

# Design of a clinical effectiveness trial of in-home cognitive processing therapy for combat-related PTSD

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## ABSTRACT

Approximately 14% of military personnel and veterans who have deployed to the combat theater are at risk for combat-related posttraumatic stress disorder (PTSD). The treatment of combat-related PTSD in active duty service members and veterans is challenging. Combat trauma may involve multiple high levels of exposure to different types of traumatic events (e.g., human carnage after explosive blasts, life threat/injuries to self/others, etc.). Many service members and veterans are unable or unwilling to receive treatment in government facilities due to avoidance, scheduling difficulties, transportation or parking problems, concerns about career advancement, or stigma associated with seeking treatment. Innovative treatment-delivery approaches are needed to help overcome these barriers.

The present study is a randomized clinical trial to evaluate three versions of Cognitive Processing Therapy (CPT; [54]) for the treatment of combat-related PTSD in active duty military service members and veterans: (1) standard In-Office CPT, (2) In-Home Telebehavioral Health CPT from the provider's office to the participant's home, and (3) In-Home CPT in which the provider delivers treatment in the participant's home. Use of an equipose-stratified randomization design allows participants to decline one of the treatment arms. This research design partly overcomes the problems active duty military and veterans face when receiving PTSD treatment by allowing them to opt out of one inappropriate or unacceptable treatment modality and still permitting randomization to the two remaining treatment modalities. This manuscript provides an overview of the research design and methods for the study.

**Abbreviations:** AE, adverse event; CAPS-5, Clinician-Administered PTSD Scale for DSM-5; CPT, Cognitive Processing Therapy; DoD, U.S. Department of Defense; DSM-5, Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition; PCL-5, PTSD Checklist-5; PHQ, Patient Health Questionnaire; PTSD, posttraumatic stress disorder; STRONG STAR, South Texas Research Organizational Network Guiding Studies on Trauma and Resilience; U.S., United States of America; VA, U.S. Department of Veterans Affairs

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## 1. Introduction

Over the past 50 years, approximately 14% of U.S. military personnel and veterans returning from deployments to military combat theaters have suffered from combat-related posttraumatic stress disorder (PTSD; [23,25,58,64,68]). The development and evaluation of the most effective treatments possible for combat-related PTSD is a high priority for the U.S. Department of Defense (DoD) and the U.S. Department of Veterans Affairs (VA). Cognitive Processing Therapy (CPT; cognitive version, without written accounts, [54]) is a trauma-focused,

cognitive-behavioral therapy for PTSD that has been demonstrated to be effective for the treatment of PTSD. However, numerous reports show that a large percentage of active duty military and veterans are not receiving adequate care for combat-related PTSD [24,47]. Hypothesized reasons for this include instrumental barriers to care (e.g., distance from treatment facilities, mobility limitations) and stigma associated with seeking mental health care. Previous studies have compared CPT delivered in person in the traditional office setting with CPT delivered through telebehavioral health from a large VA medical center to a smaller clinic nearer to an individual's home [43,44]. These studies

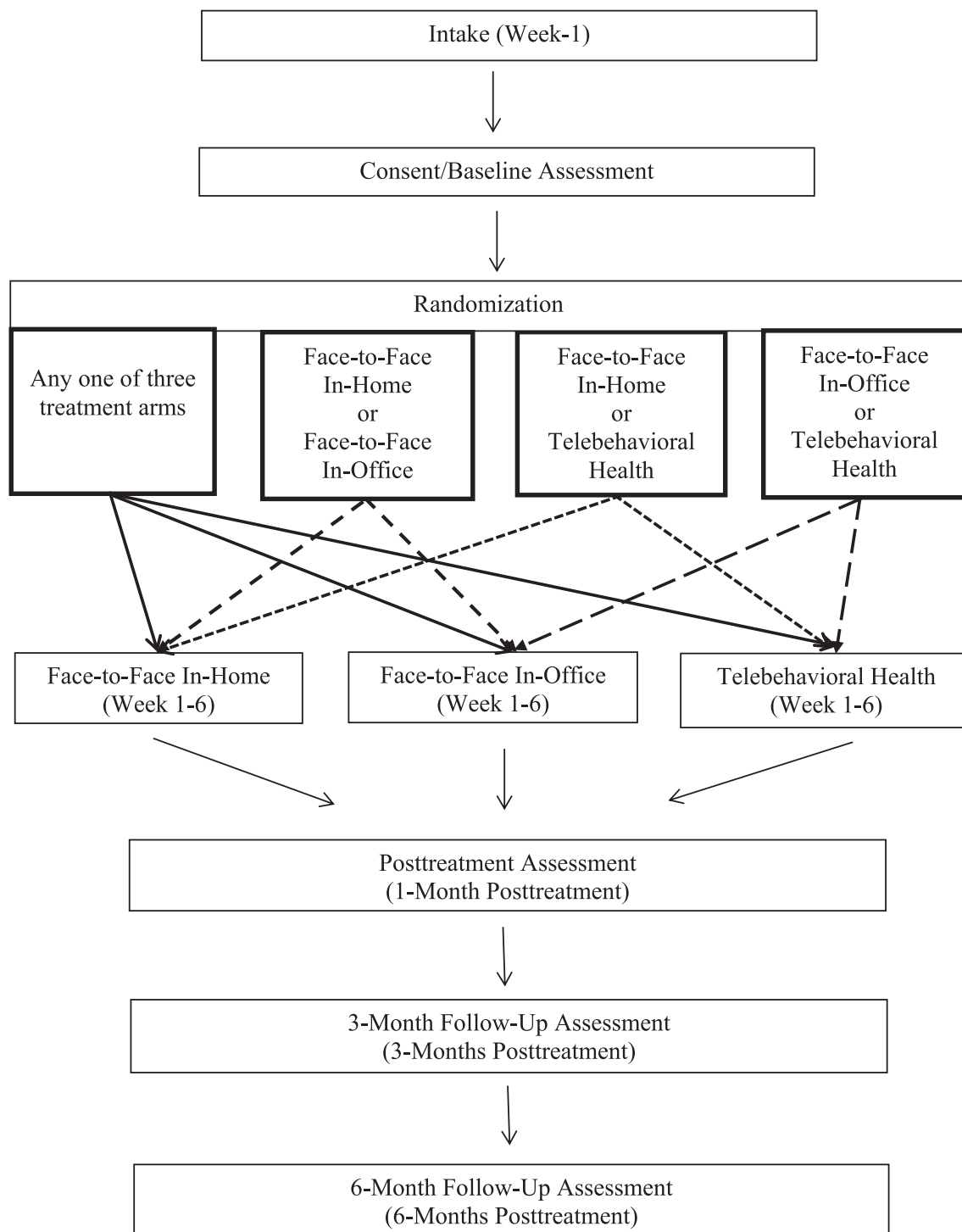


Fig. 1. Participant Flow for Equipoise Design and Follow-up.

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