The Study of Cognitive Rehabilitation Effectiveness

The SCORE clinical trial is a randomized controlled treatment trial evaluating the effectiveness of cognitive rehabilitation in post-deployment military service members who sustained a concussion.

Chapter 6: Implementation of the SCORE Clinical Trial in DoD and VA Healthcare Settings: Administrative Considerations

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Congress established DVBIC in 1992 after the first Gulf War in response to the need to treat service members with TBI. DVBIC's staff serves as the Defense Department's primary TBI subject matter experts. DVBIC is part of the U.S. Military Health System and is the TBI operational component of the Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury (DCoE). Learn more about DVBIC at dvbic.dcoe.mil.

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SCORE Disclaimer

Chapter 6:
Implementation of the SCORE Clinical Trial in DoD and VA Healthcare Settings: Administrative Considerations

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Introduction

This chapter illustrates the contexts, processes, and core components of the Study of Cognitive Rehabilitation Effectiveness (SCORE) interventions. The purpose of this illustration is to support discussions of the trial findings and to underscore considerations to be made when extending those findings to current clinical practices in Departments of Defense (DoD) and Veterans Affairs (VA) healthcare settings.

An essential consideration in the discussion and extension of trial findings is that the SCORE intervention team created and implemented the treatments, resulting in a high degree of fit between the intervention and the Brooke Army Medical Center (BAMC) clinical contexts. This likely makes direct transfer of SCORE interventions to other settings unachievable.[1] Additionally, overemphasis of internal validity is a considerable threat to the replication of outcomes, especially in light of the diversity of DoD and VA treatment settings that ultimately must engage to reach their target populations.[2] Likewise, blind "drag and drop" of SCORE materials and processes into new settings may hinder the future optimization of the new intervention.[2] Adaptation of the intervention is therefore inevitable, and indeed should be encouraged.

At the same time, there is a link between improved patient outcomes and adherence to the program model, referred to as program fidelity.[3] Research in multiple areas - including psychiatric rehabilitation, interventions for juvenile justice-involved youth, psychotherapies for depression, drug abuse prevention programs, and educational motivation interventions - have all found associations between better outcomes and fidelity to core program components.[4-7] In a healthcare setting, program fidelity serves as a process check, ensuring that patients receive the active ingredients of an intervention. Additionally, program fidelity can guard against "gaming the system," using biased patient selection or ignoring other important processes in order to demonstrate artificially improved outcomes.

Discussion, extension and implementation of trial findings must, therefore, balance adaptation and fidelity. This chapter will explain the SCORE contexts and process, as well as the core components, to help stakeholders strike the appropriate balance. Following is a discussion of the challenges of implementing cognitive rehabilitation interventions, as well as suggested next steps. Appendix B contains a Fidelity Tool, a set of program fidelity indicators that may be useful to providers who implement SCORE interventions in other clinical settings. The following sources provided the structure and content for this chapter: Consolidated Framework for Implementation Research, or

CFIR[1]; Chambers, Glasgow, & Stange's publication on dynamic sustainment,[2] and the Blase & Fixsen research brief on core intervention components.[3]

Contexts and Processes

The program setting is a critical factor affecting the success of program implementation, as well as replication of program outcomes. As defined and detailed by CFIR,[1] even with high intervention fidelity, significant decrease in intervention effect (i.e., voltage drop) can occur as a result of the mismatch between the intervention and characteristics of the following:

- Outer setting
- Inner setting
- Individuals involved
- Implementation process

Outer Setting

The outer setting encompasses the economic, political, and social contexts of the implementing organization. The SCORE trial had an outer setting ideally suited to the development and implementation of innovation. Due to scientific advances in the understanding of traumatic brain injury (TBI), as well as the attention devoted to military- and sports-related TBI in the popular press, TBI had become a rising issue in the national consciousness.

Although there was significant public pressure for effective treatments, there was a lack of evidence regarding the rehabilitation of cognitive deficits attributed to repetitive mild TBI (mTBI), posttraumatic stress disorder (PTSD), or co-morbid mTBI/PTSD that resulted from frequent blast exposures occurring over multiple deployments. TRICARE, the primary insurer of service members and veterans, denied claims for cognitive rehabilitation because of this lack of standardization and evidence.

These outer setting factors created a need to establish evidence about specific cognitive rehabilitation practices. Against this backdrop, the TBI Clinic at BAMC was in an ideal position for such development due to several factors, including being highly networked with other external organizations (i.e., *cosmopolitan*, in CFIR terms). For example, BAMC was a Defense and Veterans Brain Injury Center (DVBIC) site, the host of a national monthly TBI Grand Rounds cyber seminar presentation, and a regional resource on TBI care. By virtue of its relationships and prominence, the TBI Clinic at BAMC received encouragement from peer organizations to innovate in this area of care.

Inner Setting

The inner setting includes the various levels (e.g., team, clinic, hospital) and interacting constructs within an implementing organization. As with the outer setting, there were numerous, strong inner setting constructs that facilitated the development and implementation of SCORE. Chief among these was the climate for implementation. A desire for change and the existence of a clinical problem within the TBI Clinic, for example, made the development and implementation of SCORE interventions a priority. There was an inherent fit with the intervention as it was designed for the clinic, and motivation to ensure replicability of the program structure in other clinics. Further, the

Note: The material in Contexts and Processes was adapted from: Damschroder, L. J., Aron, D. C., Keith, R. E., Kirsh, S. R., Alexander, J. A., & Lowery, J. C. (2009).[1]

TBI clinic had extensive clinical experience with treating service members with mTBI and co-occurring psychiatric conditions (3 or more years of high-volume referrals), as well as a rich learning environment within the TBI Clinic that included ready access to content experts and active journal clubs. Finally, leaders were engaged, well-resourced and informed. The team had worked together for a number of years, had set aside time for communication, and were all invested as co-creators of the interventions.

Characteristics of the military medical center beyond the TBI Clinic also facilitated implementation. BAMC is one of the largest military medical centers in the country. Home to over 60 accredited medical, nursing and allied health educational programs, the center is a medical education hub with a diverse set of knowledge and many thought leaders.

Research Team

The individuals involved in development and implementation of the SCORE interventions were an accomplished team. The principal investigators of the SCORE trial were core members of the working group who developed the VA/DoD Clinical Practice Guideline for the Management of Concussion/mTBI. [8] Other team members were participants on DoD working groups who developed treatment toolkits and presented at national military conferences on the assessment and treatment of cognitive and behavioral symptoms following TBI.

The SCORE clinical leaders had more than 10 years' experience in rehabilitation of TBI, and more than 5 years of experience in applied military settings. The rehabilitation therapists (representing occupational therapy, speech language pathology, physical therapy, and recreational therapy) medical treatment providers (including physician assistants and nurse practitioner) and behavioral health providers (clinical psychologists) all had several years of experience working collaboratively in the treatment of mTBI in a military setting. Before the trial began, the TBI clinic treatment team had more than 2 years' experience utilizing the VA/DoD Clinical Practice Guidelines for the Management of Concussion/mTBI[8] and implementing it in their clinical practice.

Implementation Process

The implementation of SCORE was a dynamic process that facilitated the adaptation of the intervention in the clinical setting. The SCORE program development lead was an integrated member of the clinical team who maintained ongoing communication with the clinic leads regarding intervention development and implementation. All the individuals involved were co-creators of SCORE and clinical champions[1] of the intervention. As such, SCORE was inherently engaging and did not require an implementation campaign to build support.

Individuals involved in implementation were part of a workshop for the development of the manualized (e.g., standardized) treatments, which included discipline experts from DoD and VA. Prior to implementation, the team refined the manual using an iterative development process that included formulation of team roles, a format for regular feedback, explanation of the various individuals' contributions and how these contributions fit together, a format for problem-solving system-level barriers, and facilitation. Communication among treatment providers implementing the SCORE trial occurred during formal weekly team meetings and informally as needed.

The research team specifically designed the cognitive rehabilitation interventions to be delivered by either occupational therapists or speech language pathologists. The treatment providers decided *a priori* to integrate the SCORE clinical trial into the routine clinical processes, which included participation by all clinic staff. Upon enrollment in the study, participants received assignments to providers (behavioral health; speech language pathology; occupational therapy) based on scheduling convenience and availability during designated appointment times (i.e., same time each day) rather than a specific discipline or expertise. Providers rotated in their roles as leaders of the cognitive rehabilitation and behavioral health groups at regular intervals to ensure participants' access to the individual therapists.

Summary of Contexts and Processes

Taken together, the contexts, people and processes that led to the SCORE intervention development and implementation at BAMC were particularly facilitative. SCORE developers were explicit about integrating the trial in routine clinical care to promote broad uptake of the intervention.

In view of variation in DoD/VA healthcare settings, researchers who wish to conduct this work elsewhere should do so with the realization that they will likely face challenges if attempting an "off-the-shelf" implementation. Differences in practice settings (including the structure, culture or experience of an implementing team), lack of fit between the intervention and other clinical contexts, and differences in the implementation climate, along with other factors, may present obstacles that researchers need to address as they consider implementing a SCORE trial in their treatment settings.

Core Components

Core components are the principles and process elements that are critical to program success.[3] The term principle here refers to a guiding belief of the SCORE intervention team about the rehabilitation of cognitive problems in military-related mTBI. The principles, which are described in detail in the following section, were the result of both the treatment experience of the team and the development of the VA/DoD Clinical Practice Guideline for the Management of Concussion/mTBI.[8] The term key element refers to the intervention practices, competencies, and contextual factors – the everyday treatment activities – believed by the SCORE team to be critical to achieve outcomes. The key elements derived from the treatment manuals were refined in conjunction with the SCORE intervention team.

The principles and key elements of the SCORE intervention were elucidated during two face-to-face meetings of the SCORE fidelity team (i.e., the authors of this chapter) at BAMC, and in teleconferences. The team reviewed the SCORE treatment manuals prior to the site visits and discussed them during the meeting. The primary goals of the first face-to-face meeting were 1) to understand how the manualized treatments were operationalized and integrated into the clinical environment, and 2) to detail the SCORE trial components that the team perceived to be key elements for implementation integrity.

Note: The material in Core Components was adapted from: Blase, K., & Fixsen, D. (2013).[3]

The SCORE fidelity team used Perepletchikova's framework[7] to describe the concept of treatment integrity to the SCORE intervention team:

1. **Competence**. The level of the therapist's skill and judgment with the treatment
2. **Adherence**. The degree to which the therapist utilizes prescribed treatment procedures and avoids proscribed treatment procedures
3. **Differentiation**. Whether treatments differ from each other along critical dimensions

The fidelity team recorded interviews with members of the SCORE intervention team during the first site visit, and subsequently reviewed and analyzed the interview transcripts in conjunction with notes taken during the meeting. The primary goal of the second face-to-face meeting was to present data generated during the first site visit to the SCORE intervention team for review, revision and further elaboration. The resulting elements represented the consensus perspectives of the SCORE intervention and fidelity teams.

Principles

Three main principles guided the SCORE team during routine decisions and were especially important when the correct course of action was unclear. These principles are Aura, Integration and Reframing. The team chose these labels to refer to them collectively by the acronym AIR, in the hope of facilitating recall of the guiding principles during clinical planning and decision-making. These principles also served as the basis for service organization and helped develop a shared understanding of treatment rationales and expectations with patients. As suggested by Blase and Fixsen, living these values promotes consistency in intervention development, resulting in improved treatment integrity.[3]

Aura principle

Patient engagement depends on the patients' perception of a high degree of treatment expertise and the collective efficacy of the treatment team.

In their experience with treating patients, the SCORE team members observed that dissonance between the verbal messages to patients and the actions taken by the treatment team during therapeutic encounters could leave patients doubtful about their prospects for recovery. For example, referring patients to multiple additional providers should be unnecessary if the SCORE team is expert and the treatment is the right approach. Likewise, scheduling patients for 2 years of upcoming appointments would appear to undermine the representation of SCORE as an innovative, effective intervention. Treatment materials that are disorganized or poorly presented may also negatively influence patients' perceptions of the providers and the treatment.

The team members recognized the necessity of being mindful of patient perceptions of clinical processes, practices, materials, and messages to maintain patient confidence and engagement.

Integration principle

Behavioral health must seamlessly integrate with cognitive rehabilitation. In the experience of the SCORE treatment team, behavioral health intervention that is not integrated with cognitive rehabilitation often results in inconsistent messaging to the patient, including attribution of cognitive symptoms to one potential etiology over another.

Discordant provider perspectives often confuse patients, leading them to feel that there may be something particularly difficult about their circumstances and symptoms that they may not be able

to overcome. The SCORE team controlled the integration of behavioral health in the treatment of those with mTBI in the facility.

In their interactions with patients, providers at BAMC consistently framed SCORE interventions as rehabilitation for cognitive problems, regardless of the cognitive or behavioral nature of the specific treatment activities. The SCORE team believes the branding of all SCORE treatment approaches as cognitive rehabilitation was a key factor in mitigating the stigma associated with mental illness and behavioral health treatment in the military.

Reframing principle

Providers must convey and reiterate three critical messages to patients to build therapeutic alliance and commitment to the treatment approach:

1. Cognitive symptoms are nonspecific, often multifactorial in nature
2. Symptom chronicity is the result of the complexity of the condition
3. Full recovery is expected but perhaps will occur over a longer time

The SCORE team encountered many patients who expressed frustration about the lack of symptom recovery and feelings of personal failure due to their persistent symptoms. A key message that the SCORE team conveyed to patients who expressed these feelings was, "No, you didn't mess up. It's bigger than you." In addition, the team framed the effects of co-morbid conditions as special and unique, and, therefore, distinct from the expected course of recovery from general mTBI.

Framing the problems and recovery course as unique allowed the team to present SCORE as a unique solution. Armed with a new understanding of the problem and a fresh approach to treatment, patients could set aside past treatment failures, earnestly commit to and follow through with the SCORE program, and develop greater self-efficacy for symptom management. By reframing the issues and underscoring the expertise of the treatment team, the message communicated to patients echoed the old Home Depot tagline: "You can do it. We can help. ®"

Key Elements

The key elements, also known as active ingredients in the clinical trial, refer to those everyday treatment activities that the SCORE team believed were instrumental in achieving the study outcomes. The team developed a set of indicators composed of these active ingredients for assessing fidelity, or treatment integrity. Appendix B, Fidelity Tool, outlines the fidelity indicators the team developed for Arm 3 (traditional cognitive rehabilitation) and Arm 4 (integrated behavioral health). The indicators for Arm 3 are a subset of those for Arm 4, reflecting the integration of behavioral health intervention components in Arm 4.

The indicators may form a useful basis for triangulating various perspectives: A clinician could use them for self-assessment, a peer or supervisor could use them for performance assessment purposes, and a patient and provider could use them together in a team conference as a tool for facilitating a progress review or formulating a discharge plan. The SCORE team has not developed indicators for study Arms 1 (psychoeducation) and 2 (computer-based interventions), as there were few instrumental provider actions associated with these treatments.

The SCORE team chose the term indicators, rather than measures, to emphasize that they are preliminary and require validation, perhaps both empirically and via consensus. Future validation of the fidelity indicators should focus on the response format, which was arbitrary, as well as the

possibility that there may be core elements not currently included that are also instrumental in achieving outcomes.

Summary of Core Components

The SCORE team members attribute the study outcomes to the principles and key elements detailed in this chapter. DoD/VA researchers who wish to tailor and implement the SCORE intervention to their particular clinical settings should do so with these guiding principles and active ingredients in mind. The SCORE team developed preliminary fidelity indicators for study Arms 3 and 4 with the intention of facilitating the assessment of treatment integrity. Fidelity indicators, as well as the core components themselves, will require future expansion, refinement, and validation.

Discussion

The SCORE trial is one of relatively few randomized controlled trials (RCT) of cognitive rehabilitation. The explanatory evidence generated in a real clinical setting with a diverse group of participants speaks to both the efficacy and effectiveness of cognitive rehabilitation as operationalized in the trial. Given the lack of a strong body of evidence for alternative approaches, there may be considerable gravity within the military health system (MHS) toward the SCORE intervention. The information in this chapter about the intervention contexts, processes and core components support further study and implementation of the SCORE study.

Research teams elsewhere in the DoD/VA system interested in implementing SCORE should acknowledge the differences between their implementation environment and the environment at BAMC for developing the clinical trial, and tailor the intervention accordingly. Tailoring should be sensitive to the principles and key elements identified by the SCORE team as the necessary ingredients for success.

Researchers should recognize that the SCORE intervention has been tested once, but not yet optimized.[2] Implementers should recognize that the opportunity to adapt the SCORE intervention incurs a responsibility to document, share, and maintain engagement with the BAMC team and the practice community that may develop around the intervention, including those involved in the MHS TBI Pathway of Care, managed by DVBIC. Active communication among implementation teams will promote the integration of practice-based evidence produced by program adaptation, thereby realizing the full impact of the SCORE intervention.

Determining the optimal intensity, duration, and combination of all SCORE treatment elements is not possible for particular patients and contexts by drawing on the experience of a single RCT, or series of RCTs. Moreover, attempting to draw inferences from a single implementation may compromise the ability of the intervention to maximally affect health, as freezing an intervention would preclude opportunities to enhance and refine promising findings using real-world evidence.[2] However, pressure within the MHS to implement the SCORE intervention may make further study of SCORE under tightly controlled circumstances (i.e., RCTs) impracticable.

It is important for researchers and providers to appreciate the current practice realities of cognitive rehabilitation after TBI. Existing research is scant, but it suggests that few clinicians adhere to evidence-based cognitive rehabilitation procedures, and nearly one-half make clinical decisions regarding cognitive rehabilitation based on intuition and experience alone.[9] Why there is such variability in cognitive rehabilitation practice is unclear, but factors contributing to the research-to-practice gap may include the limited training required of primary cognitive rehabilitation providers,

the lack of a standard curriculum and credentialing process, the confusion of providers regarding roles on an interdisciplinary cognitive rehabilitation team,[10] the wide variability in the structure and focus of cognitive rehabilitation programs, and theoretical perspectives in rehabilitation. These factors underscore the importance of establishing clinical evidence regarding cognitive rehabilitation and designing interventions that will improve on the current state of practice while contributing to the body of knowledge regarding the effectiveness of these treatments.

In light of the challenges and limitations associated with RCTs and the need to document adaptation, practice-based evidence (PBE) research may be the most appropriate avenue for enhancing, extending and refining SCORE study findings. Prospective PBE studies complement RCTs by accommodating a more diverse set of performance sites, a more diverse study population, and dynamism in both interventions and treatment environments.[11] These are inevitable considerations as clinical teams adapt implementation of SCORE to other settings.[2]

The rigor in PBE studies results from controlled measurement of an extensive number of patient characteristics, clinical processes, and outcomes. PBE studies are highly collaborative, which inspires a high level of buy-in from participating sites and, accordingly, a high degree of confidence in the study findings. Because PBE studies generate real-world evidence, they hold enormous potential for enhancing understanding of SCORE trial findings, extending the impact of treatment interventions, and improving real-world clinical care.

Fidelity Tool

During the development of the SCORE clinical trial, the SCORE team determined that tools designed to assess program fidelity would be helpful, particularly for later use in the implementation of these manualized rehabilitation interventions. The team met on several occasions to extract the most critical components of treatment Arms 3 and 4, the traditional cognitive rehabilitation and integrated behavioral health interventions. These discussions resulted in a prototype of a fidelity tool for the cognitive rehabilitation aspects of the clinical trial, shown in Appendix B.

However, the fidelity tool the research team developed over the course of the SCORE trial was not used during the study, and therefore has not been empirically validated. The SCORE team encourages clinicians, researchers, and administrators to use and build upon this tool in their efforts to implement SCORE treatment interventions in settings throughout the DoD and VA healthcare systems.

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Appendix A: Acronyms

AIR	Aura, Integration, and Reframing (guiding SCORE principles)
BAMC	Brooke Army Medical Center
CFIR	Consolidated Framework for Implementation Research
DoD	Department of Defense
DVBIC	Defense and Veterans Brain Injury Center
MHS	Military Health System
PBE	Practice-based evidence
PTSD	Posttraumatic stress disorder
RCT	Randomized, controlled (treatment) trial
SCORE	Study of Cognitive Rehabilitation Effectiveness
TBI/mTBI	Traumatic brain injury/mild traumatic brain injury
VA	Veterans Affairs

Appendix B: Fidelity Tool for Traditional Cognitive Therapy

Over the last month, how often have you incorporated the following SCORE elements in the traditional cognitive therapy that you have delivered?	**Less than half of the sessions**	**More than half of the sessions**	**Nearly all of the sessions**	**Every session**
	0	**1**	**2**	**3**
1. Cataloguing the compensatory systems currently used by the patient (**RATE INTAKE SESSIONS ONLY)**				
Notes/Evidence supporting self-rating:				
2. Introduction of audio-based mindfulness exercise as "attention exercise" **(RATE MINDFULNESS INTRODUCTION SESSION ONLY)**				
Notes/Evidence supporting self-rating:				
3. Use of goal attainment scaling				
Notes/Evidence supporting self-rating:				
4. Use of in-session structure: educate, practice, provide generalization strategies				
Notes/Evidence supporting self-rating:				
5. Use of Predict-Perform-Evaluate				
Notes/Evidence supporting self-rating:				
6. Completion of patient self-rating (see questions)				
Notes/Evidence supporting self-rating:				
7. Attention Process Training procedures				

Over the last month, how often have you incorporated the following SCORE elements in the traditional cognitive therapy that you have delivered?	**Less than half of the sessions**	**More than half of the sessions**	**Nearly all of the sessions**	**Every session**
	0	**1**	**2**	**3**
Notes/Evidence supporting self-rating:				
8. Completion of patient engagement ratings **(RATE WEEKLY COMPLETION SESSIONS ONLY)**				
Notes/Evidence supporting self-rating:				
9. Weekly review and adaptation of goals				
Notes/Evidence supporting self-rating:				
10. Maintain order of individual sessions				
Notes/Evidence supporting self-rating:				
11. Completion of homework, if not worksheets				
Notes/Evidence supporting self-rating:				
12. Maintain intensity (< 1 week absence) of service provision				
Notes/Evidence supporting self-rating:				
13. Completion of mindfulness audio exercise as relaxation (**NOT** attention and engagement in the moment and context)				
Notes/Evidence supporting self-rating:				