WILL I BE PAID FOR MY TIME?
To compensate you for your time, you will receive up to $225 for attending all study visits, completing questionnaires and completing a daily pain diary. In addition, you will receive about $100 worth of food each week for 3 months. You will also be reimbursed for parking.

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.

HOW DO I JOIN THE STUDY?
Contact Chanee Lynch or Kim Faurot (919) 966-8586 or Food4relief@med.unc.edu

UNC School of Medicine
Departments of Neurosurgery, Physical Medicine & Rehabilitation
Program on Integrative Medicine
CB# 7200
Chapel Hill, NC
27599-7200
Phone (919) 966-8586
Fax (919) 843-5452
http://pim.med.unc.edu

This study was funded by the North American Spine Society and Mayday Fund

Kevin Carneiro, MD
Principal Investigator

Suffering from Chronic Leg and Back Pain?
Help us learn more by participating in this research study:

Nutrition for Lumbar Radiculopathy
NUTRITION FOR LUMBAR RADICULOPATHY

Lumbar radiculopathy is a syndrome of buttock/leg pain, weakness, and/or numbness/tingling caused by a pinched nerve in the back. Although some people recover quickly from this problem, others go on to have chronic debilitating pain. Preliminary evidence suggests that dietary changes may help patients with chronic pain, 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 chronic lumbar radiculopathy sufferers.

WHAT ELSE SHOULD I KNOW?

The diets will be flexible, and can be modified to meet your taste preferences under the care of a dietitian. Neither of the diets will limit calories nor exclude any food groups. Both diets involve eating a variety of healthy foods. Approximately $100 worth of food per week is provided for 3 months. Foods will be picked up at the UNC Department of Physical Medicine & Rehabilitation every 2-6 weeks.

WHAT WILL HAPPEN IF I JOIN THE STUDY?

Dr. Carneiro is an Attending Physician at the UNC Spine Center and will be responsible for your safety in the study. If you decide to participate, you will meet with the study coordinator to review consent forms and fill out questionnaires. Dr. Carneiro will review your medical records to find out if you are eligible to participate.

For the next 1-4 weeks, you will fill out a daily pain diary. At the end of those weeks, the researchers will review your diary with you and let you know if you qualify for the study. If you qualify, the researchers will make an appointment for you to meet with the research dietitian. You will be assigned to one of 2 dietary interventions, randomly by a computer program. You will continue to fill out your diaries for another 18-20 weeks and will fill out questionnaires 4 more times and give blood samples 3 times.

After you are assigned to an intervention, you will meet with the research dietitian 4 times for dietary advice. At your visits with her, you will be given food items. After the first 3 months, you will be asked to follow the diet without supplemental foods. At the end, you will have a final meeting with the study staff.

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 diary, if you are pregnant or if you have one of the following conditions:
(1) severe mental or physical illness;
(2) food allergies or intolerances;
(3) pending law suits for back injury;
(4) on long term disability.

WHAT ARE THE POSSIBLE BENEFITS?

Being in this study may reduce your pain 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; we know of no serious effects from the diets. However, the following may occur:
1. Upset stomach
2. Allergic reaction
3. Food intolerance
4. Transient worsening of pain

You are encouraged to report to the dietitian and study staff any symptoms which may be possibly due to side effects of the diet.