Online Treatments for Mood and Anxiety Disorders in Primary Care

This study is ongoing, but not recruiting participants.

Sponsor:
University of Pittsburgh

Collaborator:
National Institute of Mental Health (NIMH)

Information provided by (Responsible Party):
Bruce Rollman, University of Pittsburgh

ClinicalTrials.gov Identifier:
NCT01482806

First received: November 22, 2011
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History of Changes

Purpose

Depression and anxiety are common in primary care practice and are associated with substantial reductions in health-related quality of life. This Project will test the comparative effectiveness of two **on-line treatments** for these conditions provided through the context of a Collaborative Care program: (1) moderated access to a proven-effective computerized cognitive behavioral **therapy** (CCBT) program; versus (2) moderated access to CCBT plus an Internet support group (CCBT+ISG). The Project will also compare the effectiveness of these **treatments** to PCPs' "usual care" for these conditions, and evaluate the adoption and maintenance of CCBT+ISG by practices following the conclusion of the **trial** to provide a greater understanding of how to best scale the delivery of these interventions into a variety of primary care settings.

Condition	Intervention	Phase
Depression Generalized Anxiety Disorder Panic Disorder	Behavioral: CCBT+ISG/Collaborative Care Behavioral: CCBT/Collaborative Care	Phase 2 Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Factorial Assignment
Masking: Single Blind (Outcomes Assessor)
Primary Purpose: **Treatment**

Official Title: **Online Treatments** for Mood and Anxiety Disorders in Primary Care

Resource links provided by NLM:

MedlinePlus related topics: Anxiety

U.S. FDA Resources

Further study details as provided by University of Pittsburgh:

Primary Outcome Measures:

- SF-12 MCS [Time Frame: 6-Month Follow-up] [Designated as safety issue: No]

  The investigators will assess all study patients' mental health-related quality of life (HRQoL) on the SF-12 MCS via telephone at 6-months follow-up, and we will monitor patients for an additional 6 months to evaluate the durability of our interventions.

Secondary Outcome Measures:

- Hamilton Rating Scale for Depression [Time Frame: 6-Months] [Designated as safety issue: No]

  The investigators will assess all study patients' mood symptoms using the HRS-D via telephone at 6-months follow-up, and we will monitor patients for an additional 6 months to evaluate the durability of our interventions.

- Hamilton Rating Scale for Anxiety [Time Frame: 6-Months] [Designated as safety issue: No]
- WHO Health and Work Performance Questionnaire [Time Frame: 6-Months] [Designated as safety issue: No]
- Health Services Utilization and Costs [Time Frame: 12-Months] [Designated as safety issue: No]
- Attitudes to Computerized CBT [Time Frame: 6-Months] [Designated as safety issue: No]
- Computerized CBT and Internet Support Group Usage [Time Frame: 12-Months] [Designated as safety issue: No]

Estimated Enrollment: 700
Study Start Date: February 2012
Estimated Study Completion Date: December 2016
Primary Completion Date: December 2015 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Computerized CBT + Internet Support Group Guided patient access to Beating the Blues plus access to a moderated ISG where patients will be able to communicate confidentially to receive and provide advice and peer-support from other study participants (CCBT+ISG; N=300).	Behavioral: CCBT+ISG/Collaborative Care Guided patient access to the Beating the Blues CCBT program plus access to a moderated ISG where patients will be able to communicate confidentially to receive and provide advice and peer-support from other study participants These interventions will be delivered as part of a collaborative care intervention provided in concert with their usual source of primary care. Patients will also have the option of pharmacotherapy for their mood and/or anxiety disorder and referral to a community mental health specialist per their preference.
Experimental: Computerized CBT Alone Guided patient access to Beating the Blues, a proven-effective, **on-line** 8-session CCBT program approved for use in the United Kingdom (CCBT-alone; N=300).	Behavioral: CCBT/Collaborative Care Guided patient access to the Beating the Blues CCBT program. This interventions will be provided as part of a collaborative care intervention provided in concert with their usual source of primary care. Patients will also have the option of pharmacotherapy for their mood and/or anxiety disorder and referral to a community mental health specialist per their preference.
No Intervention: Usual Care Primary care physicians' "usual care" for mood and anxiety disorders (UC; N=100).	

Detailed Description:

Depression and anxiety are prevalent in primary care practice, associated with substantial reductions in health-related quality of life (HRQoL), and generate a significant excess of morbidity. In response, dozens of trials have demonstrated the greater effectiveness of "Collaborative Care" for these conditions vs. primary care physicians' usual care. Yet for a variety of reasons, these models have not been widely implemented. Therefore, an urgent need remains to develop and test more scalable, powerful, and innovative versions of Collaborative Care while simultaneously developing a greater understanding of how best to provide these interventions through primary care where the majority of depressed and anxious patients seek treatment.

Thousands of web sites provide medical information and the number of Internet support groups (ISG) where the public can exchange information about treatments is proliferating. Still, clinical trials have not established the benefits of utilizing the Internet in this manner. Concurrent with these developments, several computerized cognitive behavioral therapy (CCBT) programs have been proven effective at treating patients with mood and anxiety disorders and used by hundreds of thousands of patients outside the U.S. Yet CCBT remains little utilized inside the U.S., and no trials have incorporated CCBT into a Collaborative Care intervention or examined the effectiveness of combining CCBT with an ISG for these disorders.

We propose a 4-year comparative effectiveness trial that will randomize 700 primary care patients aged 18-75 who have at least a moderate level of mood and/or anxiety symptoms and reliable access to both the Internet and e-mail to either: (1) guided patient access to Beating the Blues, a proven-effective on-line CCBT program (CCBT-alone; N=300); (2) guided patient access to Beating the Blues plus access to a moderated ISG (CCBT+ISG; N=300); or (3) their PCP's "usual care" (N=100). Our primary hypothesis is that patients in our CCBT+ISG arm will report a clinically meaningful 0.30 effect size (ES) or greater improvement in HRQoL on the SF-12 MCS compared to patients in our CCBT-alone arm at 6-months follow-up, and we will monitor patients for an additional 6 months to evaluate the durability of our interventions. Our secondary hypothesis is that CCBT-alone patients will report a 0.50 ES or greater improvement in HRQoL on the SF-12 MCS versus "usual care" at 6-months follow-up. To better understand how online mental health treatments are best provided through primary care, we will also evaluate: (a) their effectiveness across and within age strata; (b) their cost-effectiveness; (c) how patients utilize the components of our interventions; (d) patient subgroups for whom our interventions may be particularly effective; and (e) the adoption and maintenance of our interventions by practices following the Intervention Phase of the Project. Study findings are likely to have profound implications for transforming the way mental health conditions are treated in primary care and focus further attention to the emerging field of e-mental health by other U.S. investigators.

Eligibility

Ages Eligible for Study: 18 Years to 75 Years (Adult, Senior)
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- 18-75 Years of age.
- Current major depression, panic, and/or generalized anxiety disorder on PRIME-MD.
- At least a moderate level of mood and/or anxiety symptoms (PHQ-9 ≥ 10 or a GAD-7 ≥ 10).
- Not receiving treatment for a mood or anxiety disorder from a mental health specialist.
- Has a telephone, e-mail address, and reliable access to the Internet.
- Stable medical condition and life expectancy greater than one year.

Exclusion Criteria:

- Active suicidal ideation or psychotic disorder.
- History of bipolar disorder.
- Alcohol dependence or other substance abuse disorder within the past three months.
- Plans to leave present source of care over the following year.
- Non-English speaking, illiterate, or having a visual or auditory barrier limiting ability to participate in telephone assessments, interventions, or provide signed, informed consent.

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT01482806

Locations

United States, Pennsylvania

University of Pittsburgh Medical Center
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Sponsors and Collaborators

University of Pittsburgh

National Institute of Mental Health (NIMH)

Investigators

Principal Investigator: Bruce L. Rollman, MD, MPH University of Pittsburgh

More Information

Additional Information:

Related Info

Publications:

Rollman BL, Herbeck Belnap B, Rotondi AJ. Internet support groups for health: ready for the Affordable Care Act. J Gen Intern Med. 2014 Nov;29(11):1436-8. doi: 10.1007/s11606-014-2884-z.

Responsible Party: Bruce Rollman, Professor of Medicine, University of Pittsburgh
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Keywords provided by University of Pittsburgh:
Depression
Anxiety
Primary care
Cognitive Behavioral **Therapy**
Internet
Support groups
Technology assisted

Additional relevant MeSH terms:
Disease
Depression
Anxiety Disorders
Panic Disorder
Pathologic Processes
Behavioral Symptoms
Mental Disorders

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