

Welcome to the LEAP Study Participant Newsletter!

This newsletter is our way to connect you to the larger study. We want to share important information about the study with you because you are important to the success of the study. With the LEAP newsletter, we will keep you up to date on key study milestones, share information about the participating clinic sites and study staff, and highlight some of the wonderful things that you are doing in the study. We want to keep you informed about the study because without your participation, we would not be able to conduct the research. By keeping you informed, we hope that you will understand the impact of your participation on this study and the health of people everywhere who are trying to lose weight and get healthy.



*Dr. Kristina Lewis
Co-Principal Investigator
for the LEAP Trial*

The LEAP Origin Story

Research often takes a while to materialize, going from a brainstorm or simple idea to a complex, coordinated plan that involves lots of moving parts. The LEAP study is an example of that journey. It has taken a whole host of people to reach this point where LEAP is a reality and could answer some very important questions in the field of obesity medicine.

In 2015, Wake Forest School of Medicine was very fortunate to recruit Dr. Kristina Lewis from the Atlanta area. Dr. Lewis was interested in obesity medicine and some of her work focused on bariatric surgery and the benefits and risks of various procedures. However, she was also curious about medication options used for the treatment of obesity. "I had always been taught that using phentermine was only for short-term treatment of obesity. However, when I joined the Weight Management Center practice at Atrium Health Wake Forest Baptist, I saw others using phentermine long term, and patients seemed to do well with it. I have to admit, it made me a little nervous, but it really sparked my curiosity."

This curiosity led Dr. Lewis and a group of researchers to look at medical records of over 13,000 patients who were prescribed phentermine at least one time from 2010 to 2015. The researchers wanted to know if using phentermine continuously over 2 years was associated with better weight loss outcomes. They also wanted to know if people were healthier because of taking the medication. It turns out that people who took the medication long term seemed to lose more weight after 2 years and had slightly lower blood pressure. There did not seem to be any sign of worsening health or major side effects with long-term use. Dr. Lewis and colleagues published this work in 2019; however, they noted that while these results were interesting, the best way to know the true impact of long-term phentermine use is to study it in a clinical trial where people are randomly assigned to the actual drug or placebo and studied under similar conditions for a period of time.

Who are the people in LEAP?

As a participant in LEAP, you might wonder if other people are experiencing a similar journey. We wanted to share some information with you about who else is participating in the study. Our study goal is to recruit 1000 participants. We have a long way to go yet, but we are excited about getting off to a great start in 3 of our locations. The table on the right shows some stats on who is currently enrolled in LEAP.

Our goal is to recruit a diverse participant pool, and it appears that we are well on the way. **We certainly need more men**, so if you want to refer a male who you think would be a good LEAP participant, please let your local staff know and they will be happy to reach out

Characteristic	Average or Number (%)
Age, years	46.8
Male	11 (20.4%)
Female	43 (79.6%)
Race	
Black	12 (22.2%)
White	35 (64.8%)
Biracial	4 (7.4%)
Other	3 (5.6%)
Spanish, Hispanic, or Latino origin	6 (11.1%)



The Last Word from Ha Sprinkle

One of the key people who makes the LEAP study happen is Ha Sprinkle, Business Administrator in the Department of Epidemiology and Prevention at the Wake Forest School of Medicine in Winston Salem, NC. Ha is primarily responsible for making sure the funds from the NIH get to all the study sites and that each study team has the resources needed to conduct the trial. She is our fearless (and fear-inducing) leader. For each edition of the LEAP newsletter, she has commissioned this space to share some words of wisdom, encouragement, and generally grace us with her effervescence. To kick off the inaugural edition of the newsletter, we thought it would be a good idea to ask Ha a few questions that might give you better insight into who she is and why she is so critical to LEAP.

Q: How long have you worked at Wake Forest?

A: I've worked at Wake Forest for 20 years. I look the same as I did when I first started. It's quite remarkable.

Q: Yes, that is remarkable indeed. What do you enjoy most about the job?

A: I enjoy making things happen! It's impressive to wield the type of power that I have.

Q: Yes, it's quite impressive. What do you do when you're not wielding all this power?

A: don't know what you mean. I am never not wielding power.

Q: Yes, that's true. What about what you do for fun?

A: I practice light saber fight scenes from my favorite movie—The Empire Strikes Back.

