Title: Personalized Targeted Nutrition Via StructurEd Nutrition Delivery Pathway to Improve Resilience in Older Adult Trauma

NCT number: NCT05544162

Document date: 8/23/2023

DUKE UNIVERSITY HEALTH SYSTEM

**Consent to Participate in a Research Study**
Personalized Targeted Nutrition via StructurEd Nutrition Delivery Pathway to Improve Resilience in Older Adult Trauma Patients (SeND Home)

CONCISE SUMMARY

The purpose of this study is to test a pilot program called SeND Home for older adult trauma patients to see if it is feasible, acceptable to patients, and can help improve outcomes after hospitalization for trauma.

If you decide to take part in this study, you will be randomly assigned to the SeND Home program or standard of care. For every four subjects enrolled, 3 will be randomized to SeND Home program, and one to standard of care. If you are assigned to the SeND Home program you will receive oral nutrition supplements (Ensure shakes) up to 3 times per day while you are in the hospital and for 4 weeks after discharge. Some patients will be asked to participate in an interview after being discharged from the hospital. If you are assigned to standard of care you will receive normal nutrition recommendations from your clinical providers. Participants in both groups will undergo non-invasive tests that measure how much energy (calories) you are using, your body composition, and muscle mass. You will also be asked to complete walking and strength tests, and surveys about your quality of life while in the hospital and at a 3 month follow-up visit. We will also collect your information from your medical record.

Risks associated with the walking and sit-to-stand tests include shortness of breath, fatigue, and muscle soreness. Muscle soreness may also occur after completing the strength tests. Risks associated with this study include those associated with Ensure. These include upset stomach, loose stools, and constipation. There are additional risks if you have diabetes or kidney disease. These are described in the Risk section of this consent form.

If you are interested in learning more about this study, please continue reading below.

You are being asked to take part in this research study because you are an adult 60 or older who has presented to Duke University Hospital with a traumatic injury or illness.

Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask them to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below. Please tell the study doctor or study staff if you are taking part in another research study.

DUKE UNIVERSITY HEALTH SYSTEM

**Consent to Participate in a Research Study**
Personalized Targeted Nutrition via StructurEd Nutrition Delivery Pathway to Improve Resilience in Older Adult Trauma Patients (SeND Home)

A grant from the Duke Center for Aging will sponsor this study. Portions of Dr. Krista Haines' and her research team's salaries will be paid by this grant. Abbott Nutrition is supplying the oral nutrition supplements for this study.

**WHO WILL BE MY DOCTOR ON THIS STUDY?**
If you decide to participate, Dr. Krista Haines will be your doctor for the study and will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

**WHY IS THIS STUDY BEING DONE?**
Trauma can impact older adults in a variety of ways that can affect how their care is managed. Current data shows that trauma patients can experience problems with physical function, muscle weakness, and poor quality of life after they are released from the hospital. This study is to test a pilot program called SeND Home for older adult trauma patients to see if it is feasible, acceptable to patients, and can help improve outcomes after hospitalization for trauma.

**HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?**
Approximately 40 people will take part in this study at Duke.

**WHAT IS INVOLVED IN THE STUDY?**
If you agree to be in this study, you will be asked to sign and date this consent form.

You will be randomly assigned, like pulling numbers from a hat, to the SeND Home program or routine care. For every 4 people enrolled, 3 will be assigned to the SeND Home program and 1 will be assigned to routine care.

Standard of Care Program
You will receive standard nutrition delivery as determined by your clinical providers. Upon discharge you will be sent home with standard nutrition information.

SeND Home Program
Once it is determined by your treating physicians that you are able to have a liquid diet or more, you will begin receiving oral nutrition supplements in the form of Ensure shakes. You may be given these supplements up to 3 times a day. The amount you receive will be determined by a clinical dietitian involved with this study based on the non-invasive FDA evaluated indirect calorimetry test. If your clinical dietician determines a different nutritional supplement is better for you then you will be excluded from this study.

DUKE UNIVERSITY HEALTH SYSTEM

**Consent to Participate in a Research Study**
Personalized Targeted Nutrition via StructurEd Nutrition Delivery Pathway to Improve Resilience in Older Adult Trauma Patients (SeND Home)

At the time you are discharged from the hospital you will be given 4 weeks' worth of nutrition supplement/shakes.

You may be asked to participate an interview with a trained interviewer from Duke University. Not all research participants will be asked to be interviewed. These interviews may be done in-person or via phone. Interviews will occur around 3 weeks after you leave the hospital. Each interview will last about 1 to 1.5 hours. We would like to record the interview. This is so we can remember what you said. If you do not want to be recorded, we can take notes instead. A Duke-approved company called GMR Transcription will make a written record of the interview. We will remove any information that could identify you from the written record. The recording and written record will be stored securely at Duke University and GMR, and not shared with anyone who is not part of this research.

**The following information in this section describes tests being done for all patients enrolled in this study, regardless of what group you are assigned to.**

You will receive a phone call from a member of the study team at 2 and 4 weeks after you leave the hospital to discuss your how much you have been eating and drinking, your nutrition, and to provide any needed information or resources. You will be asked to return to Duke for a follow-up visit 3 months after you are discharged.
These tests are being done for the purposes of this research study and are not part of routine care.

- Indirect calorimetry (IC) will be used to determine how much energy you are using and therefore, how many calories you need each day. You will be asked to wear a mask for the IC device to take samples of oxygen and carbon dioxide in order to calculate calorie needs. You will wear this mask for 10-20 minutes. This will be done every 3 days while you are in the Intensive Care Unit (ICU) and every 7 days once you are out of the ICU until you are discharged from the hospital.
- You will have a urine sample collected to measure your urinary nitrogen balance. This will be done every 7 days throughout your hospital stay.
- You will be asked to complete questionnaires about your symptoms and nutrition.

You will undergo the following tests as soon as possible after your hospital admission and on day 14 of your hospital stay or at discharge, whichever comes first. If you have the following tests within 2 days prior to your discharge they will not be repeated.

- Bioelectrical impedance analysis (BIA) will be used to measure your body composition and muscle mass. BIA uses bioelectrical impedance spectroscopy (BIS). The BWA 2.0 Body Water Analyzer will be the BIS device used to obtain BIA, and is a non-invasive test involving attaching

electrodes to the participant's fingers and ankles. These electrodes will be attached for approximately 5 minutes.

- Approximately ¼ teaspoon of blood will be drawn to look at your kidney function.
- Your muscle quality will be measured using ultrasound devices. Ultrasound is an imaging method that uses high-frequency sound waves to produce images of structures within your body. The ultrasound probes will be put on your quadricep (thigh) muscle. These ultrasounds should take less than 15 minutes to complete.

You will be asked to complete the following tests as soon as possible after hospital admission, at day 14 or hospital discharge, whichever comes first, and at your 3 month follow-up visit. If you have the following tests within 2 days prior to your discharge they will not be repeated. Questionnaires will not be completed at the day 14/discharge timepoint. If you are still hospitalized at day 21 you will undergo the physical assessments, but will not complete any study questionnaires.

If you are unable to complete this visit in-person you will be contacted via phone by the study team and asked if you are able to complete the visit virtually (via Zoom or other platform). If you cannot complete the visit virtually you will be asked to complete the study surveys via phone. If you have the capability to do a virtual visit, you will complete the study surveys and may complete some of the tests indicated below depending on your ability. The tests that may be done virtually are the Six Minute and 4-Meter walk tests and the 30 second Sit-to-Stand test.

- Six Minute Walk Distance Test: You will walk at your own pace and the distance walked in 6 minutes will be measured.
- 4-Meter Walk: You will walk for 4 meters (about 13 feet) at your normal pace and we will measure how fast you walk.
- 30 second Sit-to-Stand: A physical therapists will assist you with this test. You will sit in a straight-backed chair with your feet flat on the floor and shoulders-width apart. At the start of the test, you will be asked to stand. If successful, you will return to sitting and repeat the sit to stand sequence for up to 30 seconds. You will be allowed rest breaks if needed. Pain intensity will be recorded before, at approximate 10- second intervals, and at completion of the test.
- Grip Strength: You will be given a hand held hydraulic dynamometer (a device that measures force) and asked to squeeze as hard as you can for 2-3 seconds. You will do this 3 times with each hand. Strength measurements will be recorded.
- Quad Strength: A hydraulic dynamometer will be used on your calf. You will be asked to squeeze as hard as you can for 2-3 seconds. You will do this 3 times with each leg. Strength measurements will be recorded.
- Bioelectrical impedance analysis (BIA)
- Muscle Ultrasound

- PROMIS: You will be asked to complete this survey. It is an assessment of your pain intensity, pain interference, sleep disturbance, physical function, depression symptoms, anxiety symptoms, and social function.
- You will be asked to complete surveys about how well you can perform your daily activities and to measure your cognitive function, as well as your health and resilience.

All devices used to perform these tests have been evaluated by the Food and Drug Administration (FDA).

We will collect information from your medical record related to your ICU stay throughout your hospitalization. This may include, but is not limited to, your medical history, demographics, results of blood and imaging tests, nutrition information, and medications you are receiving.

**HOW LONG WILL I BE IN THIS STUDY?**
If you agree to be in this study, your participation will be for up to 3 months after you are discharged from the hospital. If you are hospitalized for longer than 3 weeks your participation will end after day 21 of your hospitalization.

You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

**WHAT ARE THE RISKS OF THE STUDY?**
Indirect calorimetry (IC) measures the exchange of gases from your lungs and it does not interfere with breathing. There are no anticipated side effects.

Possible side effects associated with the use of the muscle ultrasound and BIA are skin irritation, itching and redness from the electrode pads and ultrasound probe.

Risks associated with the walking and sit-to-stand tests include shortness of breath, fatigue, and muscle soreness. Muscle soreness may also occur after completing the strength tests.

Risks associated with taking Ensure include upset stomach, loose stools, and constipation. If you have diabetes there is a risk of hyperglycemia (high blood sugar) that may require insulin to manage. If you have severe kidney disease or renal insufficiency there is a risk of hyperkalemia (high potassium level in your blood).

DUKE UNIVERSITY HEALTH SYSTEM

**Consent to Participate in a Research Study**
Personalized Targeted Nutrition via StructurEd Nutrition Delivery Pathway to Improve Resilience in Older Adult Trauma Patients (SeND Home)

There is a risk of loss of confidentiality of your private information. Every effort will be made to protect your information, but this cannot be guaranteed.

There may be other risks that are unknown at this time.

**ARE THERE BENEFITS TO TAKING PART IN THE STUDY?**
If you agree to take part in this study, there is a potential benefit of improved nutrition for subjects randomized to nutritional supplementation but this is not guaranteed. It is hoped the knowledge gained from this study may improve future patient care and clinical outcomes.

**WILL MY INFORMATION BE KEPT CONFIDENTIAL?**
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be shared if required by law.

Your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives of the Federal Office for Human Research Protections (OHRP), the U.S. Food and Drug Administration (FDA), the National Institutes of Health (NIH), the Duke University Health System Institutional Review Board, and others as appropriate. If any of these groups review your research record, they may also need to review your entire medical record. In addition, the study supporter, Abbott Nutrition, may receive your de-identified data.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);
2) you have consented to the disclosure, including for your medical treatment; or
3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

DUKE UNIVERSITY HEALTH SYSTEM

**Consent to Participate in a Research Study**
Personalized Targeted Nutrition via StructurEd Nutrition Delivery Pathway to Improve Resilience in Older Adult Trauma Patients (SeND Home)

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

The study results will be retained in your research record for at least six years after the study is completed. At that time, either the research information not already in your medical record will be destroyed, or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your identity will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

**WHAT ARE THE COSTS?**
There will be no cost to you for your participation in this study. All nutrition supplements for those in the SeND Home program will be provided for free. Any testing done for research purposes will be paid for by the study.

**WHAT ABOUT COMPENSATION?**
You will be compensated $100 for completion of the 3 month follow-up visit.

The collection of your social security number by the Duke study team is required in order to set up payment. If you do not want to share your social security number you can still be in the study, but you will not be compensated.

**WHAT ABOUT RESEARCH RELATED INJURIES?**
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians, or the study supporter,

DUKE UNIVERSITY HEALTH SYSTEM

**Consent to Participate in a Research Study**
Personalized Targeted Nutrition via StructurEd Nutrition Delivery Pathway to Improve Resilience in Older Adult Trauma Patients (SeND Home)

Abbott Nutrition, to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. Krista Haines at 919-681-3784 during regular business hours and at 919-684-8111 and asked that she be paged after hours and on weekends and holidays.

**WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?**
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study no new data about you will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record. All data that have already been collected for study purposes, and any new information about an adverse event related to the study, will be maintained.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Haines or a member of the study team via phone or mail and let them know that you are withdrawing from the study. The mailing address is DUMC Box 2837, Durham, NC, 27710.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Your doctor may decide to take you off this study if your study doctor determines that it is no longer in your best interest to continue.

Your data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, is removed. If your identifying information is removed from your samples or data, we will no longer be able to identify and destroy them.

**WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?**
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Krista Haines at 919-681-3784 during regular business hours and at 919-684-8111 and asked that she be paged after hours and on weekends and holidays.

DUKE UNIVERSITY HEALTH SYSTEM

**Consent to Participate in a Research Study**
Personalized Targeted Nutrition via StructurEd Nutrition Delivery Pathway to Improve Resilience in Older Adult Trauma Patients (SeND Home)

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

**STATEMENT OF CONSENT**
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

| _____ | _____ | _____ |
|---|---|---|
| Signature of Subject | Date | Time |
| _____ | _____ | _____ |
| Signature of Person Obtaining Consent | Date | Time |