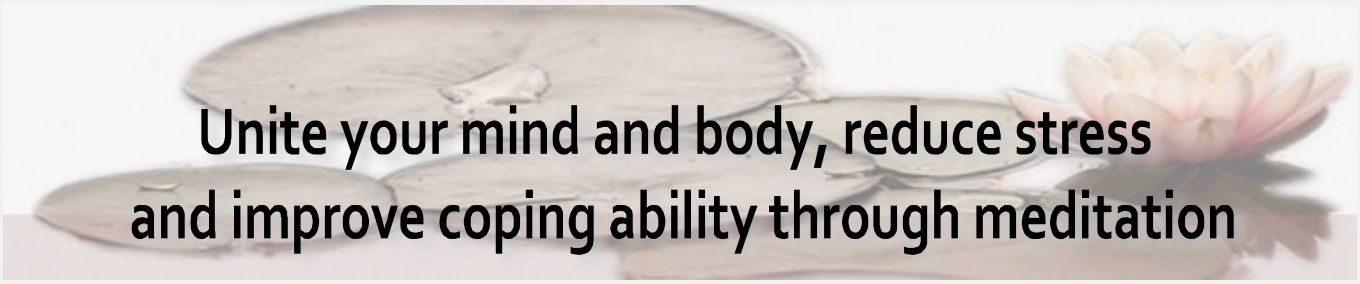
SEPTEMBER 2008



Unite your mind and body, reduce stress and improve coping ability through meditation

Beginning this fall HAPS is offering a meditation course for those with Parkinson's disease and/or their caregivers. The course is based on Mindfulness Based Stress Reduction (MBSR) program. MBSR programs are taught from a non-religious perspective and non-judgmental process that focuses on incorporating mindfulness into daily life. Mindfulness is an ancient Buddhist self-regulation practice that trains one's attention and awareness promoting mental well-being. Mindfulness includes awareness of bodily sensations, emotions and thoughts; it encourages living in the now by staying focused on the present. When you are focused on the present, you are less likely to be stuck in the past or worrying about the future. Meditation is the method that helps cultivate the mental discipline skills and environment needed to help you achieve mindfulness.

The goal of this course is to introduce students to the practice, theory and philosophy of meditation. The course has been designed to include guided meditation, class discussion and lecture. Throughout the course students will become familiar with different meditation and mindfulness techniques which will allow them to choose the practices that are most responsive to their personalities. These meditation and mindfulness techniques will help students develop the mental discipline, awareness, concentration and calmness needed to respond in an effective way to the challenges of everyday life.

HAPS is currently enrolling students for the upcoming course titled *Cultivation a sense of well being, an introduction to the practice, theory and philosophy of Meditation* with instructor, Stanley Merrill. HAPS will take the first 30 students interested in participating. The six week course will be held every Tuesday from 2:00-3:30pm in central Houston and is scheduled to begin Tuesday, September 23rd and end Tuesday, October 28th. If you would like to enroll or have additional questions, please contact Kathleen Crist, LMSW at 713-626-7114 or crist@hapsonline.org.

– CLINICAL TRIALS –
DRUG DEVELOPMENT AND THE APPROVAL PROCESS

Nina Brown

As we wait for the pharmacist to fill a new prescription, most of us don't stop to consider the complicated, time-consuming, costly process that it took for that medication to actually get to us. As one of 26 people across the country recently invited by Parkinson's Disease Foundation (PDF) to attend their inaugural Clinical Trial Learning Institute in New York, I would like to share a small bit of what I learned from this outstanding seminar.

Having participated in a number of clinical trials over the years, I have always felt that it was a win-win situation. And, it is estimated that less than one percent of the one million people with Parkinson's disease currently participate in trials, which is far less than needed. Altruistically, I feel that I am helping further knowledge about Parkinson's disease and possibly to identify new treatments, and, I must admit the idea of receiving cutting-edge treatments and having an increased level of care and monitoring during the trial period, typically at no cost, is also enticing.

Clinical trials are designed to determine whether a new drug will work and is safe to take. While clinical trials are not without risks, they are regulated by the Food and Drug Administration (FDA) and overseen on multiple levels by medical experts whose role is to protect those participating in the trials from *unnecessary* risk. Since there are now blind studies involving surgery, you have to weigh the decision--whether you're helping find a cure--against the risk.

As a prospective participant, you should receive an **informed consent document** which spells out the details of the study in simple language and who has access to your study information.

In **open trials** all participants get the drug or treatment in question.

In **randomized trials** participants are divided into groups, and some get the active treatment while others get a placebo or sugar pill. Getting a placebo may not be all bad. In a study of six people with Parkinson's who were given placebos, but who anticipated having a high chance of getting a beneficial drug, actually *physically created* dopamine in their brains.

In **double-blind studies**, neither investigator nor patients know who received the treatment or placebo. Ask what the odds are that you will receive the drug or placebo, as participants usually don't learn whether they received the drug or the placebo until the study ends.

Discovering a new drug has been likened to searching for the proverbial needle in a haystack, making the development of safe and effective new medicines a long, difficult and expensive process. The realities are:

☹ Only ONE in 1,000 compounds that enter pre-clinical testing makes it to human testing.

☹ Approximately one in five of the medicines that begin clinical testing make it through the trials and the approval process.

☹ It takes 12 years on average for an experimental drug to travel from the lab to your medicine chest.

☹ It can cost anywhere from $110 million to $500 million to get a new medicine from the laboratory to the pharmacist's shelf.

The U.S. system of new drug approvals is perhaps the most rigorous in the world. As you can see from the following steps, the FDA does not take getting a drug to market lightly.

Even still, problems may show up after long-term use. For example, the dopamine agonist, Permax, revealed a significant increase (approximately ¼) of those who took the drug developed heart valve disease.

CLINICAL TRIALS, DRUG DEVELOPMENT AND THE APPROVAL PROCESS continued

FDA Approval Process

Preclinical Testing. A pharmaceutical company conducts laboratory and animal studies to show biological activity of the compound against the targeted disease, and the compound is evaluated for safety. This may take up to seven years.

Investigational New Drug Application (IND). After completing preclinical testing, the company files an IND with the Federal Drug Administration (FDA) to begin to test the drug in people. The IND shows results of previous experiments, how, where and by whom the new studies will be conducted; the chemical structure of the compound; how it is thought to work in the body; any toxic effects found in the animal studies; and how the compound is manufactured. In addition, the IND must be reviewed and approved by the **Institutional Review Board** where the studies will be conducted. Progress reports on clinical trials must be submitted at least annually to the FDA.

Clinical Trials, Phase I. These tests take about a year and involve about 20 to 80 normal, healthy volunteers. The tests study a drug's safety profile, including the safe dosage range. The studies also determine if the drug is getting to its intended target and any side effects that may occur.

Clinical Trials, Phase II. In this phase, controlled studies of approximately 100 to 300 volunteers with the disease assess the drug's effectiveness, which can take about two years. There is often a range of doses and a placebo group. This phase is not intended to show that the drug "works" – but just to determine if it's worth further study.

Clinical Trials, Phase III. This phase lasts about three years and usually involves 1,000 to 3,000 patients in clinics and hospitals to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow it to be used safely. It can take another seven years to get to the point where a New Drug Application can be filed with the Federal Drug Administration.

New Drug Application (NDA). Following the completion of all three phases of clinical trials, the company analyzes all of the data and files an NDA with the Federal Drug Administration if the data successfully demonstrate safety and effectiveness. The NDA must contain all of the scientific information that the company has gathered. These applications typically run 100,000 pages or more. By law, the FDA is allowed six months to review an NDA. In almost all cases, the period between the first submission of an NDA and final FDA approval takes longer than six months.

Approval. Once the FDA approves the NDA, the new medicine becomes available for physicians to prescribe. The company must continue to submit periodic reports to the FDA, including any cases of adverse reactions and appropriate quality-control records.

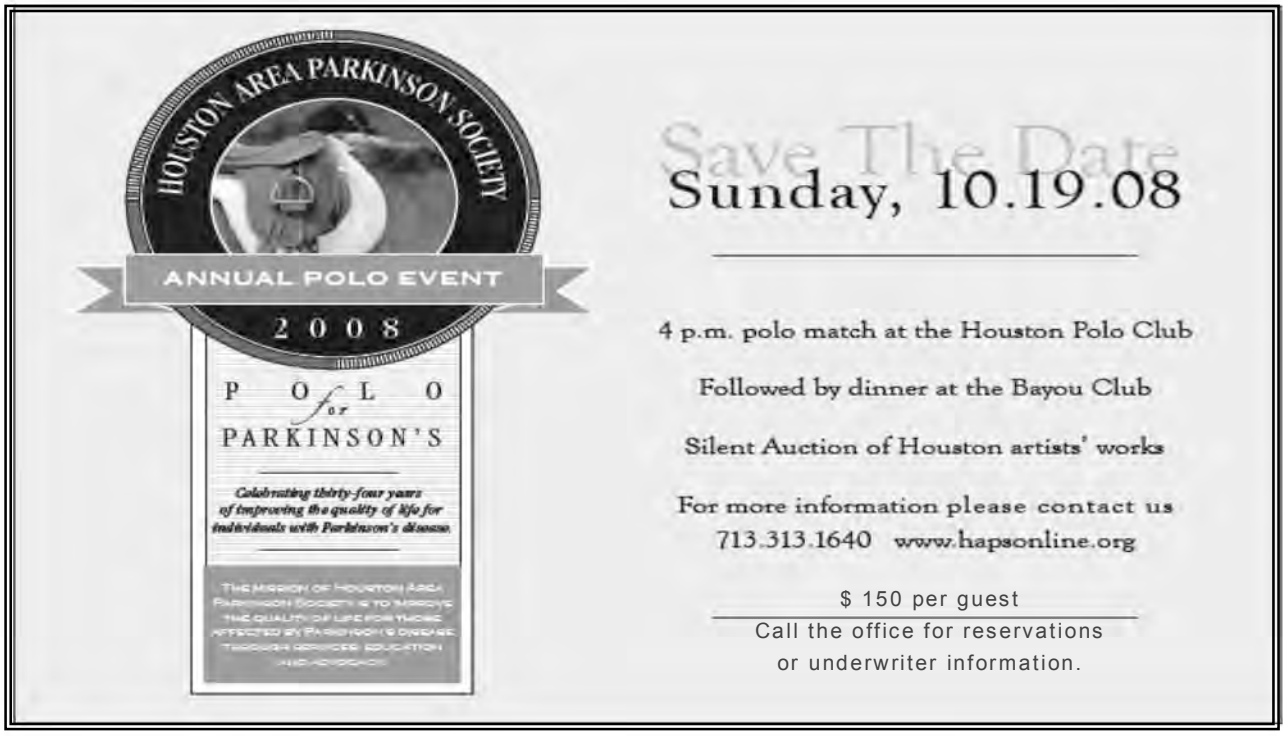
Clinical Trials, Phase IV: The FDA requires additional studies to evaluate long-term effects.

Stem cells may move Parkinson's and other diseases into the test tube where cells can be developed and treated in a Petri dish rather than a person. Long term, scientists will be able to develop therapies that use a person's own cells that have been coaxed into repairing the damage caused by the disease.

WHAT CAN YOU DO?

It is projected that ten to fifteen thousand people will be needed to properly test for Parkinson's. **Consider participating in a clinical trial. Ask your doctor about available trials** or check out www.pdtrials.org on the Internet.

When I was diagnosed, I was told there would be a cure for Parkinson's within 5-10 years. Now, 24 years later, scientists continue to say we are so close; there should be a cure within 10 years. I don't have the time to wait. Do you? Check with me about how you can **become proactive in securing government funding for basic research**. HAPS advocates for you, but more voices need to be heard. Call the office today and volunteer to help.



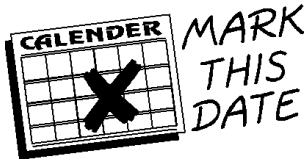
MARCIA PUMPELLY IS HOT-HOT-HOT TOO!

Nina, again, spoke the truth on the SPOT
And wrote of deep sweats that are steamy and HOT.
I, too, moan and suffer from these deep sweats ALOT
Which cause de - hy - dra - tion since I am so HOT
Which causes me to drink and seek bathrooms ALOT.

On top of all that, dys - kin - e - sia I've GOT
Which causes deep sweats while I am still HOT!
I will use a cool fan and change wet clothes ALOT
In hopes that I will not leave wet, ugly SPOTS.

Since deep sweats remain and I still will be HOT
You will know who I am as I contemplate my hot LOT.
I'll try not to complain about being sweaty and too HOT
And speak the truth like Nina who writes wise words on the SPOT.

Parkinson's Science: Innovations and New Perspectives



Saturday, October 11, 2008

Surgical Advances in Parkinson's Disease

Parkinson's experts will discuss the latest advances in research and treatments via webcast presented by the Parkinson's Disease Foundation (PDF) Saturday, October 11. Webcast viewers can watch the presentations in real time from their home computers and can also submit their own questions to the experts. Those who cannot join the webcast live can still view the symposia 24 hours a day, 7 days a week, for one year following each event. Webcast access is free. For more information, please contact PDF at webcast@pdf.org or at (800) 457-6676 or visit http://www.pdf.org/webcast/.

CONTRIBUTIONS

Your donation is much appreciated. Your thoughtfulness helps HAPS continue to provide much needed services to people with Parkinson's and their families.

GIFTS

Susan and Edward Swift
Maria C. Gonzales
Karen A. Cardiello
Reida and Roy Aldridge
Wilma and William Doty
Josephine and William Beck
Mr. and Mrs. James C. Holland
Anna and Charles Brewin
Linda and Jay Herson
Susan T. Laufman
Edith L. Little
Lynn S. Bliss
Evelyn J. Simon
J. Patrick Blande
Wava June Blande
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In honor of Joe V. Longoria
Anonymous

In honor of Dorothy Wong
Kay Lau

IN MEMORY OF

In memory of Maurice Childers
Betty Childers

In memory of Donnie Allen Carlisle
United States European Command
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In memory of Jim Fonteno
Charles Kolb
Mischer Investments

In memory of J. Allen Carpenter
Mrs. Maggie B. Carpenter

In memory of William Dobbins
Linda and Herbert Lesser

In memory of Baine P. Kerr, Sr.
Carol McDonald

In memory of Mary Lee Thomas
J.E. Englebright
Eloise Spears
Deborah and William Hardin and James Hardin

In memory of Estelle L. Malcher Bayer
Jo Nell and James Canova

-Your donation is tax deductible-

- Jeans Week -
A Creative Way to Help HAPS Help

Houston Area Parkinson Society would like to thank the many people who support our efforts by contributing to HAPS. Every gift *does* matter and you *have* made a difference! An example of how gifts, no matter how small, can add up to major contributions was demonstrated in a recent donation that HAPS received when employees of AIG Retirement Client Services Operations Department collected money during a "Jeans Week" campaign for which HAPS was named the selected charity. Each person who donated $5.00, qualified to wear jeans for the entire week—a privilege for that company. The total added up to over $1,000. What a creative way to support HAPS and we are grateful!

HAPS HAPPENINGS

HAPS HAPPENINGS is published monthly by Houston Area Parkinson Society Editor: Nina P. Brown