Jordan F. Karp, MD *Principal Investigator*
Bruce Rollman, MD, MPH *Co-Investigator*
Debra Weiner, MD *Co-Investigator*
Jill A. Tarr, LCSW *Project Coordinator*

ADAPT: ADDRESSING DEPRESSION AND PAIN TOGETHER 2011 Summer

What is ADAPT?

Funded by the National Institute on Aging for the next 4 years, the ADAPT study will test whether combined treatment with antidepressant medication plus behaviorally activating, pain and depression-specific psychotherapy (compared to medication alone), is required to improve pain, depression and disability.

Eligibility for ADAPT:

- Both men and women
- Age 60 and over
- Experiencing low back pain and low mood

How can I make a referral?

Referrals can be made 3 ways

1. EPIC Best Practice Alert for ADAPT (triggered by 'back pain' in the problem list or diagnosis for the encounter)
2. Sending a pooled email to "p ADAPT" in EPIC.
3. Calling 412-246-6006. Ask for Jill Tarr.

We screen all referred patients over the telephone to confirm they meet criteria for low back pain and depression. We then ask all eligible patients to meet with study staff and sign our IRB-approved consent form. We complete a comprehensive evaluation to ensure that all eligibility requirements are met. Evaluations and treatment are offered at the Late Life Depression Program located in Bellefield Tower in Oakland, at the patient's Primary Care Office, or if they live within 5 miles of Oakland, in their home.

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What happens during the study?

Participants meet regularly with the study team (clinicians and study psychiatrists). In phase 1, patients have 6-weeks of open-treatment with low-dose venlafaxine (up to 150 mg/day) and care management.

If they are still experiencing symptoms of low back pain **or** depression they will move into Phase 2. During the 14 weeks of Phase 2, patients are randomized to either high-dose venlafaxine (up to 300 mg/day) and care management or venlafaxine 300 mg/day and Problem Solving Therapy for Depression and Pain (PST-DP)

Why Venlafaxine (EFFEXOR)?

We chose venlafaxine because at doses > 150 mg/day, norepinephrine reuptake is inhibited. This may lead to greater improvement in **BOTH** depression and low back pain.

FAQ's

Q. Does the study provide medication for my patients?
A: Yes, Venalafaxine and other interventions are provided at no cost to the patient.
Q. Who will my patient call with questions while they are participating?
A. The Late Life Depression Clinic at 412-246-6006. This number answers 365/24/7, with a physician always on-call.
Q. How do I learn about my patient's progress during the study?
A. The Project Coordinator will chart updates in EPIC and via email.

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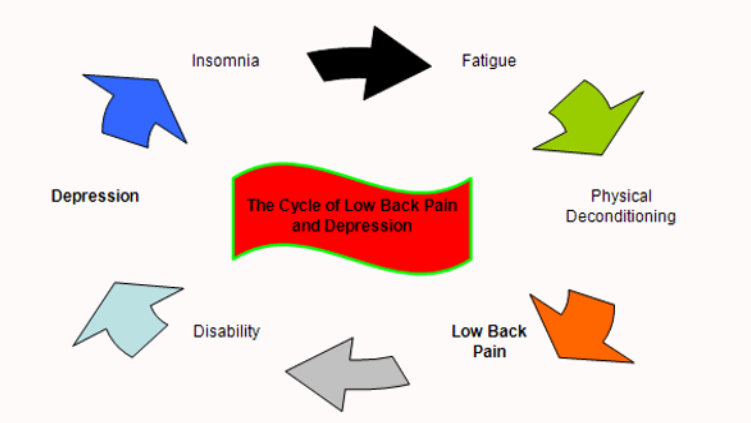
The Cycle of Low Back Pain and Depression:



We are testing whether adding PST-DP to higher-dose venlafaxine results in superior mood and pain outcomes.

PST-DP focuses on:

1) Improving problem solving skills
2) Implementing pleasurable activities, movement, and activity into daily life.
3) Learning behavioral interventions for non-restorative sleep and fatigue.
4) Learning how to more effectively use analgesics and self-management treatments for pain.
5) Learning relaxation skills to reduce muscle tension and promote distraction from pain.

WE ARE ON THE WEB:

WWW.ADAPTstudy.COM

Patient Stories:

Initially **Fred*** was hesitant to join our study; he is a self-described "medication hater." Despite his reservations, Fred stuck with us and the medication through the entire 20 weeks of the study. In phase 2, the dose of Effexor was increased to 300 mg and he was randomized to receive PST-DP. Fred said that his therapist, Rachel, "made me think—why put up with pain if I can do something about it?" Fred optimized his analgesic use, started physical therapy, obtained a wheeled walker, is communicating more effectively with his family and PCP, is walking more often, and is better able to make decisions positively affecting his health. His back pain is virtually gone, and it has had a positive impact on many aspects of his life.

At her first visit, **Beatrice*** was experiencing intense low back pain and was severely depressed. Now she is near completing the second phase of the study and speaks very highly of the program. Beatrice received supportive management in addition to the increased dose of Effexor. "The study helped me get my life back, I feel much better than when I first started. I hope this program can help others. I'm feeling good and grateful for all you've done for me." Her pain is now rated at a fraction of when she entered the project. While she was not randomized to receive PST-DP, the attention to adherence, management of treatment-emergent side effects, and close monitoring of improvement led to good outcomes.

** Indicates that names have been changed, but these are indeed recent "graduates" of ADAPT.*

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Chronic Pain Gets National Scientific Attention:

The staff of ADAPT applaud the recent publication by the prestigious Institute of Medicine (IOM) entitled "Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research." The first two sentences of the report observe that, "Chronic pain affects at least 116 million American adults – more than the total affected by heart disease, cancer, and diabetes combined. Pain also costs the nation up to $635 billion each year in medical treatment and lost produc¬tivity." Given that the population of Pittsburgh and Allegheny County is among the oldest in the country (in 2009, 16.8% of the residents were older than 65 compared to a US average of 12.9%), and that many painful conditions, especially arthritis, increase with age, Pittsburgh may be considered to be experiencing an epidemic of persistent pain. This long overdue monograph from the IOM finally brings national attention to two problems that we see daily: 1) chronic pain whittles away at patient's quality of life, robs them of restorative sleep, strains relationships, leads to overuse of analgesics, and is associated with high rates of depression; and 2) many physicians are poorly trained in the assessment and successful management of chronic pain. Hopefully the research and clinical initiatives at Pittsburgh-based hospitals (such as the ADAPT Project) will assure the mission of the IOM's paper - to educate physicians, prevent the conversion of acute to chronic pain, and treat patients using self-management and aggressive pharmacologic and non-pharmacologic treatment approaches.

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Quick Facts about ADAPT

- Everyone receives active treatment. There is no placebo.
- The medication we use is Venlafaxine xr.
- Our offices are located at Bellefield Towers, Oakland, near Webster Hall, Library of Information Science School, and Heinz Chapel.
- Participants are seen weekly, but sometimes visits can be spaced out or assessments done by phone.
- Participants can continue to take any currently prescribed analgesics during the study, but we ask they not start any new treatments or increase the dose. We have observed decreases in use of opioids during participation.
- Patients receive **medication and treatment at no cost** and can be reimbursed up to $130 for participating**.**

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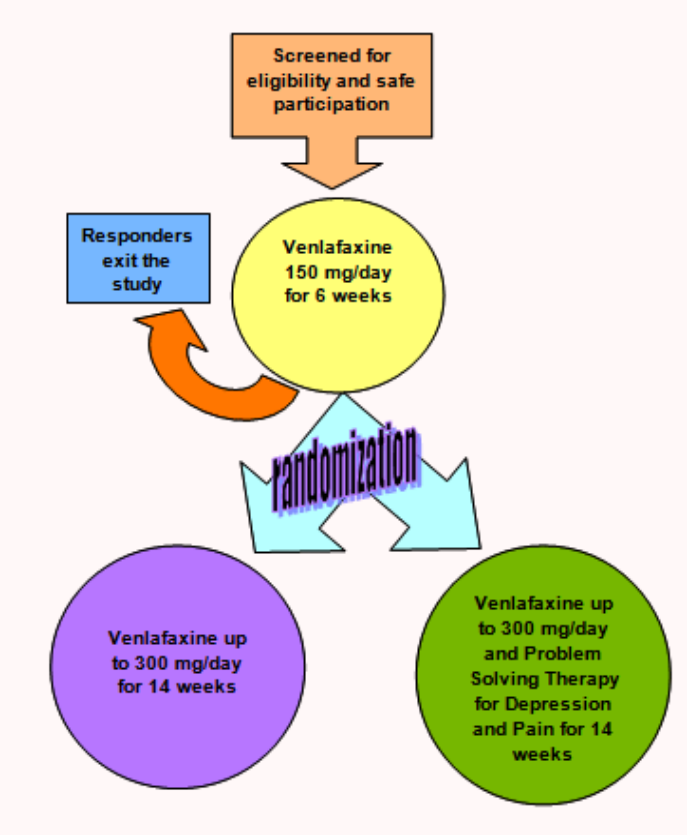
Study Design:



Meet the Staff of Adapt

Jordan Karp, MD Principal Investigator
Dr. Karp is board certified in psychiatry with added qualifications in geriatric psychiatry. He is Medical Director of Geriatric Psychiatry at UPMC Pain Medicine at Centre Commons, the University of Pittsburgh Medical Center's multidisciplinary pain clinic. Dr. Karp's NIH-funded research focuses on: 1) primary care-based treatments for older adults living with co-morbid pain and depression, and 2) stepped care treatments for older adults with difficult to treat depression. Dr. Karp has published extensively in these areas and speaks often about the treatment of depression in medically ill populations both locally and nationally.

Jill A. Tarr, LCSW, Project Coordinator
Jill is a Project Coordinator with the ADAPT Research Study. After receiving her MSW from the University of Pittsburgh, she worked in various positions as a community social worker ranging from community mental health, adoption, and geriatrics. Her research experience started in 2004 at WPIC and has included the Pittsburgh Girls study and the Puberty Study.

Sunita Chickering, MA Senior Clinician
Sunita graduated from the University of Iowa with a B.S. in Psychology and an M.A. in Rehabilitation Counseling. In the past, Sunita has worked with individuals with a wide range of disabilities including mental health problems such as depression and anxiety, as well as substance abuse problems. Sunita believes passionately in helping others to remove obstacles in their lives and obtain the quality of life they desire.

Rachel San Pedro, LSW Senior Clinician
Rachel is a clinician with the ADAPT Research Study. After receiving her MSW from the University of Pittsburgh, she worked as an inpatient psychiatric social worker. Her research experience started in 1999 at WPIC and has included studies on borderline personality disorder, eating disorders, post-partum depression, and childhood trauma.

Chloe Bolon, B.S.
Research Specialist
Chloe graduated *magna cum laude* from the University of Pittsburgh with a B.S. in psychology and political science. She sees patients in phase 1 of the ADAPT study. She also works on Dr. Karp's studies using buprenorphine for treatment resistant depression.