



# HEART BEAT

Cardiovascular Health Study

Spring 2000

Inside:  
Info about a  
new Ginkgo  
study. Don't  
miss it!



## Why We Just Love to Keep Talkin'

*John Grissinger and Pat Smith, Johns Hopkins University*

**W**hen we make our telephone call to you every six months, the conversation between interviewer and participant sometimes goes like this:

The interviewer will say, "It's time to do that six-month interview with you to bring us up to date about your health and any changes that may have occurred since we last spoke with you." The CHS participant may respond by saying, "Oh, nothing's changed. Everything's the same as it was when we talked the last time," and seems to be surprised that we want to go on with the individual questions.

Why continue with these interviews, even though you're no longer coming in for clinic visits? And why ask the same questions we've asked every six months for the past 12 years?

Well, there's a method to our madness, and it has to do with the high standards required for doing scientific research. We never take things for granted. We ask detailed questions so that nothing is overlooked or left to chance. That's why we keep probing for specific answers, even

when you tell us that "everything's the same": We want to make sure everything is indeed the same.

So when we call you, simply asking, "Is everything the same?" just isn't enough. We need to keep asking you the same *specific* questions year after year. Although it may seem redundant and unnecessary, this type of detailed questioning helps us make sure we don't miss slight changes or small bits of information about your health that are important in studying how to prevent heart disease and stroke in older adults. Every bit of information has the potential to make an important difference in the way we interpret the CHS data and in the outcomes of our study.

"No, sir, I 'm not crazy.

I just need 3 or 4 hours of your time to ask you a few hundred questions about your health."



## Thanks a Million!

Without *you*, the Cardiovascular Health Study would have been... well... nothing! Your dedication to this quest for vital information about the lives and health of older Americans has been the backbone of this study. Over the years you've patiently answered our questions and filled out our forms. You've been poked and prodded and scanned probably more times than you'd care to remember. Well, we remember. Your participation in the study has given CHS the ability to answer important questions about the causes of cardiovascular disease and stroke as people age. We are grateful for your commitment.

**Our heartfelt thanks to each and every one of you!**

# The Ginkgo Evaluation of Memory (GEM) Study: A Diamond in the Rough?

Maggie Williams, Editor, Coordinating Center

**T**he folks who brought you the Cardiovascular Health Study are back at it again, and they'd like you to join them.

In the coming months, a group of researchers, many of whom were part of CHS, will be starting a research study called Ginkgo Evaluation of Memory (GEM). The GEM Study is sponsored by the National Center for Complementary and Alternative Medicine, the National Institute on Aging, and the National Heart, Lung, and Blood Institute (all part of the National Institutes of Health).

The goal of the GEM Study is to find out if medicine made from the plant *Ginkgo biloba* can prevent or delay the changes in memory and thinking that can occur as people get older. Doctors refer to these changes as "dementia," the most well known being Alzheimer's Disease.

GEM will enroll 3000 people, 1500 of whom will be CHS participants (that's where you could come in). Participants will be randomly assigned to take either pills that contain *Ginkgo biloba* or pills that do not. In six years, when the study is finished, researchers will compare the two groups to see if there are differences in how memory, thinking, and personality have changed, and to see if *Ginkgo biloba* has been effective in preventing these changes.

Why participate? Recent studies have shown that *Ginkgo biloba* may help people who already have Alzheimer's by improving their mental abilities and social functioning and by possibly slowing the progression of mild disease. These findings are not definitely proven, however, and whether *Ginkgo biloba* will be effective in preventing dementia has never been evaluated in a study like GEM.

GEM will give researchers the opportunity to determine if *Ginkgo biloba* can help to prevent the development of Alzheimer's Disease and other types of dementia. GEM researchers will also be able to evaluate the side effects and safety of a standardized dose of *Ginkgo biloba*. This study is essential to scientists' efforts to find out if *Ginkgo biloba* should be recommended for preventing memory loss and to determine whether its benefits, if any, are worth its costs or any possible side effects. Researchers hope that what they learn from this study will benefit both the participants and their families and anyone else interested in preventing and treating Alzheimer's Disease or other types of dementia.

For more information about GEM, read on. If you'd like to take part, check the "yes" box on the enclosed postcard and drop it in the mail, and we'll contact you. If not, check the "no" box, and we will not contact you about GEM.

## WHAT IS GINKGO BILOBA?

*Ginkgo biloba* is probably the oldest living tree species in the world, dating back at least 200 million years. Charles Darwin called the tree "a living fossil." *Ginkgo* trees have green, fan-shaped leaves that turn yellow in autumn. The tree can grow to a height of over 100 feet and live as long as 1000 years. *Ginkgo biloba* was once common throughout Europe and North America but was almost wiped out in the Ice Age. It was later cultivated in China as a sacred tree and as a medicinal plant. The Chinese have used the leaves of the *Ginkgo* tree for thousands of years to treat diseases of the heart and lungs and to "benefit the brain." Today *Ginkgo biloba* is one of the most extensively researched herbs in the world and is commonly prescribed by doctors in Europe.

## Is GINKGO BILOBA SAFE?

Like all drugs, *Ginkgo biloba* can have side effects. People taking *Ginkgo biloba* have reported headache, upset stomach, and allergic reactions; but these side effects are rarely severe enough to make people stop taking the drug. There is also some evidence that *Ginkgo biloba* may cause thinning of the blood, which could cause bleeding or make existing bleeding problems worse. A few people who were taking *Ginkgo biloba* have experienced bleeding into the head; but we do not know if this was caused by the drug.

## Interested in Another Study? GEM Wants You!

If you're going to miss those CHS clinic visits or you just want another chance to contribute to the public health, consider joining up with GEM! People who fit the criteria listed below may be eligible to participate in GEM.

*In the GEM Study, you must have a proxy to be eligible to participate. Read more about proxies and why they are so important to this study on page 4.*

- You must be willing to participate in the study for 5–6 years.
- You need to have a proxy who knows you well enough to answer questions about you.
- If you are already in CHS, you can be any age. People who are not part of CHS must be at least 75 years old.
- You need to be fluent in English.
- You must be willing to stop any *Ginkgo biloba* supplements that you are now taking.
- Results of blood tests done at your first clinic visit need to be within certain ranges.
- You cannot have Alzheimer's Disease or other types of "dementia" (changes in memory, thinking, and personality).
- You cannot be receiving treatment for depression or have been hospitalized for depression within the last year.
- You cannot have had a diagnosis or treatment of cancer in the last five years.
- You cannot have certain types of congestive heart failure or Parkinson's Disease.
- You cannot be taking anti-coagulant ("blood-thinning") drugs, such as warfarin (Coumadin), or have a history or symptoms of bleeding problems.
- You cannot be taking the drug Aricept.
- You cannot be taking more than 400 IU ("international units") a day of vitamin E.
- You cannot be taking certain types of antidepressant drugs.

If you meet these criteria, you may be able to participate in GEM. But the investigators won't know if you're eligible until you come to the clinic to fill out some questionnaires and undergo a few tests. This can be done during one or two screening visits. Ideally, both you and your proxy will be present at the screening visit(s).

You and your proxy will first need to read and sign a study consent form. You will then take part in some preliminary neuropsychological testing, and your proxy will fill out a questionnaire. This will take about an hour.

If the results of these preliminary tests show that you are still eligible, you and your proxy will continue on to the second phase of screening, which will last about three hours. You will undergo neuropsychological testing that will more thoroughly evaluate abilities such as learning skills and recall. Clinic staff will ask you for information about your medical history and medications you may be taking. You will have a blood test and a weight and blood pressure check. Both you and your proxy will complete additional interviews.

If the results of the screening exams show that you are still eligible, you will come back for an EKG and a physical exam, and we will ask you some additional questions. At that time, if you have met all the study requirements, and if you're still interested in participating, you will be enrolled in GEM. We will give you your study medication, instructions about taking it, and an appointment for a return clinic visit in six months.

# The Importance of Proxies in the GEM Study

Alison Book, Recruitment Coordinator, University of California at Davis

After many years of participating in CHS, the term “proxy” is probably familiar to you. As you know, your proxy is someone you have designated to answer questions on your behalf, if we cannot reach you. For example, if you are hospitalized, your proxy can tell us about your health and how you are doing.

For the Ginkgo Evaluation of Memory (GEM) study, having a proxy is so important that we have made it a *requirement* for participation in the study. If you are interested in GEM, begin thinking about who your proxy will be. You should also have a “backup,” in case your proxy is unable to continue with you for the duration of this 5 ½-year study.

Your proxy should be someone who is familiar with your habits, behaviors, and history—your spouse, child, or other close family member or friend, for example—anyone you spend time

with on a regular basis—preferably at least several hours a week. Your proxy will need to answer questions about your activities and memory every six months for the entire study.

Why is a proxy so important? GEM is a study of memory and how it changes as we age. These changes can affect both our ability to complete daily activities and our *perception* of our abilities. People who have problems with cognition (brain functioning) often underreport problems with their everyday activities. The more cognitive problems they have, the more inaccurate their self-report becomes. In addition, problems may be so subtle that a person may not even be aware of them. For this reason, a proxy acts as a checkpoint—an outside opinion of your memory, habits, and abilities as time goes on. Together, you will make a vital contribution to our understanding of how older people can stay mentally and physically healthy as they age.

If you know anyone who might be interested in participating in the GEM study, include their names and addresses on the enclosed post card. We will mail them a brochure with more information about the study. You or anyone else may also get more information about the study by calling the number listed on the enclosed post card.

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