



THE PRI BULLETIN



A NEWSLETTER OF SCIENTIFIC RESEARCH FOR QUALITY MEDICAL CARE

Physical and Emotional Costs of Anxiety Disorders

by Nader Oskooilar, M.D., Ph.D.

Stress could be defined as anything (real, symbolic or imaged) that threatens an individual's well-being and survival. Stress can be physical or emotional. When under stress, our body activates a large number of biological mechanisms that seek to diminish the impact of

The most important hormones of the stress system are adrenaline and cortisol. Adrenal glands (located one on top of each kidney) secrete the hormone adrenaline into the bloodstream. Adrenaline, like the involuntary nervous system, also prepares the body for a fight or flight response. For example, it increases the heart and breathing rates, elevates blood pressure and raises metabolic rate.

Adrenal glands also produce cortisol. This hormone increases blood pressure, mobilizes fat and glucose, subdues allergic reactions, reduces inflammation and can decrease the number of some white blood cells that are involved in dealing with invading particles or bacteria. Consequently, increased cortisol levels over a prolonged period of time lowers the efficiency of the immune system and makes a person potentially more susceptible to infections and even to cancer. Constant secretion of cortisol under chronic stress can also diminish the number of cells in certain parts of the brain and result in memory problems and scarring of the brain. Recent evidence shows it can also lead to osteoporosis.



the stress and restore balance. Intense or perpetual stress, however, may tax a person's physiological and psychological resources, harm the brain and its function, as well as damage the body.

The body responds to stress mainly through two systems: first by activating the involuntary (autonomic) section of the nervous system; and second, by secreting hormones. These two systems are closely connected and complement each other. The first system works directly and instantly. The latter reacts slowly but has a wider effect on the body.

In terms of evolution, stress might have been protective. It would have helped one to either fight with the source of the stress or flee from it, so that life is preserved. But in modern times, the activation of biological reactions to stress is not channeled into the right conclusion (fight or flight). Instead of being released in a burst of physical exertion,

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What Did a National Survey of Clinical Trial Participants Reveal?

by Amy L. Thach, R.N., M.S.N., N.P.

The array of medications now available to treat illnesses is the product of thousands of clinical trials involving millions of volunteers. CenterWatch, an organization that specializes in covering the clinical trials industry, recently released a report entitled “2005 National Survey of Study Volunteer Experiences.” The following is a brief summary of the results.

Who volunteers for clinical trials?

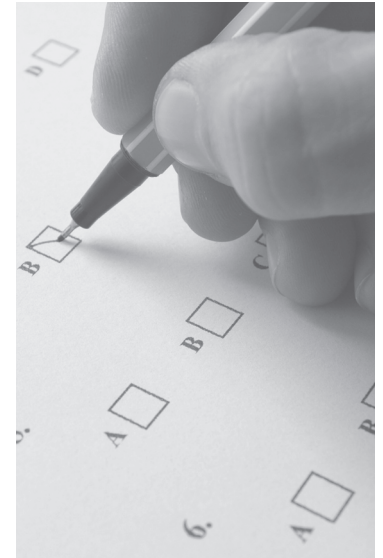
A total of 1,239 study volunteers across the nation were surveyed via questionnaires about their participation in a clinical trial in 2004. The age of the volunteers ranged from 30 to 70. More than 50% of the respondents were married and had children, approximately 50% of the participants had taken part in more than one clinical trial and 81% of the volunteers had attended either college or graduate school.

Why volunteer for clinical trials?

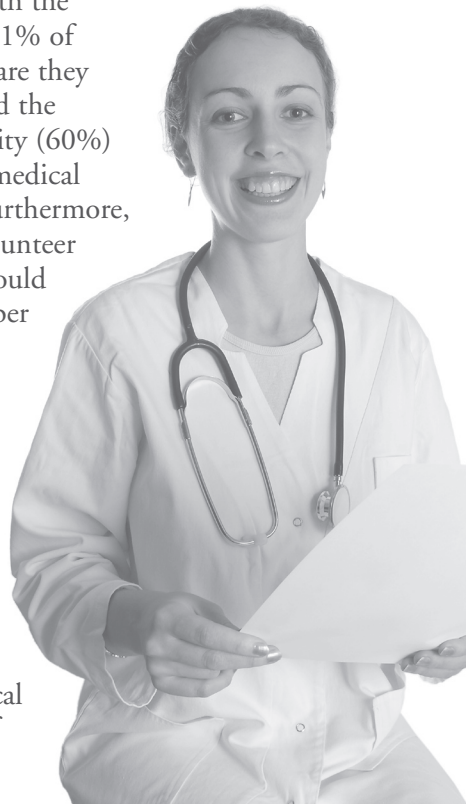
In a recent series of reports in the professional literature and general media, the pharmaceutical and clinical trials industries have been questioned and criticized. To a certain extent, these reports have shaken the public’s trust. However, a newly released report finds that the vast majority of volunteers who participate in clinical trials are quite satisfied with the medical care they received. In fact, 71% of those surveyed rated the quality of care they received as “excellent” and 22% rated the quality of care as “good.” The majority (60%) of the study volunteers stated that “medical care was helpful during the trial.” Furthermore, 91% of study participants would volunteer for another clinical trial and 84% would recommend a friend or family member to participate in a study.

The respondents to the survey gave various reasons for participating in a clinical trial. The following have been cited as the main reasons for participating: 1) Access to promising new treatments before they become widely available, 2) Extra time with physicians and nurses compared to traditional medical offices, and 3) Careful monitoring of participants through evaluation tests.

Whatever the motivation, the individuals who volunteer for clinical trials make an invaluable contribution and choosing to participate in a clinical trial is an important medical and personal decision. The following web sites can provide you with further answers to questions you may have regarding clinical studies:



- www.clinicaltrials.gov
- www.priresearch.com
- www.cc.nih.gov
- www.centerwach.com
- www.fda.gov



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The Professionals at PRI

by Charles S. Wilcox, Ph.D.

Then



A State Champion [100 meter] Sprinter, Senior Class President and Valedictorian in high school, upon graduation the local newspaper reported that Mellissa Henry stated “We each have a unique gift to give to the world and it’s our purpose in life to offer that gift. Even if only a few people benefit, the world will be a better place to live!”

Now



Mellissa Henry,
R.N., M.S.N., N.P.

As a key member of PRI’s Riverside team for a number of years, Mellissa Henry, R.N., M.S.N., N.P. works hard at giving in a way that benefits many people and definitely makes the world a better place. Building upon her remarkable breadth of successes in high school, Mellissa’s academic accomplishments in college were equally, if not more, impressive. She completed her undergraduate studies in nursing, with honors [Graduate Cum Laude] from USC. She was the recipient of numerous scholarships, awards, and honors as part of her graduate work at UCLA—where she earned both her M.S.N. degree and her Nurse Practitioner certification.

Mellissa earned recognition as a Chi Eta Phi Nursing Scholar and is a member of the Sigma Theta Tau Nursing Honor Society. Ever since first joining the PRI Research Team, Mellissa has demonstrated outstanding clinical and interpersonal skills; study participants consistently rave about her professionalism. In addition to her clinical skills she also has excellent administrative talent and often times functions as the designated Study Coordinator, as well as Research Nurse.

While Mellissa’s many duties at PRI encompass far more than the traditional 40-hour workweek, on evenings and weekends she still finds time for family and friends. In fact, just this year she was also the Head Coach of her son Peter’s basketball team, The Ravens. Indeed, while her days as a competitive sprinter have concluded, Mellissa still runs at full speed both personally and professionally; she clearly continues to be a champion!

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it is internalized. A surge of adrenaline, for example, especially on a chronic basis, causes blood to clot more easily, increasing the risk of a heart attack. Likewise, persistent activation of the autonomic nervous system can put the body in chronic overdrive and bring about premature wear and tear to the organs of the body.

Anxiety disorders are among the most prevalent psychiatric conditions in the United States and they are a major source of stress for patients who suffer from them. These disorders (e.g., Generalized Anxiety Disorder and Social Anxiety) are usually chronic stressors with unknown or multiple possible causes.

Treatment is usually very effective for anxiety disorders. Having chronic anxiety can be detrimental to one’s physical and

mental health. Anxious individuals may have more health problems, suffer emotionally for years and decades, be nonfunctional or dysfunctional and not reach their full potential in life. People around them also endure the consequences and there is a great risk for developing other psychiatric disorders such as depression, alcohol and substance abuse and other anxiety disorders. The risks of not treating anxiety disorders far outweigh the potential risks of available safe and effective remedies to treat anxiety disorders.



Present medications are obviously not perfect. They do not work well for everyone or are not well tolerated by some people. That is why pharmaceutical companies are attempting to develop other alternatives that might be more effective and with less side effects.

What's New at PRI?

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Depression

PRI has been instrumental in the early evaluation and eventual commercial availability of numerous advancements in the successful treatment of depression. While several of these medicines have helped millions of people all around the world, newer and potentially better antidepressants are currently being studied. PRI has newly initiated antidepressant research programs for both working age adults and elderly people as well.

Alzheimer's Disease

As the average life span continues to increase here in America, so too do the numbers of patients [and their families] faced with the challenge of Alzheimer's disease. Clearly, the greatest risk factors are aging and genetics. The benefits associated with early diagnosis and treatment cannot be over-emphasized; it's vitally important for patients and caregivers alike. PRI's newest anti-Alzheimer's research medication studies are *additive*: study participants now have a two-pronged approach to combat this disease: continuing on one of their marketed medications such as Aricept[®], Exelon[™] or Razadyne[™] [a.k.a. Reminyl[®]], plus the opportunity to

participate in a research study evaluating one of the newer treatments with a different *additional* mechanism of action.

Antidepressant "Poop-Out"

For the millions of adults who are prescribed an antidepressant each year, it is estimated that as many as 40-50% of patients experience only a partially therapeutic response and 10-20% of patients remain somewhat depressed after two years... while others have an initially positive response which "pooops-out" over time. Sometimes categorized as "Treatment Resistant Depression", we have new or ongoing studies specifically designed for the many people who meet these criteria.

Persistent [Adult] Developmental Stuttering

It is estimated that approximately 3 million Americans stutter. PRI's Riverside office has been awarded a new grant to evaluate a novel research medication for the treatment of stuttering in adults ages 18 to 65. Subsequent to the initial 8-week double-blind study, there is a 52-week "open-label" extension study during which all study participants receive this new anti-stuttering research medication.

For a confidential and supportive [no cost] evaluation or information on any of these programs, please call the nearest office.

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