Official Title: Predicting, Understanding, and Speeding Recovery After Total Knee Arthroplasty
IRB Date Approved 12/14/2020
NCT02685735

Wake Forest®
School of Medicine

Department/Section of Anesthesiology

PREDICTING, UNDERSTANDING AND SPEEDING RECOVERY AFTER TOTAL JOINT REPLACEMENT

Informed Consent Form to Participate in Research
James C. Eisenach, M.D., Principal Investigator

INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you are scheduled to have a total knee replacement also called Total Knee Arthroplasty (TKA) or a total hip replacement (THA). Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to help researchers better understand patterns of recovery after TKA or THA surgery. We will evaluate how pain, activity and reasoning responses determine patterns of recovery. We will also evaluate the effectiveness of gabapentin, a medication that is commonly used to treat nerve pain, compared to a placebo, which is an inactive substance, like a sugar pill, that is not thought to have any effect on your disease or condition.
Placebos are used in research studies to see if the drug being studied really does have an effect.

We are also interested in studying the diameter of the pupil in your eye(s) to better understand how a corresponding brain region, the locus coeruleus, is related to processing and interpreting pain stimuli. We will look at changes in your pupils with the use of an infrared camera.

We will ask you to complete several psychological questionnaires that tell us about your reasoning responses, thoughts, and emotional feelings.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

A total of 300 people at 2 research sites will take part in this study, including approximately 150 people at this research site. In order to identify the 300 subjects needed, we may need to screen as many as 350 because some people will not qualify to be included in the study.

WHAT IS INVOLVED IN THE STUDY?

PREOPERATIVE PROCEDURES

Once you have agreed to participate, you will be scheduled to come to our Headache and

Pain Research Unit (HPRU). We will have you wear a portable heart monitor during the study visit so that the researchers can record your heart rate to assess the state of arousal to coincide with the PAS questionnaire that will be completed. The heart rate monitor will be a non-invasive monitor.

You have the option to choose to have study visits 2 and 3 occur at your surgeon's office at Davie Medical Plaza.

STUDY VISIT 1:

Approximately 2 weeks before your surgery we will have you come to the HPRU for your first study visit. This visit will take about 2 hours. We will ask you to complete 4 questionnaires the evening before your first study visit and bring them with you during your study visit. During the first visit we will ask you about your medical history, existing pain and any medications that you are taking. If you are a female subject of child-bearing potential we will also administer a urine pregnancy test. The rest of the visit will be divided into 3 parts.

In the first part we will administer thermal heat temperatures ranging from warm but not painful to painfully hot. We will ask you to indicate when you feel warmth or pain, and to rate the pain using a scale from 0-10. The probe temperature will vary from skin temperature up to a temperature that is hot (102^{o} F to 124° F) and uncomfortable, but does not burn your skin. This will take about 15 minutes.

Next we will ask you to complete a series of 3 questionnaires on the computer, 2 questionnaires on paper, and play 2 simple card games. The card games will tell us about how you make decisions or how impulsive you are. This will take about 30 minutes.

Next we will ask you to rate the warm and hot temperatures again while we make a recording of the size of your pupils. To do this we will have you sit in a comfortable chair and position your head so your chin is resting in a chinrest (very similar to the way an eye doctor would examine your eyes). We will ask you to stay in this position for this portion of the testing. A continuous video recording will be made of the size of your pupils while you are experiencing the thermal heat temperatures applied your forearm. This video recording is being done so that we can record the changes in your pupil when you experience different temperatures allowing the researchers to better understand the role that your brain has in processing pain.
We will administer thermal heat temperatures in sequences of a low and a higher temperature to your forearm(s) and ask you to rate the pain by using a numerical rating score (NRS) from 0-10. We will use a thermal probe with a tip about the size of a penny which will be placed on the skin of your forearm and the temperatures applied will be held constant for 5 seconds. The probe temperature will vary from skin temperature up to a temperature that is hot (102^{o} F to 124° F) and uncomfortable, but does not burn your skin. After 4 sequences of temperature stimuli we will also ask you to place your foot into a bucket of cold (50°F) water for 90 seconds while we are performing some of the thermal heat testing on your forearm. This testing will take about 45 minutes.

Also during your visit we will train you to use an electronic tablet for daily diary entries, a weekly diary entry, and also in the use of an accelerometer (small device that will wear on a belt

around your waist or around your ankle to record your activity). The accelerometer tells us about your activity by counting the number of steps you take, the distance you walk while you are wearing it.

We will give you the tablet (or you may choose to use your own tablet/electronic device) and the accelerometer to take home after this visit and ask you to answer your daily diary questions each day before your surgery and wear the accelerometer each day before your surgery. We are asking you to do this so that you will be accustomed to doing these tasks before your surgery. At the end of this visit will give you a packet of 10 questionnaires that we will ask you to complete at home and bring with you on the day of your scheduled surgery.

You will be randomized into one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. You will have a one in two chance of being placed in either group.
The groups are: (1) gabapentin or (2) placebo.

Neither you nor the investigator will know which study medication you are receiving. This is done so that a fair evaluation of results can be made. This information is available to the researchers if needed in an emergency.

You will begin the study drug after this visit. You will take the blinded study drug as prescribed for the next five weeks. The study staff will call you weekly to talk to you about any questions you have about your study medication and you will be provided with a telephone number to call the study team for any questions you have.

All questionnaires/surveys and thermal heat testing are for research purposes only.

DAY OF SURGERY AND IN-HOSPITAL CARE

If you have elected to have spinal anesthesia we will also collect a small amount, less than ½ teaspoon of spinal fluid. The spinal procedure will be done per standard of care by anesthesiology faculty. After turning on your side, your back will be washed with antiseptic, local anesthetic will be injected to numb your skin, and a needle will be placed in the lower part of your back. Once the spinal needle is in place and just before the spinal medication is administered, a small amount (less than ½ teaspoon) of cerebrospinal fluid will be withdrawn (this is the clear fluid that fills the cavities of the brain and covers the surfaces of the brain and spinal cord). This sample will be used to test for neurotransmitters (chemical molecules that "ferry" nerve impulses across the synapse from one neuron to the next in the brain) this is important because the neurotransmitters tell us about how your brain processes pain.
The amount of spinal fluid we take is half as big a volume as we inject with the numbing medicine. The medication to make you numb for your surgery will then be administered.

Please initial one of the following options:
____YES I will participate in providing a CSF sample for testing of neurotransmitters.
____NO I do not want to provide a CSF sample for testing of neurotransmitters.

We will also collect information from your medical record including the type of surgery you are having, the medications that you are taking, the type of anesthesia that you have for your surgery, the type of pain you have, the amount of pain medication that you use after your surgery and the number of days you are in the hospital after your surgery as well as any other significant events that happen during your hospital stay.

HOSPITAL DISCHARGE

A member of the research team will visit you while you are in the hospital after your surgery.

We will ask you to make entries in the electronic diary as follows:

A. Evening of discharge weeks 1 through 8: You will be asked to complete an electronic diary entry each evening for 8 weeks.
B. Weeks 9 through 20: A member of the study team will call you and ask you 17 questions one evening a month for 3 months.

Each of the assessments will only require about 2 minutes to complete.
The electronic diary (tablet) will be equipped with a pre-paid wireless card so that you may connect to the internet to access the diary for completion.

You will also be asked to wear your accelerometer daily for the first 8 weeks after your discharge.

Additional postoperative hospital discharge assessments to be completed:

STUDY VISIT 2:

Approximately 8-10 weeks after your surgery we will have you return to the HPRU or we will arrange to meet you at your postoperative appointment at Davie Medical Center according to your preference and complete the set of 14 questionnaires that you completed before your surgery and you will complete the survey about how impulsive you are and play the card game. You will also return to the study team your electronic diary and the accelerometer at this visit.

STUDY VISIT 3:

Approximately 6 months after your surgery we will have you return to the HPRU or we will arrange to meet you at your postoperative appointment at Davie Medical Center according to your preference and complete the set of 14 questionnaires that you completed before your surgery and you will complete the survey about how impulsive you are and play the card game.

During your postoperative visits to your surgeon we will record information about your joint function.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for about 6-7 months.

You can stop participating at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences.

WHAT ARE THE RISKS OF THE STUDY?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff. You may experience brief pain during the thermal heat testing. There is a small risk of thermal burn during the heating part of the experiment. The use of infrared video camera will not expose you to a greater amount of light than expected in normal use of an infrared camera. We will ask you to complete various psychological tasks, which may cause you to reflect on emotional experiences or feel emotional. If you find it necessary, a list of resources are included at the end of this consent form that you may find helpful. We will not be providing immediate feedback to you from your psychological questionnaires.

You may ask us to stop the testing at any time and you may withdraw from the study at any time.

Pulmonary

Gabapentin has been associated with serious breathing difficulties in patients taking opioids and those with diseases that reduce lung function including chronic obstructive pulmonary disease (COPD). Symptoms include confusion, unusual dizziness or lightheadedness, extreme sleepiness, slowed, shallow or difficult breathing, unresponsiveness, and bluish colored or tinted skin, especially on the lips, fingers, or toes.

The most common side effects (greater than 2%) of gabapentin are listed in the table below:

Body System/Preferred Term	Neurontin® N=336	Placebo N=227 % %
Body as a Whole		
Asthenia (abnormal weakness)	5.7	4.8
Infection	5.1	3.5
Headache	3.3	3.1
Accidental injury	3.3	1.3
Abdominal pain	2.7	2.6
Digestive System		
Diarrhea	5.7	3.1
Dry mouth	4.8	1.3
Constipation	3.9	1.8
Nausea	3.9	3.1
Vomiting	3.3	1.8
Flatulence (passing gas)	2.1	1.8
Metabolic and Nutritional Disorders		
Peripheral edema (swelling in hands/feet)	8.3	2.2

Nervous System		
Dizziness	28.0	7.5
Somnolence (sleepiness)	21.4	5.3
Ataxia (lack of muscle coordination)	3.3	0.0
Thinking abnormal	2.7	0.0
Special Senses		
Amblyopia[a] (Blurred Vision)	2.7	0.9

[a] Reported as blurred vision

Other events in more than 1% of patients but equally or more frequent in the placebo group included pain, tremor (shaking), neuralgia (pain along the nerves), back pain, dyspepsia (indigestion), dyspnea (difficulty breathing), and flu syndrome (flu symptoms).

The incidence of depression (feeling sad) and confusion were reported as frequent (defined as occurring in at least 1/100 patients).

There has been one subject in this current study that reported a rash on the hands and wrists.

These side effects limit therapy in clinical trials in less than 10% of cases with chronic (3 month) dosing.

In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. There also may be other side effects that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks.

The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests. You should discuss the risk of being in this study with the study staff.

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

A Data Safety and Monitoring Committee, an independent group of experts, will be reviewing the data from this research throughout the study.

Reproductive Risks and other Issues to Participating in Research

Due to unknown risks and potential harm to the unborn fetus, sexually active women of childbearing potential must use a reliable method of birth control while participating in this study. Reliable methods of birth control are: abstinence (not having sex), oral contraceptives, intrauterine device (IUD), DepoProvera, tubal ligation, or vasectomy of the partner (with

confirmed negative sperm counts) in a monogamous relationship (same partner). An acceptable, although less reliable, method involves the careful use of condoms and spermicidal foam or gel and/or a cervical cap or sponge. We encourage you to discuss this issue further with your physicians if you have any questions.

Pregnant women are excluded from participation in this study. Because some methods of birth control are not 100% reliable, a pregnancy test is required at least 10 days from your last normal menstrual period, if you are a sexually active woman of childbearing potential.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

You are not expected to receive any direct benefit from taking part in this research study. We hope the information learned from this study will benefit other people in the future.

WHAT OTHER CHOICES ARE THERE?

This is not a treatment study. Your alternative is to not participate in this study.

WHAT ARE THE COSTS?

There are no costs to you for taking part in this study. All study costs, including procedures related directly to the study will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United

States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institute of Health which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

As part of this research study, you will be videotaped. We will only videotape the size of your pupils, your face or any other identifying characteristics will not be videotaped. This is being done so we can have a measurement of your pupils during the thermal heat testing. You understand that you may request the filming or recording be stopped at any time during the course of the research study. You can also withdraw your consent to use and disclose the photograph/videotape/audiotape before it is used. You should also understand that you will not be able to inspect, review, or approve the photographs, videotapes, audiotapes or other media (including articles containing such) before they are used in this study. The video files will be stored on a password protected network computer for indeterminate period of time.

Please choose one of the following regarding the use and disclosure of the photograph/videotape/audiotape used in this research study:

_____ I would like the videotapes of me to be destroyed once their use in this study is finished.

____ The videotapes of me can be kept for use in future studies provided they are kept secure and any future study will be reviewed by an IRB. I understand that I will not be able to inspect, review or approve their future use.

WILL YOU BE PAID FOR PARTICIPATING?

You will be paid a total; of $1000 for completion of the entire study. If you complete only part of the study or withdraw during the study you will be paid according to the schedule below:

- $300 for completion of the first HRRU study visit
- $50 for completion of questionnaires 2 months after surgery and return of study supplies (electronic tablet, charge, wireless internet card)Visit 2 at the HPRU or Davie Medical Center
- $50 for completion of questionnaires 6 months after surgery Visit 3 at the HPRU or Davie Medical Center $200 for completing at least 90% of the daily diary entries on the electronic tablet and wearing the accelerometer weeks 1 through 8 at least 90% of required time
- $400 for completion of all the scheduled study visits and postoperative assessment/questionnaires

You must return the electronic diary (including the charger) and the wireless card (if one was used) before your payment will be processed.

For your participation in the electronic survey that tells about your impulsivity, you will be given raffle tickets according to your performance. You will be given 1 ticket each time you complete the survey but according to how well you perform you will be given additional raffle tickets. Once a year, after each 40 subjects are completed, we will enter the raffle tickets for each subject and hold a drawing for the winner to receive a one-time winning of $500. You will have a minimum of 3 raffle tickets if you complete your study visits.

If you withdraw for any reason from the study before completion you will be paid according to the schedule of payment above. The accelerometer and electronic tablet must be returned if you withdraw from the study prior to completion.

To receive payment, you must provide your social security number, name and address so that we can comply with IRS (Internal Revenue Service) reporting requirements. When payments are reported to the IRS we do not let them know what the payment is for, only that you have been paid. If you do not wish to provide this information you can still take part in this study but you will not be paid.

The findings from this research may result in the future development of products that are of commercial value. There are no plans to provide you with financial compensation or for you to share in any profits if this should occur.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored National Institutes of Health. The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

Should you experience a physical injury or illness as a direct result of your participation in this study, Wake Forest University School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of such injuries or illnesses. To the extent research insurance coverage is available under this policy the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. Wake Forest University Baptist Medical Center holds the insurance policy for this coverage. It provides a maximum of $25,000 coverage for each claim and is limited to a total of $250,000 for all claims in any one year. The Wake Forest University School of Medicine, and the North Carolina Baptist Hospitals, Incorporated do not assume responsibility to pay for these medical services or to provide any other compensation for such injury or illness. Additional information may be obtained from the Medical Center's Director of Risk and Insurance Management, at [redacted]

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by

law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call Dr. James C. Eisenach at [redacted] during regular business hours and after hours you may contact the study coordinator by calling [redacted].

What About My Health Information?

In this research study, any new information we collect from you and/or information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:**

- Name
- Age (date of birth)
- Health history
- Current medications
- Questionnaires
- Surgical Experience (ie: surgeon, procedure, anesthesia, pain, medications, complications, length of hospitalization)
- Postoperative function

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS), the National Institutes of Health (NIH) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy

regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

Monitors, auditors, IRB or other regulatory agencies will be granted direct access to the participant's original medical record for verification of clinical trial procedures or data, without violating confidentiality of the participant and to the extent permitted by other applicable laws.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for an indeterminate period of time. This authorization does not expire and the study sponsor (National Institutes of Health) will be granted direct access to the participant's original medical record for verification of clinical trial procedures or data, without violating confidentiality of the participant and to the extent permitted by other applicable laws.

You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Dr. James C. Eisenach that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

James C. Eisenach, M.D.
[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people

who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

Laboratory test results and other medical reports created as a result of your participation in the research study may be entered into the computer systems of Wake Forest University Health Sciences and North Carolina Baptist Hospital. These will be kept secure, with access to this information limited to individuals with proper authority, but who may not be directly involved with this research study.

A North Carolina Baptist Hospital (NCBH) medical record will be created for all study participants. Information about your participation in the study will be placed in the NCBH medical record, along with any routine medical test results that were obtained at NCBH as part of this study.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. The investigators also have the right to stop your participation in the study at any time. This could be because we have not been able to contact you or you are not completing your questionnaires and diaries as agreed upon. You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, Dr. James C. Eisenach at [redacted] during regular business hours and after hours you may call the study coordinator by calling [redacted]

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB [redacted]

You will be given a copy of this signed consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm

Below is a list of resources that you may find helpful:

Emergencies:
Local Emergency Department
National Suicide Prevention Lifeline: 800-273-TALK (8255)

Non-Emergent:
Wake Forest Psychiatry (medical or counseling): [redacted]
Check with your insurance panel to identify therapists, doctors and other healthcare providers
Websites such as www.findatherapist.com
http://www.findatherapist.com
http://www.therapists.psychologytoday.com
http://www.find-a-therapist.com