AN INTERVIEW WITH

DR. DOUG ZATZICK

Principal Investigator, Trauma Survivors Outcomes and Support (TSOS)

Interviewed by Karen Staman, MS, Coordinating Center Staff Writer

Dr. Zatzick is a professor in the Department of Psychiatry and Behavioral Sciences at the University of Washington and a member of the Core Research Faculty at the Harborview Injury Prevention and Research Center. He provided an update on the Trauma Survivors Outcomes and Support (TSOS) project at the May 2017 Collaboratory Steering Committee Meeting (view slides).

The clinical goal of the TSOS trial is to coordinate care and improve outcomes for trauma survivors with post-traumatic stress disorder (PTSD) with an intervention that includes care management, medication, and psychotherapy elements, as well as follow-up assessments at 3, 6, and 12 months. Because evidence-based treatments for PTSD and comorbidity have not been broadly implemented throughout trauma care systems, an important, parallel goal of the trial is to provide the American College of Surgeons with evidence to inform regulatory policy. TSOS is a stepped-wedge, cluster randomized trial of 25 US level 1 trauma centers that uses electronic health records to identify patients.

We sat down with Dr. Zatzick to discuss the status of his trial, challenges and surprises, and advice he has for new investigators. As of May 2017, 350 patients have been enrolled.

Challenges

I'm happy to say that all our sites now have institutional review board (IRB) approval, but it was more of a challenge that I expected. We initially wanted to use a single IRB at the University of Washington, where the trial is based. But the University of Washington does not have the capacity to be a central IRB, so we decided on Western IRB, and we thought the majority of our sites would be able use it. However, most trauma centers that are affiliated with universities had pre-existing agreements that preclude going through a central IRB, so most sites used the IRBs affiliated with their institutions.

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>
> *– Zatzick*

Help From a Core Group

Help From the Patient-Reported Outcomes Core

We are collecting patient-reported outcomes (PRO) data at 3, 6, and 12 months, and we're not using the PROMIS measures because our outcomes measures are trauma-based. We needed help from the Patient-Reported Outcomes Core to determine the best way to capture PRO information. Ultimately, we decided to conduct 45-minute interviews with each patient at these intervals. This makes the trial slightly less pragmatic, but these data are essential for our study.

Help From the Ethics and Biostatistics Cores

Initially, getting approval from the Data and Safety Monitoring Board (DSMB) was a huge challenge. Our DSMB didn't have experience with pragmatic trails that had implementation components or with stepped-wedge designs, and this caused roadblocks. Although we wanted to nimbly roll out a pilot, the DSMB wanted to move incrementally. It was like we were playing football with a soccer referee. The Regulatory/Ethics Core and Biostatistics and Study Design Core helped our team persuade the DSMB that the stepped-wedge was is indeed a legitimate randomized trial approach. We needed champions to say: This is a new beast. We need to think about this in a new way.

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Surprises During Pilot Phase

We were surprised by the difficulties we had with IT harmonization. Our original plan didn't work because we had a foundational notion that most hospitals have readily available Wi-Fi. This wasn't the case; many of our sites had Wi-Fi blind spots or other internet encumbrances. As a result, our decision support tool didn't work in about half of the hospitals because the laptops for the study couldn't reliably connect to the Internet. We had to scrap the tool and rebuild many aspects (in RedCap). Even with the reworking of our IT approach, many sites find it most convenient to take a hardcopy of the baseline interview to the bedside, fill out the form, and send us an encrypted PDF.

Advice to New Investigators

Embed implementation teams within embedded trials. The bottom line is, go to the sites, do training at the sites and with the team, and take field notes in real time. By the time you've been to a number of sites, you will be able to identify common problems and persistent themes—in ways that don't drive up the cost of the trial—and you will be able to generate ways to incentivize change and enable the trial (and eventually the intervention) to be more sustainably implemented.

Changing actual practice is not about changing the individual behavior of the clinician; it's more about having champions and stakeholders at the site and at the regulatory/policy level. We need sound research to inform policy, sound policy to inform practice, and champions who are willing to implement change to make it happen.

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