

WILL I BE PAID FOR MY TIME?

To compensate you for your time, you will receive up to \$145 for attending all study visits, completing questionnaires and completing a daily headache diary. In addition, you will receive 2 meals each day for 3 months. You will also be reimbursed for parking and travel expenses as needed (up to \$13 per study visit).

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

It will not cost you anything in addition to your time to be in the study.

Treatment is free.

HOW DO I JOIN THE STUDY?

Call Becky Coble at 966-8586 or you can reach us by email at rcoble@med.unc.edu.

Program on
Integrative Medicine
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This study was funded by the Mayday
Foundation and the UNC Clinical and
Translational Research Center

J. Douglas Mann, MD
Principal Investigator



Suffering from Chronic Daily Headaches?

Help us learn more
by participating in
this research study:

Nutrition for Chronic Daily Headaches



NUTRITION FOR CHRONIC DAILY HEADACHE (CDH)

CDH is a common form of serious headache that affects about 4 to 5% of the US population. Conventional treatment for CDH is costly and often does not work well. Headache medications may be associated with serious side effects. When added to their medications, dietary changes may help patients with headaches, but their effectiveness has not been well studied. The purpose of this research study is to learn whether dietary changes can improve symptoms and quality of life for headache sufferers. Two diets will be studied.

WHAT ELSE SHOULD I KNOW?

Both diets will be flexible, and can be modified to meet your taste preferences under the care of a dietitian. Neither diet will limit calories or exclude any food groups. Both diets involve eating a variety of healthy foods. Approximately 2 meals a day will be provided free of charge for 3 months (**168 meals**). Foods will be picked up at the UNC Clinical and Translational Research Center every two weeks.

WHAT WILL HAPPEN IF I JOIN THE STUDY?

First, you will meet with the leader of the study, Doug Mann MD or the research coordinator, Kim Faurot, PA. Dr. Mann is a neurologist and Attending Physician in the Headache clinic at UNC and will be responsible for your safety in the study. At the first meeting, you will fill out questionnaires and review consent forms. Dr. Mann will review your medical records to find out if you are eligible to participate.

For the next 4 weeks, you will fill out a daily headache diary. At the end of 4 weeks, the researchers will review your diary with you and let you know if you qualify for the study. After another 2 weeks of keeping a diary, you will be assigned to one of two dietary interventions, randomly by a computer program. You will fill out another questionnaire at 16 and 20 weeks.

After you are assigned to an intervention, you will meet with a research dietitian seven times for dietary advice. Over a three month period, you will pick up prepared foods every two weeks. At the end, you will have a final meeting with the dietitian. You will have a follow-up phone call with both Dr. Mann and the survey specialist.

ARE THERE ANY REASONS I SHOULD NOT BE IN THIS STUDY?

You should not be in this study if you are unable to keep a daily headache diary, if you are pregnant or if you have one of the following conditions:

- (1) severe mental or physical illness;
- (2) a blood clotting disorder;
- (3) a recent history of head or neck injury/surgery

WHAT ARE THE POSSIBLE BENEFITS?

Being in this study may reduce your headache symptoms or improve your ability to function. There is no guarantee that you will receive any benefit.

WHAT ARE THE POSSIBLE RISKS?

Risks associated with dietary changes are minimal; there is no evidence that dietary changes will worsen your headaches or other conditions. However, the following may occur:

1. Upset stomach
2. Allergic reaction
3. Food intolerance

You are encouraged to report any possible side effects to the dietitian and study staff.