RESEARCHER IN THE SPOTLIGHT

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Why are clinical trials important, and why should people participate?

Clinical trials are the main way we, as medical researchers, gain new knowledge about effective treatments. There is always a need for more effective and safer treatments for a wide range of health conditions. The only way we can know if a new treatment works is by comparing it to current treatments, no treatments, or inactive placebo treatments. Participating in clinical trials is an investment for people not only in their own health and well-being but also in the health and well-being of other people with similar conditions.

People sometimes fear that they will be getting less than standard of care if they participate in a clinical trial. However, what they may not realize is that the monitoring that is required in a clinical trial is very stringent, and they often end up getting more than the usual attention by participating in a clinical trial.

RESEARCH FINDINGS

Dr. Buysse stays awake at night designing research studies to help others fall asleep. His research focuses on the evaluation and treatment of sleep problems, especially insomnia.

In a recent clinical trial conducted by Dr. Buysse and his colleagues at the University of Pittsburgh\(^1\), older adults with insomnia were divided into two groups: one group received brief behavioral treatment for insomnia and the other (control) group received informational brochures only. One month later, over 70 percent of participants in the active treatment group reported significant improvement or remission of their insomnia symptoms, compared with only 30 percent in the control group. Ongoing work from this study shows that the benefits of brief behavioral treatment for insomnia are maintained six months and even up to a year later. The results of this clinical trial suggest that brief behavioral therapy is a safe, effective, long-lasting, non-drug treatment intervention for insomnia.

Dr. Buysse shares four simple tips from the behavioral treatment program he developed that can help anyone with chronic insomnia get a good night’s sleep:

- Reduce your time in bed. The longer you have been awake, the greater your sleep drive will be.
- Get up at the same time every day of the week, no matter how much you slept the night before. Regular wake-up time and morning light help set your biological clock.
- Don’t go to bed unless you’re sleepy. This technique also helps to increase your sleep drive and reduces frustration associated with being awake in bed.
- Don’t stay in bed unless you’re asleep. If you are awake for more than half an hour in bed, get out. You can train your brain: Bed=Sleep.

INFORMED CONSENT

What is “informed consent”? For many people, those words mean long contracts and imposing legal terms. True informed consent, however, is not about signing a document. It is about understanding your role and rights as a research participant. Informed consent is an ongoing, two-way process of information sharing between the researchers and you, the participant. In this issue, we will talk about how the informed consent process works.

As a member of the Research Participant Registry, you will receive information about research studies going on at the University of Pittsburgh. If you are interested in and qualify for participation in a study, you will have the chance to speak with the study’s research team. The purpose of the discussion is for you to learn more about the research study and your part in it if you decide to participate. The discussion is the first step in the informed consent process. Some of the things that you will hear about are:

- Title: What is the study about?
- Purpose: Why are the researchers doing this study?
- Treatments/Interventions: What kinds of procedures, tests, or drugs will be involved, if any?
- Duration: How long will I be in the study?
- Risks: What are the risks of participating?
- Benefits: Are there any direct benefits for participating?
- Confidentiality: Who will have access to my medical information in this study?
- Costs/Payments: Are there any additional costs to me for participating? Will I receive any payment for my participation?
- Participant’s Rights: What are my rights in choosing or refusing to participate?
- Contact Information: Who can I call if I have questions or problems about the study or my rights as a participant?

All of the information should be presented clearly in language understandable to you. You may ask as many questions as you wish. You may take as much time as you need. The most important thing to remember is that the decision about whether or not to participate is always yours. The informed consent document summarizes the information presented during the discussion. Sign it only if all your questions have been answered to your satisfaction and only if you are comfortable with proceeding. Your signature gives the research team permission to enroll you as an official study participant.

The informed consent process does not end with your signature, however. Study information is carefully and continually reviewed by the research team. In addition, members of the research team are always available to answer any questions and address any concerns that you may have about your participation in the study.

SLEEP RECIPE

As far back as 1500 BC in ancient Indian medicinal texts, milk has been recommended as a natural and soothing sleep aid. Milk is high in tryptophan, an amino acid that is converted in the brain to the sleep inducing substances serotonin and melatonin. Try this sweet twist on an old recipe, and dream away!

Honey Nutmeg Milk

1 cup of whole or low fat milk
2 teaspoons honey
Grated nutmeg

Gently heat milk in a saucepan almost to boiling; do not boil.
Remove from heat and whisk until frothy.
Stir in honey.
Pour into mug and dust with nutmeg.

Enjoy!