TELEMEDINCE FOR PTSD (TOP) IMPLEMENTATION PROJECT

STATISTICAL ANALYSIS PLAN (SAP)
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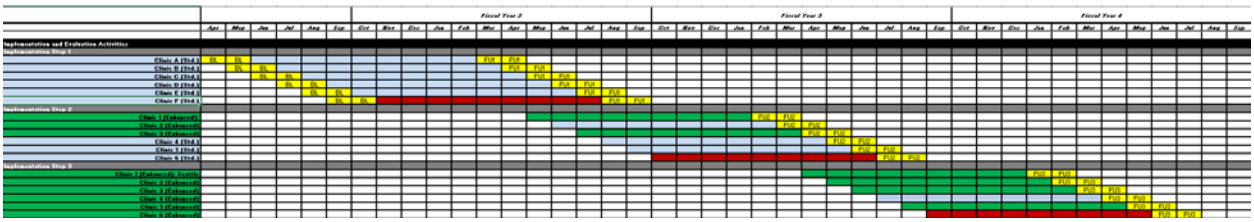
1. Introduction

This statistical analysis plan (SAP) enumerates the primary and secondary outcomes, timepoints, and corresponding analyses.

2. Study design

This is a Hybrid Type III effectiveness-implementation trial primarily designed to compare two different implementation strategies. There are three 9-month implementation stages. Following a stepped wedge trial design, implementation start dates are staggered, with the last site starting six months after the first site.



In the first 9-month stage of implementation, all sites receive standard strategies to implement a care management model designed to engage patients in trauma-focused evidence-based psychotherapy for PTSD. The implementation strategy is adaptive. Sites failing to meet benchmarks in Stage 1 are randomized when they receive the enhanced implementation strategy (Stage 2 or Stage 3). In the third 9-month stage, all sites failing to achieve benchmark success in Stage 1 receive the enhanced implementation strategy. Adaptive implementation strategies are used to customize the deployment activities for sites not meeting benchmarks. The benchmarks were having ≥75 in the care manager's panel AND 35% of patients in the panel receiving a trauma-focused evidence-based psychotherapy for PTSD, as specified below.

Implementation Success Benchmark			
Aim	***Description***	***Eligible Population***	***Measurement for Performance Commitment***
1) Patient panel*	The <u>number of enrolled</u> CBOC patients over the nine month implementation period with a diagnosis of PTSD in the 9 months before or after the implementation start date. **Success criteria:** 75 patients enrolled	**In 1st Casefinder extract <u>OR</u>** **A. Inclusion criteria** In the 9 months before or after implementation start date: • Encounter at participating CBOC • Primary or secondary diagnosis of PTSD **B. Exclusion criteria** In the 6 months period prior to implementation start: • No specialty mental health encounters at VAMC (except telepsychiatry)	• **Step 1:** Verify patient encounter at CBOC • **Step 2:** Verify patient PTSD diagnosis • **Step 3:** Verify patient received no specialty mental health encounters • **Step 4:** Track enrollment. Add a column in your tracker (i.e. Casefinder or other spreadsheet) to denote patients (and their SSNs) you have enrolled into TOP. This is equivalent to a patient receiving the initial Care Manager encounter.
2) Psychotherapy engagement	**<u>Numerator:</u>** Number of patients receiving an evidence-based psychotherapy to treat PTSD. EBTs include: • Cognitive Process Therapy		• **Step 1:** Administer PTSD Checklist for DSM-5 (PCL-5) according to clinical practice. • **Step 2:** Track evidence-based

	(CPT) • Prolonged Exposure (PE) Therapy • Eye Movement Desensitization and Reprocessing (EMDR) **Denominator:** Patient panel population as specified under Aim #1 Eligible Population **Success criteria:** 35% of patients		treatment (EBT). Please add columns to denote patients who have received EBT.

Only sites failing to meet benchmarks in the Stage 1 are included in the data analyses. The implementation stage start-dates and end-dates are listed in the table below. Each implementation period is followed by a two-month follow-up period during which a survey was administered to collect data on perceived access to care and PTSD symptom severity.

	Baseline (9 months)	Stage 1 + FU1 (11 months)	Stage 2 + FU2 (11 months)	Stage 3 + FU3 (11 months)
Site A	Sep 2015 – May 2016	Jun 2016 – Apr 2017	May 2017 – March 2018	Apr 2018 – Feb 2019
Site B	Oct 2015 – Jun 2016	Jul 2016 – May 2017	Jun 2017 – Apr 2018	May 2018 – Mar 2019
Site C	Nov 2015 – Jul 2016	Aug 2016 – Jun 2017	July 2017 – May 2018	Jun 2018 – Apr 2019
Site E	Jan 2016 – Sep 2016	Oct 2016 – Aug 2017	Sep 2017 – July 2018	Aug 2018 – Jun 2019

3. Target Population

The care management intervention was designed to target veterans with PTSD who were receiving primary care services in 12 VA Community Based Outpatient Clinic (CBOC) associated with 6 VA Medical Centers (VAMCs) and who were not engaged in psychotherapy delivered in a specialty mental health setting. To identify the population in need at each CBOC, we first identified all patients who meet all of the following inclusion criteria: 1) had an encounter at the CBOC in FY15 or the first five months of FY16 (10/1/15-3/1/16), 2) had an inpatient or outpatient encounter with a PTSD diagnosis at any facility in FY15 (ICD9=309.81) or the first five months of FY16 (ICD10= F43.10, F43.11, or F43.12) , and 3) the most recent PC-PTSD-5 screen going back to FY10 was positive (≥3). Second, we excluded all patients meeting inclusion criteria who had a specialty mental health encounter (stop codes : 500-533, 535, 536, 538, 542-599) at the Parent VAMC in the six months prior to 3/1/16. Telepsychiatry encounters were

not excluded if they meet the following criteria: 1) the stop code was Mental Health Clinic Individual (502), 2) conducted via telehealth (secondary stopcode 690, 692, 693, 644, or 645) and 3) for medication management (CPT code 90862, 90805, 90807, 90809, 90811, 90813, 90815).

Patients from this target population were sampled and recruited via opt-out cards followed by telephone calls to complete the baseline survey until 100 patients from each VAMC completed the survey. Baseline demographic and clinic characteristic were collected from the VA's electronic health record were merged with the baseline survey data. Primary and secondary outcomes were collected from chart review and follow-up surveys.

4. Outcomes

Primary outcome. The primary outcome is an implementation outcome, representing the reach of the intervention into the target population. The primary implementation outcome is receipt of trauma-focused evidence-based psychotherapy for PTSD, including Cognitive Process Therapy, Prolonged Exposure Therapy and/or Eye Movement Desensitization and Reprocessing. The variable is specified dichotomously to be 1 if the patient has a trauma-focused psychotherapy encounter in the month and 0 otherwise. Encounter dates are measured via chart review.

Secondary outcomes. This study includes 5 secondary outcomes:

1. Receipt of care management – This secondary implementation outcome also represents reach. The dependent variable is specified dichotomously to be 1 if the patient has an encounter with the care manager in the month and 0 otherwise. Encounter dates are measured via chart review.
2. PTSD Symptom Severity – This secondary effectiveness outcome represents clinical improvement. This dependent variable is measured continuously using the PCL-5 instrument and ranges from 0-80. The variable is measured at four time points corresponding to the baseline survey and three follow-up surveys administered 10-11 months later, 21-22 months later, and 32-33 months later.
3. Travel Barrier – This secondary effectiveness outcome represents changes in perceived access to care. This dependent variable is measured ordinally using a single survey question with response options . The variable is measured at four time points corresponding to the baseline survey and three follow-up surveys administered 10-11 months later, 21-22 months later, and 32-33 months later. The question is "How much does having to travel to VA appointments interfere with getting the PTSD services you want?" The response options are 1. Does not interfere at all, 2. Interferes a little bit, 3. Interferes somewhat, 4. Interferes a great deal, or 5. Completely interferes, with higher scores representing a greater barrier.

4. Wait Time Barrier – This secondary effectiveness outcome represents changes in perceived access to care. This dependent variable is measured ordinally using a single survey question with response options . The variable is measured at four time points corresponding to the baseline survey and three follow-up surveys administered 10-11 months later, 21-22 months later, and 32-33 months later. The question is "How much does having to wait for VA appointments interfere with getting the PTSD services you want?" The response options are 1. Does not interfere at all, 2. Interferes a little bit, 3. Interferes somewhat, 4. Interferes a great deal, or 5. Completely interferes, with higher scores representing a greater barrier.
5. Trust Barrier – This secondary effectiveness outcome represents changes in perceived access to care. This dependent variable is measured ordinally using a single survey question with response options . The variable is measured at four time points corresponding to the baseline survey and three follow-up surveys administered 10-11 months later, 21-22 months later, and 32-33 months later. The question is "How much does lack of trust in VA providers interfere with getting the PTSD services you want?" The response options are 1. Does not interfere at all, 2. Interferes a little bit, 3. Interferes somewhat, 4. Interferes a great deal, or 5. Completely interferes, with higher scores representing a greater barrier.

5. Analyses

For care manager and trauma-focused evidence-based psychotherapy encounters, there are three observation periods corresponding to the three implementation stages and two implementation strategies (standard and enhanced). Encounters are calculated separately for each month during each implementation stage, resulting in 31 observations over the three stages. Dichotomous indicators for having at least one encounter are modeled using mixed-effects logistic regression with fixed effects for time (months), implementation (standard or enhanced), and site (A, B, C, E). Patient-level random intercepts are also included to account for correlation of scores within patient. If there is evidence of significant interactions between implementation strategy and site in preliminary analyses, interaction terms are included. Separate models are run for care manager encounters and trauma-focused evidence-based psychotherapy encounters.

For the access metrics and PCL-5 scores, there are four observations corresponding to the four surveys and three implementation stages (pre-implementation, standard and enhanced). The pre-implementation strategy immediately precedes Survey 1 (baseline) at all four sites. The standard implementation strategy immediately precedes Survey 2 at all four sites. Survey 3 is preceded by different implementation strategies (standard or enhanced) at different sites. The enhanced implementation strategy immediately precedes Survey 4 at all four sites. To account

for the resulting rank deficiency while modeling all four stages separately, an indicator variable Prior Period Implementation Repeat (PPIR) is specified to be equal to 1 if site's implementation strategy was the same for two consecutive stages, and 0 otherwise. Surveys 1, 2 and 3 are assigned a PPIR value of zero, whereas Survey 4 is assigned a PPIR value of 1 at two sites and a value of 2 at two sites. This helps distinguish between all four of the surveys without the need to include fixed effects for Surveys 2, 3, and 4 (with Survey 1 treated as the referent survey).

Access metrics are modeled using mixed-effects linear regression with fixed effects for site, implementation (pre-implementation, standard, or enhanced) during the period immediately preceding the survey, and PPIR. Patient-level random intercepts are also included to account for correlation of scores within patient. If there is evidence of significant interactions between implementation strategy and site in preliminary analyses, interaction terms are included. PCL-5 Score is also modeled using mixed-effects linear regression with fixed effects for site, implementation (pre-implementation, standard, or enhanced) during the period immediately preceding the survey, and PPIR. Patient-level random intercepts are also included to account for correlation of scores within patient. If there is evidence of significant interactions between implementation strategy and site in preliminary analyses, interaction terms are included.