Official Title:Nutrition Education for Cardiovascular Disease Prevention in Individuals With Spinal Cord Injury
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ATRIUM HEALTH
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Nutrition Education for Cardiovascular Disease Prevention in Individuals with Spinal Cord Injury: A Randomized Controlled Trial

INTRODUCTION

Dr. Lieberman and his associates are asking you to participate in this research study of nutrition education in individuals with a spinal cord injury (SCI) at Carolinas Rehabilitation and Atrium Health. You are being asked to take part because you have a SCI. The purpose of this study is to evaluate if additional nutrition education can improve your diet, your nutritional knowledge, and some of your cardiovascular disease risk factors, like cholesterol, waist circumference, and blood sugar. You will be one of approximately 200 people involved at Atrium Health. You will either be placed in a group that will receive six nutrition education classes, or in a group that receives the usual care, which is one nutrition class.

HOW THE STUDY WORKS

After you sign a consent, you will be placed into either a group that receives six nutrition education classes, or a group that receives one nutrition class. Classes will be held in the classroom attached to the Carolinas Rehabilitation gym where the other SCI education classes are held and will last approximately one hour. You will also be scheduled to come back to the clinic at a convenient time for you. You will have to fast overnight. Your blood will be drawn, and several labs will be measured, including your cholesterol and blood sugar. You will also fill out a medical history questionnaire as well as a dietary questionnaire about what foods you eat. This should take approximately one hour. These questions and labs will be repeated approximately 12 months after you start the study. You will be compensated with $50 for your time.

RISKS

Blood Tests: Risks associated with blood drawing may include pain, bruising, and infection. Rarely, a person faint.

EXCLUSION CRITERIA

- pregnancy
- End-stage renal disease
- treatment for cancer except for non-melanoma skin cancer within the past five years, and chronic, nontobacco substance-abuse

- Stage III or IV pressure ulcer

BENEFITS

This study may or may not improve your condition. The information gained from your case may benefit others with your condition.

You will learn your cholesterol levels, your blood sugar and if you have diabetes or prediabetes, as well as some other cardiovascular disease risk factors.

ALTERNATIVE PROCEDURE/TREATMENT

You may choose not to participate in this study. This study does not offer any alternative treatments. All patients who come to Carolinas Rehabilitation will receive standard rehabilitation treatments whether they participate in this project.

ADDITIONAL COST

There are not any additional costs to you for participating in this study. The visit, blood test and procedures will not be charged to you or your insurance company.

COMPENSATION

If you are harmed as a result of your participation in this study, we will provide or arrange for treatment as necessary. This treatment, as well as other medical expenses, will be billed to you or your insurance company in the usual manner.

You will be given a total of $50 compensation at the completion of your time in the study for your time and travel required by participation in the study.

Greenphire is a company working together with Atrium Heath (AH) to manage the study participant payment process. You will be issued a Greenphire ClinCard, which is a debit card that your funds are loaded onto at the completion of each study visit. When a visit is completed, funds will be approved and loaded onto your card. The funds will be available within 2 business days and can be used at your discretion. You will be issued one card for the duration of your participation.

For Greenphire to be able to reimburse you via the ClinCard, Greenphire needs to collect certain information about you, including;

name
address
date of birth

email address (optional)
SSN
W9 or W8.

This information will be collected from you by AH teammates for the DART HT-3951 study.

All information is stored in a secure fashion on Greenphire's system. Your information will not be shared with any third parties and will be kept completely confidential. By signing this consent form, you consent to providing all the before mentioned personal information that is needed to set up the ClinCard payments. You agree that the information you provide is used by Greenphire to perform payments to you.

Your insurance company may not pay for research treatments. You may wish to discuss coverage with your insurance company before agreeing to participate in this research study.

WITHDRAWAL
Your participation in this study is completely voluntary. You should feel under no pressure to be in the study. If you decide not to be in the study that will not in any way harm your relations with your doctors or with Atrium Health. You are free to stop being in the study if you change your mind after entering it. This would not harm your relations with your doctors or Atrium Health.

We will tell you about new medical findings that may affect your willingness to continue in the study.

CONFIDENTIALITY:
The records of this study will be kept private. In any sort of report, we might publish, we will not include any information that will make it possible to identify a patient. Your record for this study may, however, be reviewed and/or photocopied by Atrium Health or by representatives of the Food and Drug Administration or other government agencies. To that extent, confidentiality is not absolute.

AUTHORIZATION
If you wish to take part in this clinical study, you will be asked to sign this consent form. It allows the study sponsor and the study investigator to collect, process and pass on to the sponsor organizations any relevant personal health information

collected from you during the study. These are activities routinely carried out during all clinical studies.

You have been told that personal information about you (including sensitive personal health information, such as your medical history and your racial/ethnic origin if relevant to the study) will be reviewed, collected on a computer database, stored in electronic or manual files, audited, and/or otherwise processed by:

- Dr. Jesse Lieberman, and research staff
- the study sponsor, the National Institute of Health
- regulatory or other governmental authorities of the United States and other countries,
- Atrium Health employees,
- other persons or agencies as required by law or allowed by federal regulations.

You have been told that your personal data are being collected and processed to:

- check your suitability to take part in the study,
- compare and pool treatment results with those of other subjects in clinical studies,

You have been told that your personal information may be processed within the U.S. or elsewhere in the world or transferred to or from the U.S. for review, processing and/or storage by an associated company or a carefully selected third-party organization. By signing this document, you explicitly consent to the transfer of your personal information, including sensitive personal information, collected during this clinical study, for review, processing and/or storage. Your personal health information may be further shared by the groups above. If shared by them, the information will no longer be covered by the Privacy Rule. However, the groups are committed to keeping your personal health confidential.

You may refuse this authorization to transfer your personal information. If you choose not to agree to this authorization, you might be ineligible to participate in the study. If you decide not to sign this authorization, that will not harm your relations with your doctors or with Atrium Health.

You have the right to inspect your medical record at any time. Your research record may be unavailable until the conclusion of the study. At that point, it will be available. Please speak with the study doctor if you desire to access your record.

You have been told whenever your personal information is processed; it will be kept confidential and secure, to the best of our ability. It will be used only for the purpose for which it was collected.

This Authorization does not have an expiration date. You have been told that according to the guidelines for good clinical practice, the study investigator and sponsor will keep your personal information for at least 6 years. If you do not withdraw this Authorization in writing, it will remain in effect indefinitely. If you wish to revoke authorization to use your personal information, you will notify the study doctor, Dr. Jesse Lieberman [redacted] in writing. Some of the data obtained from your record prior to your revocation may still be used if considered necessary for the study.

FINANCIAL INTEREST OF INVESTIGATOR

None of the doctors asking you to participate in this study have received or will receive money or other benefits for personal use from the study sponsor. However, the sponsor will give money or other benefits to a research fund, foundation, educational institution, or other organization with which the doctor or study staff is associated.

QUESTIONS

The researchers doing the study at Atrium Health are Drs. Lieberman, Dulin, Niemeier, and Hirsch. You may ask them any questions you have now. If you have questions later, you may contact the investigators at:

Department of Physical Medicine and Rehabilitation
Carolinas Medical Center
[redacted]

The Institutional Review Board is a group of people who review the research to protect your rights. If you have questions about the conduct of this study or about your rights as a research subject, you may call the chairperson of the Institutional Review Board of Atrium Health for information regarding patients' rights in a research study. You can obtain the name and number of this person by calling [redacted].

CONSENT

I have read the above information. I have asked any questions I had, and those questions have been answered. I agree to be in this study and authorize the use of my personal health information. Dr. Lieberman or his associates will give me a copy of this form.

_____ _____ _____
Patient [guardian] Print Name **Date** **Time**

_____ _____ _____
Patient [guardian] Signature **Date** **Time**

_____ _____ _____
Signature of Person Obtaining Consent **Date** **Time**

_____ _____
Investigator Signature **Date** **Time**

Identity of representative:
___Next of Kin
___Parent/Guardian
___Healthcare Power of Attorney