



## A Patient's Story

# Trial gives participant insights into diabetes

When her endocrinologist suggested she consider a clinical trial involving newly diagnosed Type 1 diabetics, Markee Flint's head nearly split in half.

"It's very difficult emotionally when you're first diagnosed," says the 27-year-old Durham, N.C., resident. "You're grieving for your health and trying to work this new chronic illness into your life. Trying to decide whether to participate in a clinical trial on top of that is hard."

The University of North Carolina was conducting a two-year Phase 3 trial of a drug that researchers hoped would preserve beta cell function in newly diagnosed Type 1 diabetics, but Markee was nervous about the risks and concerned because she'd have to miss six days of work. What's more, researchers advised participants against becoming pregnant during the trial and Markee and her boyfriend were talking about getting married and starting a family.

Markee read the trial information carefully and sought input from both loved ones and professionals. In the end, she says, "I felt like if I didn't do it I'd regret it for the rest of my life."

Markee joined the double-blind study, which called for participants to be infused with either a placebo – also known as a "dummy drug" -- or the investigational drug for eight consecutive days. Over the next two years researchers would evaluate her condition using blood

draws, meal tolerance tests, clinic visits, and information she entered in a personal digital assistant.

Markee admits the eight days spent lying in a hospital bed while she received her infusion treatments were painfully boring. Still, she says, other than an excruciating headache during one of her last treatments, for which the research staff gave her Tylenol with codeine, she didn't suffer any other side effects. As her two-year participation comes to an end, Markee says the most oppressive aspect of the research has been the mundane task of tracking her meal, insulin and blood sugar data.

But if Markee has been surprised by the tedious nature of the trial's downside, she's been even more surprised by the inspirational nature of the upside.

"When I was diagnosed, I'd never met anyone with Type 1 diabetes," Markee says. "I was really lonely because I felt no one really understood what I was going through. My coordinator at UNC helped me connect with the diabetes community and that helped me."

Those new friendships have helped change her perspective on clinical trials as well, Markee says.

"When I joined the trial I just wanted to help myself. I didn't really care about trying to help society or serving the greater good. But as you meet more people who have the same condition as you, you start to hope. Even if you didn't get the drug, you hope you're doing your small part because all of a sudden it means so much more."



# What is a placebo-controlled clinical trial?

A placebo is an inactive treatment sometimes referred to as a “sugar pill” or “dummy drug.” Placebos are used in clinical research to help scientists more clearly understand whether a new medical treatment is safer and more effective than no treatment at all.

For many years researchers have observed that volunteers who receive a placebo may improve or report having side effects, even though they haven't received any real medicine. This psychological effect is called the “Placebo Effect.”

To determine whether a new medical treatment is safe and effective, researchers need to subtract the impact of the Placebo Effect. To do this, researchers may:

- Give one group of volunteers a placebo and compare them to another group receiving the study medicine. This is called a Placebo-Controlled, Randomized, Double-Blind clinical trial.
- Have a group of volunteers take a placebo while other volunteers take the new medicine or one that is already available at the pharmacy. This is called an Active-Controlled, Randomized, Double-Blind clinical trial.
- Give volunteers both the study medication and a placebo at different times during the trial. This is called a Cross-Over study.

Placebos are not used in clinical trials where patients have life-threatening illnesses and a proven treatment already exists, nor are they used in research studies where volunteers will be harmed if they do not receive a real medical treatment for their condition.

If a study is to include the use of a placebo, study volunteers are informed before they agree to participate. However, they are usually not told what treatment they are being given until the trial is over. In most cases, the researchers themselves do not know who is receiving the placebo and who is receiving an active medicine. This helps reduce possible biases that could affect the results of the research.

Whether you receive a placebo or an active drug, however, you will be monitored carefully by the clinical research study staff. If there is a change in your medical condition while you are participating in the study, the physician will inform you immediately and discuss the situation with you. He or she may recommend that you drop out of the trial or receive an active medical treatment. In a trial conducted among critically-ill patients for whom there is no effective treatment, however, a volunteer is usually not switched from one group to another.

It is important to remember that trial volunteers who receive a placebo get the same attention, monitoring, care and follow-up as those who receive an active treatment. Remember, the choice to participate in a trial is yours and if you ever have any concerns about your trial, you should speak with the research investigator, study staff or a patient advocate.