could be bad for me?

There are risks to participating in this research. The study doctor and study team will monitor you to see if you are experiencing any harm related to your participation. If you experience any pain or discomfort, you must inform the study team as soon as possible.

- **Physical Risks:** Completing study assessments and the exercise program may lead to risk of injury, pain or discomfort but there is a low likelihood to occur and risks are minimal. This may include muscle strain or soreness, particularly if you are not used to performing resistance training. The resistance bands provided will be of light to medium weights and can be adjusted based on your comfort.
- There are no associated nutritional risks. This study will provide simple nutritional guidelines in terms of caloric and protein goals, but are not stringent or required.

As with all research, there is a chance of a breach of confidentiality (your personal information could be seen by people outside of the research study without your permission). To minimize the risks of breach of confidentiality, we will not include any information that directly identifies you on the specimens and information we collect, and on the data resulting from the research. Instead, we will

use a code on the information, and we will keep a link between the code and your identity in a different location.

Will being in this study help me in any way?

Being in this study may help you increase strength and stamina before surgery. There have been other studies with patients with different cancers (lung, colorectal, etc) that have shown a benefit from 2-weeks or prehabilitation prior to major surgery. Patients with increased muscle mass tend to tolerate treatment better. The study treatment may work better than the routine care for your condition, which does not include a standardized prehabilitation program. However, it is possible that there is no benefit to being in this study and there may be unanticipated side-effects of participating in exercises that you are not accustomed to. Even if the study does not help you directly, your taking part in this study may help other people in the future by helping us learn more about safety and acceptability of the exercise and nutrition program.

This study is not a substitute for your regular medical care. You should continue to see your regular medical providers.

Will being in this study cost me anything?

There will be no cost to you for the following tests: handgrip, skinfold thickness, 6-minute walk test, timed up and go test, questionnaires, exercise and nutritional program participation or use of pedometer or exercise bands that are done for research purposes only and are not part of your regular care. You will have to pay for basic expenses like any childcare, food, parking, or transportation related to study activities. You or your health plan will be billed for the costs of routine medical care you receive during the study. These costs may include operating room fees, pharmacy charges, treatments, hospitalization, scans, etc. You will be expected to pay for the usual deductibles and co-payments, and for any routine care that is not covered. Only the costs of research or experimental procedures, described above, will be paid by the study**.**

For more information about possible costs, please contact the research team. The research team can follow UC Davis Uninsured Non-Emergency Estimate Policy (Policy ID 1883) to work with their department and Decision Support Services to get you a cost estimate.

Will I be paid or receive anything for being in this study?

We will not pay you to take part in this study or pay for any out of pocket expenses related to your participation, such as travel costs.

Biospecimens (such as blood, tissue, or saliva) collected from you for this study and/or information obtained from your biospecimens may be used in this research or other research and shared with other organizations. You will not share in any commercial value or profit derived from the use of your biospecimens and/or information obtained from them.

What happens if I am injured or get sick because of this study?

If you are injured as a result of being in this study, the University of California will provide the necessary medical treatment. Depending on the circumstances, the costs of the treatment may be

covered by the University or the study sponsor or may be billed to your insurance company just like other medical costs. The University and the study sponsor do not normally provide any other form of compensation for injury. For more information about compensation, you may contact the IRB Administration at (916) 703-9151 or HS-IRBAdmin@ucdavis.edu.

What happens to the information collected for the research?

We will do our best to limit the use or disclosure of your personal information, including information from this research study and from your medical records, to people who need to review this information. We cannot promise complete confidentiality. Some organizations may be required to inspect and copy your information including the IRB and other University of California representatives responsible for the management or oversight of this study.

We have strict rules to protect your personal information and protected health information (PHI). We will limit who has access to your name, address, phone number, and other information that can identify you. We will remove identifiable information from the data we collect about you. After we remove all of the identifiers, we will place a code on the information. The code will be linked to your identity but the link will be kept in a location that is separate from your study data. We will maintain your study data on encrypted computers and access to the information will be limited to only members of the research team who need the access to properly conduct the study.

However, we cannot promise complete confidentiality. If you agree to be in this study, Federal or state laws may permit or require us to show information to university or government officials responsible for monitoring this study. We may also show your medical records to study monitors, auditors, the IRB, and the FDA. These groups are required to keep these records confidential. The following is a list of individuals who may access your records:

- Members of the research team
- Offices and committees responsible for the oversight of research

If you agree to participate in this research study, a signed copy of this consent document and the privacy authorization form may be filed in your electronic medical record (EMR) and your study participation may be added to your EMR. This information will be used for your care and treatment and for healthcare operations, which may include billing and payment. Federal and state privacy laws give patients the right to access information about their care and treatment contained in their medical record. During this study, you may not be able to access certain information related to this study in your EMR until the study is complete to ensure that the study remains unbiased. By consenting to participate in this study, you are also consenting to this possible temporary withholding of your research records.

We will access protected health information (e.g., your medical record) for this study and you will be asked to sign a separate form, commonly referred to as a HIPAA authorization, to give your permission. Your medical records may become part of the research record. If that happens, your medical records may be looked at by the sponsor of this study and government agencies or other groups associated

with the study. They may not copy or take your personal health information from your medical records unless permitted or required by law.

Federal law provides additional protections of your medical records and related health information. These are described in the UC Davis Health System Notice of Privacy Practices (http://www.ucdmc.ucdavis.edu/legal/privacy/) and in an attached document.

Will I receive any results from this research?

You will not receive any results from this research.

Will information or leftover specimens be used for other research?

We will use your information to conduct this study. Leftover data collected for this research may also be used for future research studies. We will not share any personally identifiable information. Our goal is to make more research possible. These studies may be done by researchers at this institution or other institutions, including commercial entities. Data may be placed in one or more external scientific databases for access and use. We will not ask you for additional permission to share de-identified information.

May we contact you by e-mail?

We are requesting your email address so we can contact you for scheduling and providing information purposes. Email is generally not a secure way to communicate about your health, as there are many ways for unauthorized users to access email. You should not send sensitive, detailed personal information by email. Email should also not be used to send urgent information. If you need to talk to someone right away, please contact Marianne Abouyared, Principal Investigator, 916-734-2801. You do not have to give your email address to be in this study. Please initial one of the lines below.

_____ Yes, you may use email to contact me for this study.

My email address is: _____

_____ No, I do not want to be contacted by email.

Do not write below this line. For IRB stamp and version date only.

APPROVED by the Institutional Review Board at the University of California, Davis	
Protocol	APPROVED
2072911	November 28, 2023

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

[Add the following block if a witness will observe the consent process. E.g., short form of consent documentation or illiterate subjects.]

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

Signature of witness to consent process	Date
Printed name of person witnessing consent process	

Do not write below this line. For IRB stamp and version date only.

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