

# vitalnews

Sticht Center for Healthy Aging  
and Alzheimer's Prevention

**vital:** volunteers in touch with aging and life

## Can When you eat be as important as What you eat?



Since we ARE the Sticht Center for Healthy Aging and Alzheimer's Prevention it only makes sense that the focus of everything we do is to work to learn new ways for older adults to achieve and maintain body and brain health.

To that end, it has long been known that an older adult who is significantly overweight is at greater risk of health issues such as osteoarthritis, cardiovascular disease, and diabetes. Clues to reduce this risk come from studies in animals. When animals eat fewer calories than they want it delays the onset of numerous age-related health conditions. Eating all one's calories during a shorter period of the day (known as time-restricted eating or intermittent fasting), may also prolong lifespan and healthspan.

So, what is the best thing for older adults to do?

Researchers at the Wake Forest School of Medicine's Sticht Center and Wake Forest University have partnered to launch an innovative pilot study called

**HALLO-P** that will evaluate the potential benefits of three different types of diet interventions. Two of the study groups will follow meal plans with reduced calories, with participants in one group meeting in person and the members of the second group meeting virtually. The third group will have no restrictions on their daily calories but will limit their meals to be eaten during a specific 8-hour period of each day. Participants in all groups will be asked to increase their physical activity by increasing their walking.

The ultimate goal of the 9-month **HALLO-P** study, sponsored by the National Institutes of Health (NIH), is to begin to understand whether older adults experience health benefits from long-term caloric restriction or time-restricted eating. The total number of participants will be limited to 120 with volunteers randomly assigned, (like flipping a coin) to one of the three study groups.

To learn more about the **HALLO-P** study please see the ad on page 2.

## Fall/Winter 2022-23

### What's Inside:

AHEAD	5
BEAT-AD	11
BEST trial	9
FASTEST	8
FOCUS	5
Gut Microbiome	10
HALLO-P	2
INVEST	4
MAP	10
PRECICE Pain Study	7
PREVENTABLE	9
SenNet	2
SKOAP	6
SNIFF combo	6
SToMP AD	3
Wake Forest University School of Medicine ADRC	4





## Do You Consider Yourself Healthy?

*If so, we invite you to be a part of a research study that is designed to help us better understand how cells in your muscles age over time.*

- This is an observational study, which means that there are no medications or lifestyle changes involved.
- You will be compensated up to \$150.00.
- This study only involves 4 visits over the 3-year study period: two visits in the first year and two visits 3 years later. Urine will be collected every 7 months throughout the 3-year study.

**You may qualify if you are:**

- ◆ Healthy and between the ages of 20-30 or over age 70.
- ◆ Not pregnant or have any disease limiting your abilities.

To learn more, please call: **336-713-8539, option 4**  
or e-mail: [SenNetStudy@wakehealth.edu](mailto:SenNetStudy@wakehealth.edu)  
[WakeHealth.edu/BeInvolved](http://WakeHealth.edu/BeInvolved)

IRB00077384

## Could *When* You Eat Be As Important As *How Much* You Eat?

The HALLO study is working to discover if certain eating patterns can slow the aging process.



**BE INVOLVED. VOLUNTEER FOR A CLINICAL TRIAL**

### **Study participants will receive at no charge:**

- Bone Density Screening
- Cholesterol, Blood Pressure and Glucose Screening
- Weekly (either group or individual) nutrition and physical activity counseling with a registered dietitian and a health coach

### **To be eligible, participants:**

- Must be 60 years of age or older and overweight (BMI 27-35)
- Cannot have type 1 diabetes, uncontrolled type 2 diabetes or be on insulin
- Must be willing to come to the clinic for weekly visits during the 9-month study

For more information: **336.713.8539, option 3** or e-mail: [HalloStudy@wakehealth.edu](mailto:HalloStudy@wakehealth.edu)

**WakeHealth.edu/BeInvolved**

# ARE YOU, or IS SOMEONE YOU KNOW, HAVING MEMORY PROBLEMS?

**TODAY** is the day to start the conversation and **do something about it!**



## BE INVOLVED. VOLUNTEER FOR A CLINICAL TRIAL

Researchers at the Alzheimer's Disease Research Center, part of Wake Forest University School of Medicine, are conducting a research study, **SToMP-AD**, to evaluate a new treatment for mild memory impairment or early Alzheimer's disease.

### Participants will receive at no cost:

- A physical exam and memory testing.
- Scans of your brain, and blood tests to check your general health before, during and after the study. The results of some of these tests will be shared with you.
- Compensation for your travel and time.

### You may be eligible to participate if you:

- Are over 60 years of age and in good general health.
- Are currently experiencing memory problems or have a diagnosis of early/mild Alzheimer's disease.
- Have a study partner who can attend some study visits with you and answer questions about your memory and general day-to-day activities.

### What is involved when participating in SToMP-AD?

- Eligible volunteers will be placed in one of two groups at random (like flipping a coin). Half will receive the study drug and half will receive matching placebo capsules.
- Participants will receive study medication (or placebo) for 12 weeks, with 3 follow-up visits over the next 9 months. Total study participation will be for one year and may include up to 18 visits.
- Participants will receive a lumbar puncture (a common medical procedure) to collect a small amount of fluid twice during the study to look for the presence of a protein associated with Alzheimer's disease risk. The results of this test will be shared with you.

To learn more, call **336-716-MIND** (6463).  
[WakeHealth.edu/BelInvolved](http://WakeHealth.edu/BelInvolved)

IRB00067429

# Ready to LOSE WEIGHT but don't know where to start?



We're searching for the **best** way for older adults to lose body fat **WITHOUT** losing muscle & bone.

## Study participants receive, at no cost:

- 1-year weight loss program led by a registered dietitian
- A popular, name-brand, meal replacement program delivered to your home
- Possibility of a supervised strength or vest training program

## You may qualify to participate if you are:

- Age 60-85 and overweight
- Willing to travel to Wake Forest University up to 3 days per week for 1 year
- Not currently smoking or using insulin



To learn more please call: 336-713-8539, option 2,  
or e-mail us at: [InvestStudy@wakehealth.edu](mailto:InvestStudy@wakehealth.edu),  
or visit: [https://redcap.link/INVEST\\_STUDY](https://redcap.link/INVEST_STUDY)



IRB00058279

***For you and those you love...***

***It's never been more important to take care of yourself and protect your memories!***

Today, more than ever, we know how important it is to keep our bodies healthy. We do this by having a physical exam every year. So what about a check-up for your brain?



***The Wake Forest School of Medicine's Alzheimer's Disease Research Center has a wide range of studies that provide memory and health exams at NO CHARGE.***

Participating in these studies gives you the information you need to **TAKE CHARGE** of your brain health!

***Our studies need volunteers who are age 55 and over and have:***

- ♦ Concerns about your memory or thinking abilities
- ♦ A diagnosis of mild cognitive impairment (MCI) or Alzheimer's disease

So for you and those you love... consider getting involved and learn how you can protect your brain health and your memories!

IRB00026543



## Help us get **AHEAD** of Alzheimer's Disease!

Did you know that brain changes related to Alzheimer's disease can begin up to 20 years before a person notices any symptoms?

The **AHEAD** Study tests whether an investigational treatment can slow or stop the earliest brain changes due to Alzheimer's disease in people with a higher risk of developing the disease later in life.

We are looking for healthy adults who:

- Are between the ages of 55 and 80
- Have normal memory and thinking abilities
- Are willing to have an MRI and PET scan of their brain
- Have a family member or friend who can attend clinic visits once a year and answer questions about your memory and normal daily activities

To find out more about the study or to see if you qualify, please call **336-716-MIND (6463)** or

e-mail Karen Gagnon at: [kgagnon@wakehealth.edu](mailto:kgagnon@wakehealth.edu)

IRB00064409

## *Are you a cancer survivor?*



## *Need more energy?*



We are looking for cancer survivors age 65 and older to help us evaluate the effect of muscadine grape extract on fatigue.

Participation in this research study involves:

- 2 in-person visits and 4 visits by phone
- Completing surveys, blood draws, physical testing (walking, grip strength)
- Taking 8 capsules daily of muscadine grape extract or placebo for 12 weeks

You may be eligible for this study if:

- You are age 65 or older and had cancer in the past
- You feel fatigued

*This study is open to all survivors regardless of where you were treated & you will be compensated for your time.*

To learn more about the FOCUS trial please contact us:

**336-713-4121** or [focus@wakehealth.edu](mailto:focus@wakehealth.edu)

# Feeling Forgetful? Are you or a loved one experiencing memory problems?

## Participate in a Research Study!

The team at the Alzheimer's Disease Research Center, part of Wake Forest University School of Medicine, is conducting a research study: **SNIFF Combo** - The Study of **N**asal Insulin to **F**ight **F**orgetfulness, a combination therapy trial. This study is evaluating the combined use of two medications commonly used for diabetes to treat memory problems.



### Participants will receive at no cost:

- A physical exam and memory testing
- Scans of your brain, and blood tests to check your general health before, during and after the study. The results of some of these tests will be shared with you.
- Compensation for your travel and time.

### You may be eligible to participate if you:

- Are a non-diabetic, over 55 years of age and in good general health.
- Are currently experiencing memory problems or have a diagnosis of early/mild Alzheimer's Disease.
- Have a study partner who can attend some study visits with you and answer questions about your memory and general day-to-day activities.

### What is involved when participating in SNIFF Combo?

- Eligible volunteers will be placed in one of 4 groups at random (like flipping a coin). One group will receive both study drugs, two groups will receive a placebo for one of the study drugs but not the other, and one group will receive placebo for both study drugs.
- Participants will receive memory tests, brain imaging and a lumbar puncture (a common medical procedure) before and after taking the study drugs (or placebo) for 4 weeks. In total, there are 6 visits over 8 weeks.
- Participant blood and fluid samples will look for the presence of proteins associated with Alzheimer's disease risk. The results of some of these tests will be shared with you.

To learn more: call 336-716-MIND (6463)

IRB 75245

## Do you have chronic knee pain?



Volunteers are NEEDED for a nationwide research study that evaluates the effectiveness of non-surgical treatments to reduce knee pain and improve function.



### You may be eligible if you:

- Are between 18 and 90 years old
- Have chronic knee pain
- Have knee pain most days for at least 3 months

### This study involves:

- Questionnaires
- Random assignment to conservative treatment(s)
- Random assignment to a non-surgical procedural treatment
- Online follow-up

#### Part 1: Conservative Treatments

- **Best Practice:** Like pain relievers, physical therapy, weight management, acupuncture, yoga
- **Duloxetine:** A medication that improves knee pain and function
- **Online coping skills training:** An online tool that teaches skills to decrease and manage pain

#### Part 2: Non-surgical Procedural Treatments

- **Joint Injection:** Decreases swelling in the knee joint
- **Long acting nerve block:** to stop pain signaling nerves
- **Nerve ablation:** to destroy the nerves signaling pain

Participants that have tried Part 1 treatments may qualify for Part2.

**You may earn \$270-\$550 for completing study visits and we will cover parking expenses.**

Most procedures are covered by insurance. You may have to pay a copay. Insurance/ability to pay for medical treatments is required.

For information, please call  
**336-716-8791**

or go to:  
[www.skoapstudy.org](http://www.skoapstudy.org)



A Sequenced-strategy for improving outcomes in people with Knee Osteoarthritis Pain (SKOAP Trial)

JHM IRB Application No.: IRB 00238678  
Steven Cohen, MD. Principal Investigator  
410-955-1822

IRB#00063834

# GOT PAIN? WE'D LIKE TO HELP.



You may qualify to participate in a research study on how to manage persistent pain.

If you are interested in learning more, please contact us at 336-716-5633.

You may be compensated.

# When someone has a stroke, every second counts.



*We need your input on an emergency care research study of bleeding in the brain. Atrium Health Wake Forest Baptist is joining researchers at more than 100 other hospitals across the United States and other countries to conduct a research study of bleeding in the brain called **FASTEST**.*

## **What is a brain hemorrhage?**

A brain hemorrhage or intracerebral hemorrhage (ICH) is a type of stroke that accounts for more than 10% of the estimated 17 million strokes worldwide annually, or about 1,700,000 cases per year.

- More than 40% of patients die and only 20% of survivors are functionally independent after 6 months.
- The size of blood in the brain is the most important determinant of outcome. Most bleeding occurs within 2-3 hours from onset of symptoms.
- There is no scientifically proven effective treatment for ICH.

## **What is the FASTEST research study?**

FASTEST is a research study being done to determine if recombinant Factor VIIa (rFVIIa), a protein that our body makes to stop bleeding at the site of injury to a blood vessel, can slow bleeding in the brain and improve outcome.

## **What are potential benefits?**

- If rFVIIa slows bleeding and improves outcome, participants may benefit from this research study.
- Future patients with bleeding in the brain may benefit from what is learned in the research study.

## **What are potential risks?**

- Since rFVIIa helps stop bleeding by enhancing blood clotting, there is a risk of heart attacks, strokes due to blockage of brain arteries, and clots in the lung.

Some patients may be enrolled before consent if unconscious or a family member or representative is not rapidly available.

Research study may affect you or someone you know, and we need to find out ahead of time what the community thinks about it. THANK YOU for your help and time in completing this survey. Please complete the survey by using the QR or link below or contact the study team listed. Your participation in this survey is completely voluntary.

<https://redcap.link/FASTEST>



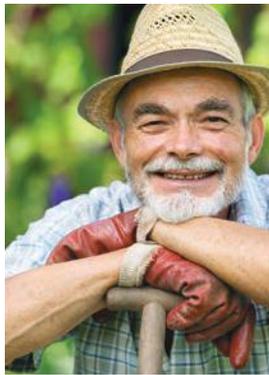
## **To learn more:**

Contact Krystal Schmidt, Study Coordinator  
at: 336-716-9603  
or e-mail: [kschmidt@wakehealth.edu](mailto:kschmidt@wakehealth.edu)

# Join the largest dementia prevention study.

You could help researchers understand if taking a statin can help adults aged 75 and over maintain health by preventing dementia, disability, and heart disease.

To learn more and to see if you qualify, please call us at 336-713-8659 or e-mail us at: [jbetanco@wakehealth.edu](mailto:jbetanco@wakehealth.edu)



## WHY IS PREVENTABLE IMPORTANT?

The benefits of taking statins for older adults without heart disease are not fully understood. By taking part in the PREVENTABLE study, you could help us learn if taking a statin is helpful for older adults like you.

## HOW CAN I PARTICIPATE?

You may be a good fit for the study if you are 75 years or older, not taking a statin, and do not have:

- Heart disease (heart attack or stroke)
- Dementia
- A significant disability that limits your basic everyday activities



**PREVENTABLE**

Pragmatic Evaluation of eVENTs And Benefits of Lipid-lowering in oLdEr adults

IRB00079556

This study was reviewed by an Institutional Review Board (IRB).



## The BEST Trial

Biomarkers for Evaluating Spine Treatments

Join the BEST Trial and help us learn how to better personalize treatment plans for low back pain.



**BEST**

Biomarkers for Evaluating Spine Treatments

NIH  
**HEAL BACPAC**  
INITIATIVE

To learn more about the BEST Trial, visit [besttrial.org](http://besttrial.org) or contact: [BACPAC@wakehealth.edu](mailto:BACPAC@wakehealth.edu)

Study investigators: Dr. Robert Hurley and Dr. Amber Brooks

Atrium Health-Wake Forest Baptist



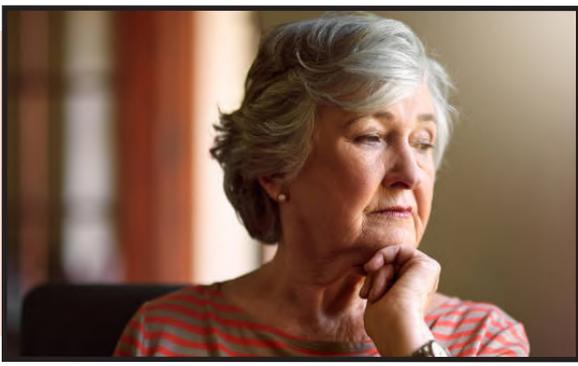
This research was supported by the National Institutes of Health through the NIH Helping to End Addiction Long-term<sup>SM</sup> Initiative, or NIH HEAL Initiative<sup>SM</sup>, under award number 1U24AR076730.

IRB#00079479

You may be eligible to participate in the BEST Trial if you:

- Have had low back pain for at least 3 months
- Are 18 years old or older
- Are willing to try one or two treatments for chronic low back pain

Study participation lasts about 9 months and involves at least 4 in-person clinic visits and other study procedures completed from home. More in-person visits may be required for some study treatments. Participants will be compensated for time spent on study activities.



## *Do you have memory concerns, forgetfulness or memory loss?*

Previous research has shown that metformin may prevent the worsening of memory problems in people with mild cognitive impairment who do not have diabetes. Researchers at Wake Forest are testing the effectiveness of metformin as a treatment for memory decline in individuals with mild memory problems, such as forgetfulness or memory loss.

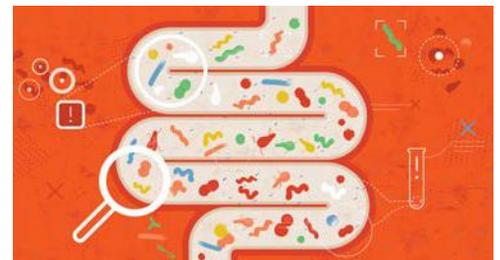
### **You may be eligible for the MAP study if you:**

- Are between the ages of 55 and 90
- Do NOT have a current diagnosis of diabetes
- Have a study partner who can accompany you to a clinic visit every 6 months and answer questions about your memory and daily activities

To find out more about the study or see if you qualify, please call: **336-716-MIND (6463)** or e-mail: [MINDADRC@wakehealth.edu](mailto:MINDADRC@wakehealth.edu)

IRB00067274

## What does a healthy gut have to do with a healthy immune system?



You can be a part of exciting research with the gut microbiome to help researchers better understand the interactions between the bacteria in the gut and a healthy immune system.

**Who:** We are looking for participants who are 60+ years old and willing to provide a blood & stool sample. Participants will receive a \$15 gift card.

**What:** Study involves 1 visit

**Where:** Department of Health & Exercise Science, Wake Forest University

**To learn more, contact Gary Miller, 336-758-1901, or email: [millergd@wfu.edu](mailto:millergd@wfu.edu)**

IRB#00024358



# Can a healthy diet *improve* memory?

We need *your* help to stop memory loss in older adults.

The **BEAT-AD** study is a 9-month study testing two different diets that may improve memory function and brain health in older adults who are experiencing mild memory problems.

The two study diets being compared are:

**Mediterranean-style low-carb (ketogenic) diet** or **American Heart Association low saturated fat diet**.

## Who is eligible for BEAT-AD?

You may be eligible to participate in the study if you are:

- 55–85 years old
- Currently experiencing mild memory problems but do not have dementia or Alzheimer's disease
- In good general health, and not taking medications for diabetes

## What is involved when participating in BEAT-AD?

- Eligible volunteers will be placed in one of two groups at random, like flipping a coin
- One group will follow an American Heart Association low-fat diet for 4 months
- One group will follow a Mediterranean-style low-carb diet for 4 months
- Both groups will receive individual counseling with the study dietician, daily menus, and shopping lists.
- Participants receive a physical exam, memory testing, and blood tests to check cholesterol, blood sugar, and general health both before, during, and after the study. A clinician will review your results with you at the end of the study, and give you personalized dietary recommendations
- Participants will receive a lumbar puncture (a common medical procedure) to collect a small amount of fluid twice during the study to help us understand how the diets affect important chemicals that are related to brain health
- Participants will receive brain scans twice during the study that will help us understand how the diets affect the brain

To learn more, call us today at  
**336-716-MIND (6463)**

# Congratulations!

The winner of the \$100 drawing is  
**Bernice Cranford of Rural Hall, NC**



To be eligible for our next drawing you only need to be a member of Vital. By receiving this newsletter by mail you are already a member!

**J. Paul Sticht Center on Aging**  
Geriatric Research Center  
Medical Center Boulevard  
Winston-Salem, NC 27157  
336-713-8539  
Toll Free: 877-238-4825  
Deb Burcombe  
Editor/Designer  
If you would like to be added or  
removed from our mailing list,  
please call Kim Kennedy at  
336-713-8567

Wake Forest University School of Medicine is the academic core of Atrium Health.



**vital**news  
Sticht Center for Healthy Aging  
and Alzheimer's Prevention

Non-profit organization  
U.S. Postage  
**PAID**  
Winston-Salem, NC  
Permit No. 154