

AIM-HIGH STUDY PARTICIPANT NEWSLETTER

VOLUME 1, ISSUE 1

April, 2010



Study Update

Welcome to the first edition of the AIM-HIGH Participant Newsletter. We will be sending you updates about the study from time to time as well as providing you with helpful information about cardiovascular disease. We hope that you enjoy this newsletter. If you have questions that you would like us to address, please let your research coordinator know.

On September 29, 2009, we randomized our 3,300th participant. This is an important milestone for the study. As we move into the follow-up phase of the trial, your participation is extremely important for AIM-HIGH and has the potential to make a big difference in the way that all patients with heart and vascular disease are treated in the future. Although you may have heard about a small trial that looked at the effect of Niaspan compared to Zetia on carotid artery wall thickness (see “Research in the News” on page 2), AIM-HIGH is the only trial in North America that is looking at the strategy of raising HDL (“good cholesterol”) in addition to lowering LDL (“bad cholesterol”) on important clinical events. You are participating in one of the landmark National Institutes of Health (NIH)-sponsored studies in heart disease.

AIM-HIGH is monitored by an independent board, the Data and Safety Monitoring Board. This group of physicians, biostatistician, epidemiologist and medical ethicist, meets periodically to review the progress of the study. They met on December 9, 2009 and unanimously recommended that the trial continue. The Board and the project team at NIH are pleased with the progress of the study and are hopeful for a successful completion of the trial.

Aim-High is sponsored by the National Heart, Lung & Blood Institute
with additional support from Abbott Laboratories

Inside this issue:

AIM-HIGH Study Update	1
Why your participation is so important to AIM-HIGH	2
Research in the News	2
Heart-Healthy Recipe	3
How Does Diabetes Affect You?	3
Exercise for a Healthier Heart	4

WHY EVERY PERSON IN AIM-HIGH IS SO IMPORTANT!



As you know, AIM-HIGH has recruited the 3,300 patients needed for enrollment. Each and every participant is extremely important to the study because the information they provide—such as how often they take their medications, what side effects they are having, their lab values after taking study medication, etc.—is what is used to determine if the medications are working to decrease further heart and vascular events. If participants drop out of the study, we may not be able to see a difference between using Niaspan and not using it, even if the drug is really effective. We need **everyone** who signed up for the study to be in contact with their site research staff. Even if it has been a long time since you have spoken to your research coordinator or physician, please give them a call. I promise you they will be happy to hear from you!

Research in the News...

A recently published study, ARBITER6-HALT, has led to new discussions about the use of the cholesterol-lowering drug ezetimibe, also known by its brand name, “Zetia.” The study compared patients who were taking ezetimibe to those taking extended-release niacin (Niaspan). The main finding was that patients taking niacin had decreased fatty buildup in their neck blood vessels, while those taking ezetimibe did not. There were no safety issues with ezetimibe reported from this study.



While the finding that niacin reduces fatty build up is encouraging, the study was too small to make conclusions about whether ezetimibe or niacin can help prevent heart attacks, strokes, or death. In fact, the press releases from this study suggested that we need to wait for the results from AIM-HIGH to answer this question.

The AIM-HIGH Executive Committee wants to reassure you that ezetimibe is safe and that there is no reason to stop ezetimibe based on the ARBITER6-HALT trial’s results. There are many studies showing that high cholesterol can lead to heart attacks and stroke, so we strongly encourage continuing medications that your AIM-HIGH doctor has prescribed to lower your cholesterol.

Additionally, given the possible benefit of niacin, it is extremely important that you continue taking the study drug, as even small doses of niacin may help you. We appreciate your participation in AIM-HIGH. You are participating in an important study to help us learn definitively whether niacin can prevent cardiovascular events.

HEART-HEALTHY RECIPE

Mock Mashed Potatoes

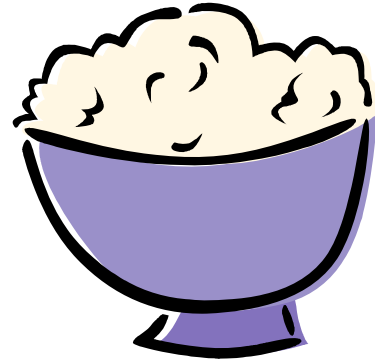
4 cups cauliflower florets (or chopped parsnips)
 2 Tablespoons fat-free butter spray
 2 Tablespoons fat-free $\frac{1}{2}$ and $\frac{1}{2}$
 Salt and pepper

Directions:

Steam cauliflower until soft. Puree cauliflower and mix in remaining ingredients.

Yield: 4 - 1 cup servings

Nutrition Information: 35 calories, 0 g fat, 0 g sat. fat, 0 mg cholesterol, 75 mg sodium, 6 g carbohydrate, 3.5 g fiber, 2 g protein



How Does Diabetes Affect You?



34% of AIM-HIGH participants have diabetes. People with diabetes are twice as likely to suffer heart attacks or strokes as those who do not have it. Here are some common myths regarding diabetes:

Myth: Eating sugar causes diabetes.

No. Type 1 diabetes is caused by genetics and other unknown factors. Type 2 diabetes is caused by genetics and lifestyle choices. Being overweight does increase your chances of developing type 2 diabetes, but age and ethnicity are also factors.

Myth: If you have type 2 diabetes and your doctor says you need to start taking insulin, it means you are not taking care of your diabetes properly.

For most people, diabetes is a progressive illness. Usually, people begin treating their diabetes through diet and exercise to see if that will control it. If this is not possible, then oral medications are given. Over time as people age, the body produces less and less insulin, which may require that additional insulin be given to control blood sugar levels.

Myth: People with diabetes get colds and flu more often.

You are no more likely to get a cold or flu than anyone else. A flu shot is recommended because an illness such as the flu can make controlling your diabetes more difficult. Also, diabetic patients who do contract the flu are more likely to develop complications than those who do not have diabetes.



Exercise for a Healthier Heart

Swimming, cycling, jogging, skiing, aerobic dancing, walking or any of dozens of other activities can help your heart. They all cause you to feel warm, perspire and breathe heavily without being out of breath and without feeling any burning sensation in your muscles. Whether it is a structured exercise program or just part of your daily routine, all exercise adds up to a healthier heart.

Here are some tips for exercise success:

- If you've been inactive for a long time, are overweight, have a high risk of coronary heart disease or some other chronic health problem, see your doctor for a medical evaluation before beginning a physical activity program.
- Choose activities that are fun, not exhausting. Add variety. Develop a range of several activities that you can enjoy. That way, exercise will never seem boring or routine.
- Wear comfortable, properly fitted footwear and comfortable, loose-fitting clothing appropriate for the weather and the activity.
- Find a convenient time and place to do activities. Try to make it a habit, but be flexible. If you miss an exercise opportunity, work activity into your day another way.
- Use music to keep you entertained.
- Surround yourself with supportive people. Decide what kind of support you need. Do you want them to remind you to exercise? Ask about your progress? Participate with you regularly or occasionally? Allow you time to exercise by yourself? Go with you to a special event, such as a 10K walk/run? Be understanding when you get up early to exercise? Spend time with the children while you exercise? Try not to ask you to change your exercise routine? Share your activity time with others. Make a date with a family member, friend or co-worker. Be an active role model for your children.

Continued on Page 5

Continued from Page 4

- Don't overdo it. Do low- to moderate-level activities, especially at first. You can slowly increase the duration and intensity of your activities as you become more fit. Over time, work up to exercising on most days of the week for 30-60 minutes.
- Keep a record of your activities. Reward yourself at special milestones. Nothing motivates like success!

Here is a list of just some of the things daily exercise can do for you:

- Reduces the risk of heart disease by improving blood circulation throughout the body
- Keeps weight under control
- Improves blood cholesterol levels
- Prevents and manages high blood pressure
- Prevents bone loss
- Boosts energy level
- Helps manage stress
- Releases tension
- Improves the ability to fall asleep quickly and sleep well
- Improves self-image
- Counters anxiety and depression and increases enthusiasm and optimism
- Increases muscle strength, increasing the ability to do other physical activities
- Provides a way to share an activity with family and friends
- Establishes good heart-healthy habits in children and counters the conditions (obesity, high blood pressure, poor cholesterol levels, poor lifestyle habits, etc.) that lead to heart attack and stroke later in life
- In older people, helps delay or prevent chronic illnesses and diseases associated with aging and maintains quality of life and independence longer

*From the American Heart Association web site:
<http://www.americanheart.org>*

If you have questions or comments about this newsletter, or there are issues or questions you would like us to address, please contact your site coordinator,

Name _____

Telephone _____