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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, 58 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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Table of Contents

	<u>Page</u>
Introduction.....	4
Body.....	4
Key Research Accomplishments.....	9
Reportable Outcomes.....	10
Conclusion.....	11
References.....	11
Appendices.....	11

Annual Technical Progress Report

INTRODUCTION:

Background: 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).

Objectives/Rationale: 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. Study Design: 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 second year of the project, the project has fully shifted from preparation to execution, and 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 Quarterly Report, we had been referred 100 veterans and had randomized 42 veterans.

We have now obtained referrals for 172 veterans.

Of the 172 referred, 58 veterans (34%) have been randomized to the study. This includes 44 men (76%) and 14 women (24%). Eleven veterans are currently in therapy, 26 have completed therapy, one just completed assessments and is awaiting the first therapy appointment, one had a medication change after randomization and is on a two month stability hold, one is on a hold until the veteran's outside therapy is complete, and 18 (32%) have dropped out of the study (9 stopped attending their sessions for unknown reasons and did not respond to phone calls and letters from study personnel; 4 did not like the type of therapy; 2 had problems with the schedule; 2 dropped before therapy began

(also scheduling conflicts); and one due to a sudden move out of state). The racial/ethnic information for the 58 randomized veterans is as follows: 32 (55%) identify as Caucasian, 10 (17%) identify as African American, 10 (17%) identify as Hispanic/Latino, 4 (7%) identify as Asian/Pacific Islander, and 2 (4%) identify as American Indian.

Of the 172 referred, 114 (66%) have not been randomized to the study. Sixty two (54%) chose not to enroll in the study (29 declined the phone screen after hearing the study description, and 33 were eligible after the initial phone screen but later declined to participate). Fourteen (12%) of those referred were not eligible (e.g., met criteria for mania in the past year). Ten (9%) are awaiting assessment appointments, which will determine whether they are eligible for treatment in the study. Eleven (10%) veterans are on “personal holds” (e.g., vacations) and requested to be contacted at a later date. Six (5%) veterans are pending initial contact from our staff. Three (3%) veterans are on a “sobriety hold” (postponed enrollment because they have been substance or alcohol dependent within the last year, and must be dependence-free for one year before being assessed for the study). Four (3.5%) of the veterans referred to the study are on a “therapy hold” (postponed enrollment because they are currently in a psychotherapy that is not allowed concurrently with the study treatment – and must wait until that therapy is completed). Similarly, four (3.5%) veterans are on a “medication hold” (postponed enrollment because their psychotropic medications were recently changed, and they must wait until they have been on a stable regimen for two months prior to being assessed for the study). The aforementioned “on hold” veterans will be re-assessed for study inclusion after their respective holds have ended.

Our recruitment strategies are evolving as we progress. I consulted with Edna Foa, Ph.D. (the developer of Prolonged Exposure therapy – PE), to benefit from her expertise in running large psychotherapy trials for PTSD. I have also consulted with Leslie Morland, Psy.D., who has run similar studies in Hawaii. We exchanged information about the challenges facing us in this type of research (e.g., technological issues, issues of hiring and training within the VA, and recruiting and retaining subjects across several months of weekly meetings) and the solutions we have devised. Dr. Morland also shared with us information she learned at the Care Coordination General Telehealth Forum (sponsored by the VA Employee Education System) that she attended. These consultation meetings resulted in several new ideas for recruitment and retention.

In recognition of the value of branding to aid familiarity and recognition for providers and veterans, we have named the study the "San Diego Telemedicine Exposure Project" (STEP). The name conveys both exposure therapy and exposure to the telemedicine mode of treatment. We also worked with a graphic artist who developed a logo for us free of charge:



The Study Coordinator continues to attend the PTSD clinic weekly team meetings to become familiar with the staff and the procedures within each clinic. We have met with primary care staff to inform them of the study as well. We have had the most success by meeting with individual mental health providers and giving them written information about the study. 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.

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 have created a study newsletter that lists eligibility criteria for veterans and broadly describes the progress of the study. We disseminated the newsletter to all mental health providers to remind them of the study and encourage their continued referrals to the study.

During the past year we started attending veteran service organization meetings in the community to recruit for the studies. Most recently, I spoke at the meeting of the United Veterans Council, which is a gathering of about 80 leaders in the veteran community. The attendees were very enthusiastic about the study. I continue to give local talks to increase awareness of PTSD and of the study as a clinical resource for veterans with PTSD:

1. May 28, 2009 for Grand Rounds: "The Psychotherapy of Combat Related PTSD"
2. August 3 and 10, 2009 for VA San Diego PTSD Seminar: "Prolonged Exposure Therapy."
3. September 18, 2009 for Mira Costa College Administrators: "PTSD and Veterans: Recommendations for a College Campus."
4. September 28, 2009 for VA San Diego PTSD Seminar: "Treatment Guidelines for Different Populations with PTSD."
5. November 12, 2009 for VA San Diego Psychology Intern Seminar: "PTSD"
6. November 18, 2009 for VA San Diego Empirically Based Psychotherapy Seminar: "Telemedicine and PTSD"
7. April 13, 2010 for VA San Diego Social Work Service: "Telemedicine in the VA"
8. May 13, 2010 for ex-Prisoners of War: "PTSD Treatment Options"

During the past year, I visited the San Diego Vet Center to share information and brochures about the study. I presented an overview of the study at a Telemedicine Symposium and a poster session at the third Military Health Research Forum (MHRF), sponsored by CDMRP. This experience was very helpful. The audience feedback was positive and there was enthusiasm about the research. I was able to meet with several other telemedicine researchers to discuss methodological issues. I also shared information about this project, as listed below, at the Updates on PTSD Conference and at the International Violence and Trauma (IVAT) conference.

Our research assistant has also spoken about our studies at several meetings of student veterans at different colleges and universities. This is a two-step process. Since

many veterans are not enrolled in the VA system, we have facilitated their entry into that system so that they are eligible to participate in the study. Our study coordinator worked with VA Member Services to facilitate that process. We have had positive feedback from college administrators and veterans, and we expect that this will continue to be a source of recruitment. We have also set up booths at all general veterans meetings at the San Diego VA (e.g., Welcome Home Event, Job Resource Fair).

We have started advertising in local newspapers. We had only a mild response from the local free paper (14 calls and 2 people enrolled in the study), so we are placing an ad in a military paper to target our population more specifically.

We have additionally been exploring online recruitment resources. We are planning to place an ad similar to our newspaper ad on Craigslist. We have advertised the study through the VA Twitter account, and the study staff created a draft of a website that we can post free of charge. The site will describe the study, telemedicine, prolonged exposure therapy, some study entry criteria, and contact information for the Study Coordinator. We have consulted with other investigators to explore recruitment through social networking sites such as Facebook and MySpace.

We have worked very closely with the San Diego VA clinical telemedicine team in an effort to educate clinicians about telemedicine. I attend the monthly meetings of this team 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. As a performance improvement project, I presented our results regarding the dissemination of telemedicine locally. There were 19 entries for a performance improvement award, and we won 2nd place:

Thorp, S. R., Raftery, J., Shah, N. H., Campbell, L. B., Agha, Z., & Fiedler, J. (September 2009). *Increasing number of unique veterans with access to telemental health services*. Poster presented at the VA San Diego Performance Improvement Fair, San Diego, CA.

We have modified our forms so that our data (over 2,000 variables for each participant) can be read by the Optical Character Recognition (OCR) service (similar to a Scan-Tron format). We had several discussions with the OCR team to ensure that the forms were still readable for our veterans (who may have vision problems due to age or injuries), and we have given them feedback after they scan each set of data so that the technology is working optimally. It would take many hours for our research assistant to enter the data by hand, and the OCR service has made that process much faster while maintaining accuracy. This has allowed our research assistant to help with recruitment and to be at remote sites when the Study Coordinator is scheduled with another subject or is otherwise unavailable.

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.

I also continued to be the Prolonged Exposure (PE) therapy consultant for the study therapists, and we have two consultation meetings each week to discuss cases. I created templates for the computerized progress notes to maximize efficiency and standardize procedures, and I co-sign each therapist's notes to monitor adherence to protocols and any safety issues. I am one of only 17 VA PE Trainers nationally, and in addition to facilitating 4-day trainings for VA clinicians, I consult with clinicians nationally (listening to their therapy tapes and giving specific feedback) on cases each week to maintain my 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).

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 I 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.

Challenges:

As we had discussed in past reports, we expected that recruitment might be challenging for several reasons. There are several local competing treatment outcome studies for PTSD that began in the past year. In fact, there are now four other psychotherapy trials for PTSD underway in the VA San Diego Healthcare System (that we are aware of), and a new telemedicine study began in January 2010. This is due in part to the emergence of the Center of Excellence for Stress and Mental Health (CESAMH) in San Diego (approximately 30 investigators focused on trauma research) and the InTrust research center (San Diego is the hub for 10 sites nationally for these trauma-focused research programs). Our project is competing with these trials for the same potential subject pool (veterans with PTSD), equipment, and space for assessments and therapy. Many of our rooms are sign-up rooms, and space is particularly limited at the remote sites.

There is also growing awareness in the field that veterans returning from Iraq and Afghanistan have many barriers to seeking treatment and continuing treatment. There are now published reports of how this reduces recruitment for research projects. In this project we have the added challenge of recruiting for a treatment type and mode that may cause anxiety in potential subjects (as some veterans are wary of both telemedicine and prolonged exposure therapy).

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.

Although we are recruiting at a steady pace, we need to recruit subjects more quickly to meet our target sample size (250) by the end of the study in mid-2012. We are pleased that we have a small rate of veterans excluded based on eligibility (12%). This suggests that our entry criteria are not too restrictive. Our current rate of dropout from therapy (32%) is a little higher than other PTSD psychotherapy studies (the average is about 20-25%). We have done our best to retain subjects (problem solving scheduling and travel issues, making multiple calls after therapy non-attendance, sending letters). We have also attempted to capture as much data as possible from those who dropped out of therapy, and we ask those veterans to continue their post-treatment and follow-up assessments if they are willing.

We have addressed recruitment in several ways: (1) We have added several recruitment sites in both primary care and specialty mental health clinics; (2) we have produced more brochures and newsletters to advertise directly to treatment providers and veterans; (3) we are attending meetings across the county to educate providers and veterans about the project; (4) the PI and Co-Is continue to give local talks to aid recruitment; (5) we are advertising in newspapers and online, and (6) we have begun tracking specifically who is referring veterans to the study and discussing recruitment strategies with them.

We had established one office in each of the remote sites (Vista, Escondido, and Chula Vista), and equipped these new offices with telephones, fax machines, and computers for the project. One of the remote clinics, Vista, closed in 2010. Fortunately, a new VA community based-outpatient clinic opened in Oceanside in May 2010, and we have successfully secured space and equipment in the new building. Our study coordinator and research assistant met the clinicians at the new site, and we have already started getting referrals from that site. We also successfully petitioned the Veterans Medical Research Foundation for additional space for staff and project duties (e.g., assessment and treatment), and the PI has opened his office for such duties as needed. Two weeks ago we moved our primary offices to a larger and more suitable location (e.g., more privacy and a waiting room).

In the past year one of our co-investigators, John Chardos, MD (our local telemedicine specialist), moved to Northern California and Ron Schmidt (a national telemedicine training specialist for the VA) also relocated. Fortunately, we were able to add Nilesh Shah, MD to our project, and he brings a wealth of telemedicine information and resources to our team.

KEY RESEARCH ACCOMPLISHMENTS:

- We continued the recruitment, screening, assessment, and treatment of subjects.

- We obtained 172 referrals to the study, and 58 veterans have been randomized to treatment.
- We have refined and added methods of recruitment, including presentations at local and national meetings, newspaper advertising, and online advertising.
- We created a name and a logo for the study.
- We refined our study brochure and developed a study newsletter for clinicians to inform them about eligibility criteria and study progress.
- I 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).
- I continued to develop an 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 won an award for contributing to the dissemination of telemedicine in San Diego.
- We have developed the formats and methods for Optical Character Recognition data scanning to make the data entry process much more efficient.
- 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 begin the project

REPORTABLE OUTCOMES:

Published Abstracts or Presentations by PI in Past Year

1. **Thorp, S. R.** (September 2009). *Psychotherapy via telemedicine for post-traumatic stress disorder*. Paper and poster presented at the 3rd Military Health Research Forum, Kansas City, MO.
2. **Thorp, S. R.** (September 2009). *Treatment guidelines for different populations with PTSD*. Paper presented at the 14th International Conference on Violence, Abuse, and Trauma (IVAT), San Diego, CA.
3. **Thorp, S. R.** (September 2009). *Delivering psychotherapy for PTSD via telemedicine*. Paper presented at the annual conference, Updates on Posttraumatic Stress Disorder (PTSD): Meeting the Challenges of the Uniform Mental Health Services Handbook , Palo Alto, CA.
4. **Thorp, S. R.** (September 2009). *Posttraumatic stress disorder*. Paper presented at the University of California, San Diego (UCSD) Health and Wellness Lecture Series, San Diego, CA.
5. **Thorp, S. R.** (September 2009). *Brief psychotherapy for military-related PTSD: Context and recommendations*. Paper presented at the Military Mental Health conference, San Diego, CA.

6. **Thorp, S. R.** (September 2009). *Current status and future directions of PTSD assessment and treatment*. Panel discussion at the conference: Healing the Hidden Wounds of War and Trauma: Understanding and Treating PTSD in the 21st Century, San Diego, CA.
7. **Thorp, S. R.** (March 21, 2010). Television news interview - CW Channel 6. Posttraumatic stress disorder (interview with Dr. Thorp and discussion of PTSD telemedicine studies).
8. Repp, A.L., **Thorp, S.R.**, Floto, E., Zuest, D.K., Ross, B.S., Moreno, L., Fidler, J., Madra, N., Zamora, T., Shah, N., & Agha, Z. (April 2010). *Cost analysis of cognitive behavioral and prolonged exposure therapy via telemedicine for treating posttraumatic stress disorder*. Paper presented at the VA Health Services Research & Development National Meeting, Little Rock, Arkansas.
9. Repp, A.L., **Thorp, S.R.**, Floto, E., Zuest, D.K., Ross, B.S., Moreno, L., Fidler, J., Madra, N., Zamora, T., Shah, N., & Agha, Z. (May 2010). *Treating veterans with PTSD via telemedicine is associated with reduced travel distance, time and costs*. Poster presented at the Veterans Health Administration Office of Telehealth Services National Telehealth Leadership Forum, St. Louis, Missouri.

Publications by PI in past year

Our statistician has advised us not to examine the outcome data prior to study completion, so we plan to publish several papers from this study after the completion of the study.

CONCLUSION:

We feel that we have made good progress in the second year of our project. Although we had hoped to recruit more subjects by this point, we have added several creative approaches to recruitment to augment our current strategies. These include the "branding" of the study through a new name and logo, presentations at local and national meetings, development of a newsletter and refinement of our brochure, and advertising in newspapers and on online sites. We were recognized for our contributions to telemedicine. We also developed a system for scanning our data via Optical Character Recognition to make data entry more efficient. 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.