Consent forms should be printed the same day as date signed
Today's Date: 1/21/2021

1.0 Participant Informed Consent

Title of Study: Integrative Medicine for Hypermobility Spectrum Disorder (HSD) and Ehlers-Danlos (EDS) syndromes: A mixed-methods feasibility study

Principal Investigator: Douglas Hanes, PhD

Clinical Investigator: Kerry Schaefer, MD

Co-Investigator: Andrew Erlandsen, ND

Study Staff: Sara Guedry

Sponsor: Healthy Living Community

The National University of Natural Medicine (NUNM) and Healthy Living Community are conducting a research study called "Integrative Medicine for Hypermobility Spectrum Disorder (HSD) and Ehlers-Danlos (EDS) syndromes: A mixed-methods feasibility study."

2.0 What is the study about?

We are doing this study to see how a diet and personalized care may impact Hypermobile Spectrum Disorder (HSD) and Ehlers-Danlos syndromes (EDS), conditions in which people have unusually flexible joints. These conditions haven't been studied very much, and no one knows for sure how nutrition or personalized care might help with the conditions. We want to learn if changes to diet and addressing patients' needs on a personal level could be used to help the healthcare community better support people with HSD & EDS.

We are asking that you join our study. If you would like to participate, this form will go over your rights and your role in the study. We will also describe the study to you in person and answer any questions that you may have.

Please read the information provided to you below and ask any questions about anything you do not understand before you decide to join the study. You will be provided a copy of this form for your records.

We hope to recruit 20 participants total.

Participant's Initials: _____

Consenter's Initials: _____

In order to be eligible to participate in this study, you must meet the following requirements:

Inclusion Criteria

- You are in the age range of 18-65
- You have a Beighton score of 4 and above (hypermobility score where your joints are measured). We'll measure this at the visit.
- You are currently experiencing pain
- You are able to provide written informed consent
- You are willing to participate in personalized care and make dietary and lifestyle changes
- You are willing to attend one in-person visit and two virtual visits
- You have access to an electronic device for food-tracker use

You will not be eligible to participate in this study if any of the following apply to you:

Exclusion Criteria

- You are currently, or already a patient of Dr. Schaefer and Healthy Living Community
- You are pregnant or a lactating woman, or are planning pregnancy over the next 3 months
- You consume more than 14 (men) or 7 (women) alcoholic drinks per week
- You have a history of disordered eating or eating disorder
- You have a body mass index (BMI) that is considered underweight (<18.5)
- You currently are experiencing weight loss from metastatic cancer
- You are unable to make dietary or lifestyle changes
- You have made significant dietary changes, or have added new medications, or new exercise routines within the past 90 days

3.0 How long will I be in the study?

Your part in the study will last 9 weeks (around 2 ½ months).

4.0 What will happen in the study?

If you meet the eligibility requirements and consent to be in the study, you will be asked to adopt an anti-inflammatory food plan and make some minor modifications to your daily lifestyle, for a total of 9 weeks. In addition to today's **in-person visit, we will ask you to make two virtual**

(online) visits with the study staff. You will fill out some surveys about your eating, your quality of life, the healthcare you may have received, and your pain. You will track your daily meals using an app on your phone or website on your computer.

Your joint flexibility will be measured for all of your major joints (9). Your weight, height, and Body Mass Index will all be measured. We will calculate your daily energy needs based on your activity level, weight, and height to make sure that your food plan provides you the right amount of calories.

We will also ask for your previous medical history, age, sex, and gender. You will be attended to by a medical doctor that will make lifestyle recommendations and provide support in areas of your self-care and mental health.

Screening Visit

During the in-person screening visit:

- We will follow COVID-19 precautions to maintain physical distance. We will wear face masks, wash our hands, or use hand sanitizer before, during, and after the visit. We will ask that you also wear a face mask and wash or sanitize your hands.
- You will provide written consent and ask any questions that you may have about the study
- We will obtain range of motion measurements at your joints
- We will capture biological information about you such as your previous medical history, age, sex, and gender
- We will collect your BMI, weight, and height measurements
- We will document any other illnesses that you may be experiencing
- We will ask you to fill out surveys regarding your pain, well-being, and medical care you may have received
- We will ask you what medications or supplements you are currently taking for pain
- We will ask you questions about what you are doing for self-care and mental health and make recommendations for lifestyle changes to support your condition
- We will prescribe a food plan to you and discuss recommendations around foods that support your overall health
- We will provide meal plan flyers and ideas for achieving a healthful diet
- We will assist you in installing a food tracker app to your phone, instruct you how to use it and give you a guide
- We will distribute food surveys to be completed by you prior to your next visit

Estimated time to complete: 90 minutes

Telephone or email check-in (Week 2)

- The student researcher will call or email you and answer questions, provide support and solutions to any dietary challenges that you may be having.

Estimated time to complete: 15 minutes

Monthly Virtual Clinical Visit (Week 5)

- We will collect your food survey
- We will ask you about your medical symptoms
- We will collect your BMI, weight, and height measurements
- We will document any other illnesses you may be experiencing
- We will ask you to fill out surveys regarding your pain and well-being
- We will document your daily food intake that you record using a food tracker app
- We will ask you questions about how your lifestyle changes to support your condition are going, and what further support you might need for self-care and mental health
- We will ask you questions your food plan and discuss any further support you may need
- We will distribute food surveys to be completed by you prior to your next visit

Estimated time to complete: 90 minutes

Telephone or email check-in (Week 6)

- The student researcher will call or email you and answer questions, provide support and solutions to any dietary challenges that you may be having.

Estimated time to complete: 15 minutes

Monthly Virtual Clinical Visit (Week 9)

- We will collect your food survey
- We will ask you about your medical symptoms
- We will collect your BMI, weight, and height measurements
- We will document any other illnesses you may be experiencing

- We will ask you to fill out surveys regarding your pain, well-being, and medical care you may have received
- We will document your daily food intake that you record using a food tracker app
- We will ask you questions about how your lifestyle changes to support your condition are going, and what further support you might need for self-care and mental health
- We will ask you questions your food plan and discuss any further support you may need
- We will close out the study, and you can decide what food plan you want to follow, and lifestyle changes you want to keep

Estimated time to complete: 90 minutes

5.0 What if I have questions?

You can contact Sara Guedry at 503.662.2956, or eds@nunm.edu if you have questions about the study. Dr. Douglas Hanes is in charge of the study. You may also contact him at 503.552.1741 if you have questions about the study.

6.0 Do I have to be in the study?

You decide if you want to be in the study. Deciding not to take part will not affect your relationship with your Healthy Living Community or NUNM. If your health care provider is an investigator for the study, you may get a second opinion from another doctor not involved in the study.

You can leave the study at any time, and you do not have to give a reason. Leaving the study will not affect your relationship with Healthy Living Community or NUNM.

If you are an NUNM student or employee, this study is completely voluntary. Your decision to not participate or to leave the study will not affect your relationship with NUNM.

The study investigators may ask you to leave the study if it is in your best interest. The study investigator may ask you to leave the study if you do not follow the study rules.

7.0 What if I don't want to be in the study?

You can choose not to be in the study, and you do not have to give a reason. You can choose to talk to your doctor about other options and investigate outside resources on your own.

8.0 Are there any costs?

All study-related visits are free.

9.0 Will I be paid for being in the study?

You will not be paid for being in the study.

10.0 Are there any risks?

There is always a small risk of a breach of confidentiality to your personal health information. However, these risks have been addressed and minimized as much as is possible.

You will be told about any new information that may affect your willingness to participate in the study.

There is limited risk involved with the physical exam and surveys that we are asking that you complete. This could include muscle soreness or mild discomfort and pain. There could be risks that we are unaware of at this time.

The dietary changes involved in an anti-inflammatory food plan are regarded as safe and have been well studied for a variety of health conditions. However, any changes to your diet may increase the risk of digestive distress that may result in gas, bloating, or constipation.

It is possible that the food plan may initially be more expensive as you purchase new ingredients. However, the cost of many of these higher quality products might be offset by the money you might have spent previously on prepackaged or fast foods.

If you experience any side effects while on the study, please contact Dr. Kerry Schaefer at 971.231.4536 as soon as possible.

11.0 What if I feel I've been hurt by taking part in the study?

If you feel you have been injured or harmed by taking part in this study, please contact Dr. Douglas Hanes at 503.552.1741. If you feel you were harmed while taking part in this study, you may be treated at NUNM. However, NUNM does not offer to pay the cost of this treatment.

If you feel your rights have been violated or you have been harmed by this study, please contact the NUNM Institutional Review Board Chair, Dr. Richard Barrett, at 503-552-1758.

12.0 Are there any benefits?

Your participation will help us learn more about health research but will have very limited benefit to you.

13.0 Your privacy is important

The Health Insurance Portability and Accountability Act (HIPAA) is a federal law to protect your privacy. Protecting your privacy is very important to us. During this study, we will ask about your (past) and (current) medical history, and we will do this with questionnaires and medical exams. This information will be used to determine your eligibility for the study and provide data for the study. Your personal health information will be kept private, and only authorized study staff will have access to this information. We will use a coded number on all of your documents, instead of your name, so that only someone who knew the code would know that the information was about you. All paper forms will be kept in a locked, secure office. All electronic data will be stored on password-protected computers. Your name will not be used in any publications or presentations about this study.

During the study, you will be given access to medical information about you that is part of the study through an encrypted, HIPAA-compliant website.

None of your personal information will be shared outside of Healthy Living Community and NUNM.

By signing this consent form, you are stating that we can use your health information in the ways mentioned above for this study. You are not waiving any of your legal rights by signing this form.

You have the right to take away your permission to use your health information collected as part of the study. In order to do this, you must send a written request to:

Douglas Hanes, PhD
National University of Natural Medicine
Helfgott Research Institute

Participant's Initials: _____

Consenter's Initials: _____

2220 SW 1st Ave
Portland, OR 97201

Once your letter is received, no additional information about you will be collected from you for this study. Any data and that were collected before we receive your letter will continue to be used for the study. Taking away your permission to use your health information will not affect your relationship with Healthy Living Community and NUNM.

We are collecting only the personal health information that we need for the specific purpose of this study. Your personal health information cannot be used for additional research purposes.

The mobile app used for the study, MyFitnessPal, does not collect personal data other than fitness and wellness data such as calories consumed and meal logs, nor does it collect any data from mobile device sensors. The parent company that owns MyFitnessPal is Under Armour. A full list of Under Armour's privacy and terms can be found on their website at the following address:

https://account.underarmour.com/en-us/privacy

NUNM may be required to provide copies of your personal information to Federal or other government agencies as required by law. It may also be required to provide copies to the Institutional Review Board (IRB) or other groups that monitor the safety and welfare of study participants.

If your personal health information is disclosed by this authorization to an individual or agency not covered by laws that prohibit re-disclosure, your personal health information may not remain confidential. However, Oregon law does not allow re-disclosure of HIV/AIDS information, mental health information, genetic information, and drug/alcohol diagnosis, treatment, or referral information.

Your permission to use your identifiable health information (your HIPAA authorization) will expire when the study is complete.

14.0 Signatures

By signing this consent form, it means the following:

Participant's Initials: _____

Consenter's Initials: _____

- I know my rights have not been waived by signing.
- I have had all of my questions answered, and I know whom to ask if I have more questions.
- I have read this form and understand it.
- I want to join the study.
- I know I can leave the study at any time and do not have to give a reason.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

(If appropriate, add a print & signature line for parent or legal guardian with date.)

_____ _____
Signature of Consenter Date

_____
Printed Name of Consenter

***** Required: A signed and dated copy of this consent form will be provided to the participants the day they have consented. (ICH [2016] Section 4.8.11)*****

Thank you for participating in our research study!