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14. ABSTRACT: <u>Background:</u> Posttraumatic stress disorder (PTSD) is considered a major public health problem in the U.S. because it has fairly high prevalence and because people with PTSD often have problems with their work, relationships, and health. There are effective treatments for PTSD, such as prolonged exposure therapy (which works by inviting people to revisit their memories of traumatic events and to face objectively safe situations they have avoided). However, individuals with PTSD may not get the treatment they need because they live in rural locations with no trained clinicians or because they have transportation problems (for example, the distance makes frequent travel unfeasible or they cannot afford gas). Some individuals with PTSD do not feel comfortable driving (due to fears of roadside bombs) or they may feel uncomfortable in formal hospitals or other crowded places. One new method of giving treatments is by using interactive video equipment (called "telemedicine"), so that the patient and his therapist can talk with each other and see each other over a monitor. <u>Objectives/Rationale:</u> The goal of the study is to compare exposure therapy in a usual format (face-to-face, in-person therapy) to the therapy in a telemedicine format. This project will help determine whether telemedicine can be used to provide needed therapies to veterans with PTSD in remote locations. <u>Study Design:</u> 250 military veterans with PTSD will receive exposure therapy either by telemedicine or in-person care. <u>Progress:</u> To date, 109 veterans have been enrolled in the study. PTSD symptoms and cognitive functioning are measured before treatment begins, at the completion of therapy, and at a 6 month follow-up assessment. At the end of therapy veterans and therapists are asked how satisfied they were with each type of treatment.						
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Annual Technical Progress Report

INTRODUCTION:

Posttraumatic stress disorder (PTSD) is considered a major public health problem in the U.S. because it has fairly high prevalence and because people with PTSD often have problems with their work, relationships, and health. There are effective treatments for PTSD, such as prolonged exposure therapy (which works by inviting people to revisit their memories of traumatic events and to face objectively safe situations they have avoided). However, individuals with PTSD may not get the treatment they need because they live in rural locations with no trained clinicians or because they have transportation problems (for example, the distance makes frequent travel unfeasible or they cannot afford gas). Some individuals with PTSD do not feel comfortable driving (due to fears of roadside bombs) or they may feel uncomfortable in formal hospitals or other crowded places. One new method of giving treatments is by using interactive video equipment (called "telemedicine"), so that the patient and his therapist can talk with each other and see each other over a monitor (like a two-way television screen).

The goal of the study is to compare exposure therapy in a usual format (face-to-face, in-person therapy) to the therapy in a telemedicine format. This project will help determine whether telemedicine can be used to provide needed therapies to veterans with PTSD in remote locations.

Two hundred fifty (250) military veterans with PTSD will receive exposure therapy either by telemedicine or in-person care. Veterans will be enrolled from the primary care and mental health clinics at the San Diego VA Healthcare System. Therapy will be provided over 12 weekly sessions lasting 90 minutes each. PTSD symptoms will be measured before treatment begins, at the completion of therapy, and at a 6 month follow-up assessment. Learning and memory tests will be given before treatment begins to examine whether cognitive functioning influences treatment outcome, and at the end of therapy veterans and therapists will be asked how satisfied they were with each type of treatment.

BODY:

In the third year of the "San Diego Telemedicine Exposure Project" (STEP), we are focused on recruitment and retention of subjects while providing psychotherapy in both in-person and telemedicine formats. We are actively recruiting, treating, and assessing subjects for the study.

At our last Annual Report, we had been referred 172 veterans and had randomized 58 veterans. We have now been referred 330 veterans.

Of the 330 referred, including 277 men (84%) and 53 women (16%), 109 (33%) veterans have been randomized to the study (i.e., we nearly doubled our sample size in one year). Ten veterans are currently in therapy, one has delayed the start of therapy due to scheduling issues, 67 have completed therapy, and 31 (28%) have dropped out of therapy. The 31 who dropped out included 4 who dropped out before their first therapy session due to scheduling conflicts, 5 who dropped out during therapy because of scheduling conflicts, 11 who stopped attending their sessions for unknown reasons and did not respond to phone calls and letters from study personnel, 6 who reported not feeling able to continue with the imaginal exposure component of treatment, 3 who cited

personal problems interfering with participation, 1 who dropped out due to medical complications, and 1 who had an unplanned move out of state. Of the 109 who were randomized, 88 (81%) are men, and 21 (19%) are women. The racial/ethnic information for the 109 randomized veterans is as follows: 60 (55%) identify as Caucasian, 19 (17%) identify as African American, 18 (16%) identify as Hispanic/Latino, 6 (6%) identified as Asian, 3 (3%) identified as Native Hawaiian/Pacific Islander, and 3 (3%) identified as Native American.

Of the 330 referred, 221 (67%) have not been randomized to the study. One hundred sixty two (73%) chose not to enroll in the study (67 declined the phone screen after hearing the study description, and 95 were eligible after the initial phone screen, but later declined to participate). Of the remaining 59, 24 (11% of the total referred) were not eligible; 16 (7%) have upcoming study assessments and their eligibility has not yet been confirmed; 5 (2%) have so far been unreachable by our staff; 5 (2%) do not have working phone numbers; 4 (2%) have asked to be called at a later date; 3 (1%) are on a "medication hold" (postponed enrollment due to a recent medication change - they must be on stable types and dosage for 2 months); 1 (1%) is on a "sobriety hold" (postponed enrollment because they have been alcohol or substance dependent in the last 12 weeks); and 1 (1%) is on a "therapy hold" (postponed enrollment because they are currently enrolled in a psychotherapy that is not allowed concurrently with the study treatment – and must wait until that therapy is completed). All veterans will be re-assessed for study inclusion after their respective holds have lifted.

We replaced the study assessor who moved, and the replacement is trained and currently conducting assessments. We continue to have weekly meetings via telemedicine for training, communication, and goal-setting.

Our biggest focus remains recruitment. Our best recruitment strategy continues to be direct contact with providers by team members and local talks by the PI and Co-Investigators to increase awareness of the study as a clinical resource for veterans with PTSD. In each study location, we continue to meet with mental health providers directly with written information about the study. We have continued going to local college campuses to speak to their campus veteran organizations.

In the past year we posted newspaper advertisements in a local free newspaper and a military newspaper to augment our other recruitment measures, and we developed a website for the study to give to potential subjects. We have distributed several study newsletters to providers to remind them of the study and encourage their continued referrals to the study. We have distributed our color recruitment brochure to clinical and administrative staff and displayed the brochures in clinic waiting rooms and public bulletin boards. We highlight the fact that we are providing empirically-based psychotherapy for PTSD in a one-on-one (vs. group) format, which is preferable to many veterans. The PI continues to give local talks to increase awareness of PTSD and of the study as a clinical resource for veterans with PTSD:

1. July 23, 2010 for PTSD Seminar in VA Healthcare System: "The PTSD Clinical Team and Older Adults with PTSD."
2. July 30 and August 6, 2010 for VA Prolonged Exposure Consultation Team: "Overview of Prolonged Exposure Therapy"
3. August 6, 2010: for PTSD Seminar in VA Healthcare System: "Psychotherapy and

Effective Case Presentations."

4. August 9, 2010 for Stein Institute Grand Rounds (UCSD): "PTSD in Older Adults"
5. August 11, 2010 for American Psychological Association's (APA's) Community Engagement Panel in collaboration with the San Diego Armed Services YMCA: "Vicarious Trauma and Self-Care."
6. February 23, 2011 for Anxiety Disorders Seminar: "Prolonged Exposure Therapy"
7. April 20, 2011 for Empirically-Based Psychotherapies Seminar: "Telemental Health"

The PI is on the Telemental Health Steering Committee at the VA, and our team has worked very closely with the San Diego VA clinical telemedicine team in an effort to educate clinicians about telemedicine. The PI attends the monthly meetings of this Committee to update telemedicine staff about our research progress and to exchange ideas (and conduct equipment troubleshooting) with the team. Our telemedicine research accounts for 30% of the telemedicine activity at the San Diego VA.

We continue to have weekly meetings for training, communication of problems and progress, and goal-setting. We conduct these meetings via the telemedicine equipment to help familiarize the staff with the technology and troubleshoot as needed. These meetings have been invaluable in identifying targets for the study and getting updates from staff. For example, we discovered that we were having video calls "drop" simultaneously in different locations. We started to track such problems systematically and we learned how to adjust bandwidth to the needs of the study so that we could minimize such problems in the future.

VA Central Office (VACO) asked the PI to participate on the Committee to Develop the Appendix to the VHA Telemental Health Operations Manual for Delivery of Evidence-Based Psychotherapy for PTSD. Additionally, through an invitation from VACO, the PI has been a member of the National Workgroup to Develop the VHA Workshop and Training Video for Delivery of Evidence-Based Psychotherapy for PTSD via Telemental Health.

Researchers and clinicians from across the United States have requested copies of our materials and consultation about clinical and research issues. We have shared information about the PE protocol we adapted for the study and about our use of telemedicine technology generally to deliver psychotherapy to remote sites. Scientific journals have sought our expertise in these areas as ad hoc reviewers as well.

The PI is the Prolonged Exposure (PE) therapy consultant for the study therapists, and we have two consultation meetings each week to discuss cases. The PI continues to co-sign each therapist's notes to monitor adherence to protocols and any safety issues, and he is one of only 17 VA PE Trainers nationally. In addition to facilitating 4-day trainings for VA clinicians, the PI consults with clinicians nationally (listening to their therapy tapes and giving specific feedback) on cases each week to maintain his expertise in the treatment.

We have maintained approval for the study through the UCSD Human Research Protections Program, the VA Research and Development Subcommittee, and Karen Eaton, MS at the Human Research Protection Office (HRPO), Office of Research Protections (ORP), United States Army Medical Research and Materiel Command (USAMRMC).

As we have discussed from the beginning of the study, we expected that recruitment might be challenging for several reasons. Although we are recruiting at a steady pace, we are attempting to recruit subjects more quickly to meet our target sample size by the end of the study in mid-2012. There are particular challenges in recruiting for multi-session psychotherapy studies for PTSD among OEF/OIF veterans. We ask our veterans to attend 17 sessions of 90 minutes or longer – including assessments, and we expect that due to PTSD (primarily avoidance of the trauma memories and activities that cause discomfort) and comorbid diagnoses (e.g., the apathy associated with depression) and logistical issues (e.g., competing demands at home, at college, and at work) that many of these veterans are having difficulties with travel, organization, and commitments.

As we have also stated in past reports, we are competing with several other treatment studies and clinical training demands that are targeting the treatment of veterans with PTSD. By design, the eligibility criteria for this study are broad so that findings will apply to most veterans with PTSD (different eras, different trauma types, etc.). We are pleased that we have a small rate of veterans excluded based on eligibility. This suggests that our entry criteria are not too restrictive. Fortunately, our rate of dropout from therapy (28%) has declined. We have done our best to retain subjects (problem solving scheduling and travel issues, making multiple calls after therapy non-attendance, sending letters). One third of the veterans referred to the study have been randomized to treatment (a higher rate than many similar studies). We have encouraged those who have dropped out of the therapy component of the study to continue their post-treatment and follow-up assessments so that we can learn more from their data.

We have been surprised at how long it takes to hire new staff through the VA. We had a study assessor and a study therapist move out of state this year, and replacing those positions has taken many months. We just learned that another study therapist must move in mid-September 2011.

Another issue that we did not anticipate is that the VA started disseminating two new empirically-based psychotherapies for PTSD (PE and Cognitive Processing Therapy) in the past two years. Dozens of new providers and trainees have been taking PTSD cases that would otherwise be directed to this study. This issue is likely to continue in coming years.

We had a poor response to our newspaper advertisements in the local free newspaper and the military newspaper. We consulted with other investigators to explore recruitment through social networking sites such as Facebook, MySpace, and Google AdWords (which directs interested veterans to the website we developed), but we had disappointing results. We have instead nurtured a more personal approach by tracking who has referred veterans to the study and facilitating future referrals.

In summary, to optimize recruitment we have: (1) added several recruitment sites in both primary care and specialty mental health clinics; (2) produced more brochures and newsletters to advertise directly to treatment providers and veterans; (3) attended meetings across the county to educate providers and veterans about the project; (4) spoken at local events to aid recruitment; (5) advertised in newspapers and online, and (6) tracked specifically who is referring veterans to the study to foster those relationships.

KEY RESEARCH ACCOMPLISHMENTS:

- We continued the recruitment, screening, assessment, and treatment of subjects.
- We obtained 330 referrals to the study, and 109 veterans have been randomized to treatment.
- We have continued to hone our methods of recruitment.
- We refined our study brochure and developed new study newsletters for clinicians to inform them about eligibility criteria and study progress.
- The PI presented at several scientific conferences and met with colleagues to discuss additional ways to improve the methods of this project (see list in Reportable Outcomes).
- The PI continued to build expertise in Prolonged Exposure therapy, including running 4-day trainings and being the consultant in 4 weekly consultation teams each week (2 for the study, one for trainees, and one for clinicians in the VA system nationwide).
- We continue to have weekly meetings via telemedicine for training, communication, and goal-setting.
- We maintained approval from all human subjects committees (VA, UCSD, and HRPO) to continue the project

REPORTABLE OUTCOMES:

Published Abstracts or Presentations by PI in Past Year

1. Bormann, J. E., Hurst, S., **Thorp, S. R.**, Kelly, A. Bone, P., von Kaenel, L., Lang, A. (July 2010). *Application of a psycho-spiritual mantram intervention to manage PTSD symptoms in veterans: A qualitative analysis*. Paper presented at the VA Office of Mental Health Services conference, Baltimore, MD.
2. Ross, B.S., Repp, A.L., Moreno, L., Fidler, J., Floto, E., Shah, N., Zamora, T., Madra, N., Hurst, S., Liu, L., Agha, Z. & **Thorp, S.R.** (August 2010). *Treating veterans with PTSD via telemedicine is associated with reduced travel distance, time and costs*. Paper presented at the 118th annual American Psychological Association (APA) national convention, San Diego, California.
3. Sones, H. M., **Thorp, S. R.**, Greene, C. J., Grubbs, K. M., & Morland, L. A. (August 2010). *Posttraumatic stress disorder in the military*. Paper presented at the 118th annual American Psychological Association (APA) national convention, San Diego, California.
4. Bormann, J. E., **Thorp, S. R.**, Wetherell, J.L. & Hurst, S. (August 2010). *Empirical Findings on the health benefits of mantram repetition: A portable contemplative practice*. Paper presented at the 118th annual American Psychological Association (APA) national convention, San Diego, California.
5. Stevens, J. M., Dahlin, K. M., Rivas, T. E., Priest, E. G., Lucas, C. M., Lightman, N. S., Toburen, L., Castilli, M., Holloway, K., **Thorp, S. R.**, Dalenberg, C. J. (August 2010). *International and multicultural citation patterns and trends in the PTSD literature*. Paper presented at the 118th annual American Psychological Association (APA) national convention, San Diego, California.
6. Priest, E. G., Dahlin, K. M., Lucas, C. M., Stevens, J. M., Rivas, T. E., Lightman, N. S., Castilli, Alhassoon, O., **Thorp, S. R.**, Dalenberg, C. J. (August 2010).

- Biologically-oriented publications in child and adult PTSD research: Emerging trends.* Paper presented at the 118th annual American Psychological Association (APA) national convention, San Diego, California.
7. Bormann, J. E., **Thorp, S. R.**, Liu, L., Wetherell, J.L. Glaser, D., & Lang, A. J. (August 2010). *Spiritual well-being mediates the effects of a psycho-spiritual mantram program on PTSD symptom severity in veterans with military-related PTSD.* Poster presented at the International Congress of Behavioral Medicine (ICBM), Washington, DC.
 8. Bormann, J., **Thorp, S.**, Hurst, A., & Wetherell, J.L. (September 2010). *Mind-body spiritual complementary approach for managing symptoms of trauma in military veterans.* Paper presented at the 15th International Conference on Violence, Abuse and Trauma (IVAT), San Diego, CA.
 9. Mackintosh, M., **Thorp, S. R.**, Sones, H. M., Hynes, A. K., Morland, L. A. (November 2010). *Cross-cultural psychometric properties of the Clinician-Administered PTSD Scale (CAPS) among mainland and Pacific Island combat veterans.* Paper presented at the 26th annual International Society for Traumatic Stress Studies (ISTSS) national convention, Montreal, Quebec, Canada.
 10. **Thorp, S. R.**, Sones, H. M., & Wetherell, J. L. (November 2010). *Older veterans with PTSD: Is exposure therapy feasible?* Paper presented at the 44th annual Association for Behavioral and Cognitive Therapies (ABCT) convention, San Francisco, CA.
 11. Moreno, L., Repp, A., Floto, E., Zuest, D.K., Ross, B.S., Fidler, J., Madra, N., Zamora, T., Shah, N., **Thorp, S.R.**, & Agha, Z. (November 2010). *Post traumatic stress disorder (PTSD) telemedicine study: The key to enrolling patients in cognitive processing and prolonged exposure therapies.* Poster presented at the 44th annual Association for Behavioral and Cognitive Therapies (ABCT) convention, San Francisco, CA.
 12. **Thorp, S. R.**, & Tuerk, P. (November 2010). *Treatment of returning service members from Afghanistan and Iraq: Efforts to enhance treatment delivery and outcomes.* Paper presented at the 44th annual Association for Behavioral and Cognitive Therapies (ABCT) convention, San Francisco, CA.
 13. Floto, E. **Thorp, S.R.**, Zuest, D.K., Repp, A.L., Moreno, L., Fidler, J., Zamora, T., Ross, B.S., Shah, N., Madra, N., Roter, D., Laud, P., & Agha, Z. (November 2010). *Prolonged exposure therapy (PE) via telemedicine for the treatment of post-traumatic stress disorder (PTSD) in veterans.* Poster presented at the 44th annual Association for Behavioral and Cognitive Therapies (ABCT) convention, San Francisco, CA.
 14. **Thorp, S.R.** (November 2010). *Portrayal of an OEF-OIF Veteran with PTSD for Prolonged Imaginal Exposure and Cognitive Processing Therapy* (Edna B. Foa and Patricia A. Resick, presenters). Presented at the 44th annual Association for Behavioral and Cognitive Therapies (ABCT) convention, San Francisco, CA.
 15. Aupperle, R. L., Allard, C. B., Grimes, E. M., Simmons, A. N., Flagan, T., Cissell, S. H., **Thorp, S. R.**, Norman, S. B., Paulus, M. B., & Stein, M. B. (December 2010). *Unique influence of PTSD symptom clusters on neural activations during anticipatory processing.* Paper presented at the 49th Annual Meeting of the American College of Neuropsychopharmacology (ACNP), Miami Beach, FL.
 16. Zuest, D., Agha, Z., Floto, E., Fidler, J., Moreno, L., Barsotti, R., Repp, A., Ross, B.,

Zamora, T., Shah, N., & **Thorp, S.** (May 2011). Treatment Avoidance in PTSD Patients: Face-to-Face Versus Telemedicine. Poster to be presented at the American Telemedicine Association 16th Annual International Meeting & Exposition in Tampa, Florida.

We also produced slides to guide the use of telemental health in the VA system:

1. **Thorp, S. R.**, Tuerk, P., & Eftekhari, A. (2011). Guidelines for PE via Telemental Health. [Online slides to guide prolonged exposure therapy via telemental health technology]. Available from all VA computers at:
<http://vaww.infoshare.va.gov/sites/pe/Lists/Useful%20Materials%20%20Information/AllItems.aspx?PageView=Shared>

Publications by PI in past year

Although the PI has had several peer-reviewed and invited chapters in the past year (on topics related to PTSD but not directly related to this project), our statistician has advised us not to examine the outcome data from the study prior to study completion. We plan to publish several papers from this study after the completion of data collection.

CONCLUSION:

We feel that we have made good progress in the third year of our project. The PI has become recognized as an expert in psychotherapy via telemedicine. We have refined our recruitment and retention strategies. To enhance recruitment, we have: (1) added several recruitment sites in both primary care and specialty mental health clinics; (2) produced more brochures and newsletters to advertise directly to treatment providers and veterans; (3) attended meetings across the county to educate providers and veterans about the project; (4) spoken at local events to aid recruitment; (5) advertised in newspapers and online, and (6) tracked specifically who is referring veterans to the study to foster those relationships. We believe that this project will add greatly to our knowledge about how best to provide psychotherapy to veterans with PTSD at remote locations.

REFERENCES: None.

APPENDICES: None.

SUPPORTING DATA: None.