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Telemental Health Treatment of Patients
Diagnosed with Anxiety Disorders

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Abstract

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Background. A prominent rationale for telemental health (TMH) adoption is that TMH can help overcome treatment barriers; however, TMH adoption has progressed more slowly than expected and questions about its utility persist. In 2013, the *Diagnostic and Statistical Manual of Mental Disorders*, 5th Edition (*DSM-5*) the anxiety disorder category changed and excluded disorders that had been the focus of videoconferenced (VC) TMH study. VC TMH anxiety disorder treatment outcome assumptions, therefore, warranted reconsideration.

Methods. The Knowledge to Action framework underpinned this retrospective, double cohort study of clinic-based individual treatment, measured by the Generalized Anxiety Disorder 7-item scale (GAD-7). Candidates were selected from military treatment-eligible patient records documenting *DSM-5* anxiety disorders. Initial TMH encounters occurred 1/1/2015 – 12/31/2015 and had ≥ 2 follow-up encounters with GAD-7 scores prior to 1/1/2017. Treatment episodes were delivered via either VC TMH or in-person treatment as usual (TAU) conditions. Treatment encounters ($n = 854$) for both TMH ($n = 612$) and TAU ($n = 233$) candidates were engaged by

eight independent mental health professionals assigned to a single clinic. Candidates were randomized and, while maintaining 15.63% female representation, 32 subjects per platform group were matched ($n = 64$) on age group, sex, race, ethnicity and service branch. Of 490 visits, a total of 391 GAD-7 scores for TMH ($n = 230$, 58.82%) and TAU ($n = 161$, 41.18%) cohorts were evaluated. The average TMH patient distance from the consulting provider was 1,377 ($SD = 314$) miles. Multiple linear regression was used to examine outcome predictors and a linear mixed effects model was fitted to examine estimated group means by visit.

Results. Unadjusted GAD-7 change scores improved by -2.77 ($SD = 5.25$) points ($t(63) = 6.50$, $p < .001$). In the TMH and TAU conditions, GAD-7 scores improved by -3.06 ($SD = 5.45$) points ($t(31) = 4.21$, $p < .001$) and -2.47 ($SD = 5.11$) points ($t(31) = 4.95$, $p < .001$), respectively. In the medication and psychotherapy treatment groups, initial-to-last GAD-7 scores significantly improved by -2.43 ($SD = 5.05$) and -3.22 ($SD = 5.58$) points respectively ($ps = .01$). These improvements were not significantly different between treatment platform or between therapy type conditions. Multiple linear regression showed that initial GAD-7 scores uniquely predicted outcome scores, $b = 3.97$, $SE = .65$, $t(58) = 6.08$, $p < .001$. Subjects who were not married outperformed married subjects by 3.78 points, $b = 1.89$, $SE = .66$, $t(58) = 2.87$, $p < .01$, and there was a significant interaction between marital status and initial GAD-7 scores on outcomes, $b = 1.41$, $SE = .66$, $t(58) = 2.14$, $p < .05$. Linear mixed effects regression showed that the fixed main effects of marital status ($F(1,52.07) = 5.23$, $p < .05$) and visit measure changes ($F(4,176.42) = 5.82$, $p < .001$) over the first five visits were significant. Again, no significant overall platform-therapy type change rate differences were found; however, two within group outcome improvements were significant. On average, at the fifth visit, TAU subjects who were

not married improved by -10.14 ($SE = 2.17$) points and the TMH married subject group improved by -3.26 ($SE = 1.08$) points ($ps < .001$).

Conclusion. The lack of differences between treatment-platforms in symptom improvement rates supported continuation of outcome assumptions based on a previously held conceptualization of anxiety disorders. GAD-7 symptoms improved significantly among treatment platform cohorts with a large effect ($f^2 = .60$) regardless of the therapy type engaged. When added to the full model, marital status predicted an outcome advantage for patients who were not married with a significant small-to-medium effect ($f^2 = .14$) that remained significant when initial GAD-7 scores were higher (+1 SD) than average ($f^2 = .07$). Over the first five visits, GAD-7 outcomes for TAU subjects who were not married ($p < .001$) and married TMH subjects improved significantly ($p < .05$). Fixed effects of visit measure change ($f^2 = .33$) and marital status ($f^2 = .29$) on GAD-7 outcomes had medium-large local effect sizes. These findings support VC TMH intervention improvements such as referral decision guidance and increased efficiency of behavioral health resource allocation. Tailoring treatment in these ways may improve access to care in locations where resources are limited and thereby advance treatment options to improve outcomes for military service members and their families.

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DEDICATION

To my dear wife, Ann Marie and my beautiful children Caleb, Maggie and Nathan.

Chapter 1. INTRODUCTION

The need for mental health care is urgent and increasing (Hubley, Lynch, Schneck, Thomas, & Shore, 2016; Kessler, Heeringa, Stein, Colpe, Fullerton, Hwang et al., 2014). In the 19th and 20th centuries, prominent barriers to care, such as distance from and access to resources, were beginning to be addressed using modern telecommunication technologies (Bashshur & Shannon, 2009). More recently, as videoconferencing capabilities have become ubiquitous, internet-based videoconferences (VC) have been used to reduce treatment barriers. According to the National Academy of Medicine (formerly the Institute of Medicine), overcoming treatment barriers has been a primary rationale for incorporating telemental health (TMH) into practice (Institute of Medicine, 2012). Decades of telehealth research, rapid technology expansion (Batterham, Sunderland, Calcar, Davey, Christensen, Teesson et al., 2015), and Agency for Healthcare and Research Quality (AHRQ) recommendations to shift focus from effectiveness to implementation research (Totten, Womack, Eden, McDonagh, Griffin, Grusing et al., 2016) have supported the use of telehealth technologies to improve health care delivery (Sunderji, Crawford, & Jovanovic, 2015). Nevertheless, routine telehealth care has remained a “moving target” (Bashshur, Shannon, Krupinski, & Grigsby, 2011, p. 485) in an emerging field (Totten et al., 2016) that has been associated with overly optimistic projections of uptake and diffusion (Dunstan & Tooth, 2012; Tucker, Lewis, Martin, & Over, 1957).

Some have postulated that presuming telehealth intervention uptake to require minimal effort may well have stymied telehealth research progress by inhibiting adoption and sustainment of mental health care improvement (Bashshur & Shannon, 2009; Tebbs, 2016). Patient and provider (i.e., TMH end user) reluctance to incorporate telehealth into routine practice may have

deeper historical roots. Empirical patient treatment traditionally involved direct examination and observation where other health-related practices (e.g., spells, blessings, curses) did not. Hippocratic tradition has been interpreted by some as a mandate for evidence-based health practitioners to be physically present to treat patients and monitor outcomes (Kleisiaris, Sfakianakis, & Papathanasiou, 2014). So perhaps it is not surprising that, despite decades of research, TMH research quality has been questioned (Chippis, Brysiewicz, & Mars, 2012) and concerns about the relationship between effective TMH care and routine care delivery persist (Totten et al., 2016). In these ways, TMH health care policy may have been limited, which, in turn, may have also limited the availability of viable mental health treatment options (Bronfenbrenner, 1979; Meurk, Leung, Hall, Head, & Whiteford, 2016).

This dissertation research proposed that collaborative examination of TMH treatment outcomes may address fundamental treatment concerns important to end users (i.e., patients and care providers). When these concerns are addressed, health care stakeholders can be better informed about care delivery modality options that might, when indicated, include TMH. The utility of this understanding may be improved by focusing on treatment outcomes of patients diagnosed with common disorders that have highly prevalent symptoms such as anxiety. Application of this information may be better incorporated into contemporary practice once it is more closely related to currently accepted diagnostic categories. Moreover, as treatment modality recommendations and decisions are more closely tailored to individual characteristics, patients may be better served, and symptom improvement will occur. This dissertation research therefore focused on two components of TMH treatment of patients diagnosed with anxiety disorders. First, TMH anxiety treatment outcome changes were evaluated for significant outcome differences compared to usual in-person intervention outcomes. Second, patient treatment

characteristics of care delivery modes for patients most likely to benefit from them were assessed. To this end, the following research is presented in five chapters (Davis, 2012): introduction, survey of research, methodology, results and analysis, and finally a summary of conclusions.

1.1 SPECIFIC PROBLEM

This dissertation addressed a knowledge-practice gap. While there is insufficient treatment of adult anxiety disorders and telehealth technology to overcome treatment barriers exists, anxiety disorder treatment rates have remained low (Combs & Markman, 2014; Katz, Kessler, Frank, Leaf, Lin, & Edlund, 1997; Kroenke, Spitzer, Williams, Monahan, & Löwe, 2007). For more than 60 years, telehealth interventions have been used to address this concern. The specific purpose of this dissertation, therefore, was to advance the evidence regarding synchronous, clinic-based, videoconferenced (VC) telemental health (TMH) care treatment outcomes of adults diagnosed with anxiety disorders as they are categorized in the *Diagnostic and Statistical Manual of Mental Disorders*, 5th Edition (*DSM-5*) by the American Psychiatric Association (APA) (2013).

Effective TMH care may hold the potential to improve health care in geographically and socially remote locations, not only beyond the borders of the United States but also around the globe (Tebbs, 2016). Current research supports VC TMH as a viable alternative to in-person mental health care (Totten et al., 2016); however, pragmatic aspects of VC TMH program adoption and sustainment have received less consideration. This research, therefore, not only examined TMH and in-person treatment as usual (TAU) outcomes but also considered individual treatment characteristics that may help tailor future interventions designed to improve mental health care for end users.

1.1.1 Research question.

What is the relationship between patient characteristics, symptom outcomes, and adults diagnosed with non-phobia anxiety disorders that are not attributable to substance abuse or a medical condition who were treated in either VC TMH or in-person TAU conditions? The primary outcome was measured using the Generalized Anxiety Disorder 7-item (GAD-7) scale (Spitzer, Kroenke, Williams, & Lowe, 2006).

1.1.1.1 Hypothesis.

Anxiety symptom improvement in VC TMH and TAU platform conditions will not be significantly different.

If confirmed, this hypothesis would be consistent with findings in extant literature based on the *Diagnostic and Statistical Manual of Mental Disorders*, 4th Edition anxiety disorder categorization (APA, 2000). This would suggest that some TMH treatment assumptions that have included obsessive compulsive disorder (OCD) and posttraumatic stress disorder (PTSD) may remain valid when applied to anxiety disorders as categorized in the *DSM-5* (APA, 2013).

1.1.2 Study aims.

1. To compare treatment outcomes of patients diagnosed with anxiety disorders who were treated by a member of a team of TMH providers, via either a clinic-based or in-person TAU episode of care.
2. To explore how patient treatment characteristics for the VC TMH and TAU mental health cohorts matched on age, sex, race, ethnicity and service branch relate to the treatment outcomes of patients with anxiety disorders. In addition to demographic data, this exploration was to include consulting provider type, visit dose

(encounters/episode), episode length, treatment interval (days/encounters/episode), factors evaluated include career phase (time-in-service), and condition severity (comorbidities treated during each episode).

1.2 IMPORTANCE

Anxiety disorders as categorized in the *DSM-IV* have been described as the most prevalent category of mental illness (Kessler, Chiu, Demler, Merikangas, & Walters, 2005). Annually, anxiety disorders have impacted 40 to 68 million adults ages 18 to 64 years in the United States (Kessler, Chiu, et al., 2005; Kessler, Petukhova, Sampson, Zaslavsky, & Wittchen, 2012; Schubert, Coles, Heimberg, & Weiss, 2014). Anxiety disorders in the United States have been described as having the greatest lifetime prevalence (28.8%) of any mental illness category (Kessler, Berglund, Demler, Jin, Merikangas, & Walters, 2005; Olatunji, Cisler, & Tolin, 2007), have been shown to carry a 41.7% lifetime risk of occurrence, and have disproportionately affected women ($OR = 1.6$, 95% CI [1.5, 1.8], $p \leq .05$) (Kessler, Berglund, et al., 2005; Kessler et al., 2012). The direct annual financial burden related to anxiety disorders has been estimated at \$190 billion in the U.S. (Konopka, Leichsenring, Leibing, & Konig, 2009; Marciniak, Lage, Dunayevich, Russell, Bowman, Landbloom et al., 2005; U.S. Census Bureau [USCB], 2010). An important confound to this understanding of anxiety disorders, however, is that in 2013, the APA (American Psychiatric Association) reorganized how anxiety disorders are categorized in the *DSM-5*. Importantly, OCD and PTSD (12-month prevalence among US adults: 1.2% and 3.4%, respectively) are no longer categorized as anxiety disorders, (APA, 2013). Furthermore, OCD and PTSD have been considered different enough both from anxiety disorders and from each other to now warrant separate diagnostic categories. It is therefore important to revisit assumptions about TMH and anxiety disorders without these two major mental health disorders.

Despite VC TMH having had the potential to help overcome barriers to the delivery of evidence-based anxiety disorder treatment for decades, the adoption of VC TMH has progressed more slowly than predicted (Bashshur & Shannon, 2009; Dijkman, Dinant, & Spigt, 2013; Dunstan & Tooth, 2012; Hilty, Ferrer, Parish, Johnston, Callahan, & Yellowlees, 2013; Tucker et al., 1957). There is a dearth of high-quality VC TMH adult anxiety disorder treatment studies based on *DSM-5* criteria. So, in order to contribute to the discussion of TMH diffusion, this dissertation research evaluated how VC TMH-enabled treatment of patients diagnosed with *DSM-5* anxiety disorders compared to standard in-person care in terms of symptom outcomes (APA, 2013; Bolton & Dorstyn, 2015; Condi, 2015; Hilty et al., 2013). The long-term goal of this dissertation research is to foster a better understanding of how VC TMH treatment of patients with anxiety disorders impacts our ability to overcome barriers, advance treatment options, and improve outcomes for military service members and their families.

1.3 RESEARCH APPROACH

The research approach for this dissertation informed data collection and data analysis planning. The primary data collection was quantitative and intended to inform future mental health treatment decisions. To accomplish this, a planned action theory (Graham & Tetroe, 2010; Moodie, Kothari, Bagatto, Seewald, Miller, & Scollie, 2011) underpinned development of a retrospective, matched, double-cohort study design to examine GAD-7 outcomes. The theoretical framework emphasized the needs of end users, stakeholder engagement, and process accessibility (Graham & Tetroe, 2010; Mitchell, Fisher, Hastings, Silverman, & Wallen, 2010). The research question centered on changes in what was previously understood about anxiety disorders. The hypothesis previously supported was that outcomes for patients with anxiety disorders, primarily PTSD and OCD, were not significantly different if treatment was delivered

via TMH or TAU. Data collected and analyzed for this dissertation were intended to help form a better understanding of anxiety disorders as they are currently categorized. In addition, data collection targeted related patient and treatment episode characteristics that might better inform future treatment efforts. The data analysis approach therefore was primarily deductive.

Inferential statistics were informed by descriptive statistics. Data were examined for significant correlations ($\alpha = .05$) to inform a linear regression model to determine uniquely predictive independent variables as well as significant interaction. To augment how multiple subject visit characteristics were understood, visit data were then fitted for a linear random intercept and slope mixed model. Measures, platform, and treatment mode were then treated as fixed effects to facilitate analysis of outcomes by visit.

1.4 ASSUMPTIONS AND LIMITATIONS

This study was relatively inexpensive to conduct, and less time consuming than other designs might have been. Subject recruitment was not necessary for this retrospective study design. As a matter of routine intake procedure (U.S. Department of the Army, 2010), prior to treatment eligible candidates consented to the possibility of their data being used for record review (DA8001, Limits of Confidentiality) and research and compilation of statistical data (DD2205, Privacy Act Statement). (See Appendices A and B.) A quality improvement project focused on 2015 new intake procedure adherence at this study site clinic found that patient signatures were uniformly present on these intake documents (Tebbs, 2018). In addition, a request for the Waiver of HIPAA Authorization for this study was approved on 8/13/18 by the Regional Health Command-Pacific (RHC-P) Institutional Review Board (IRB) (U.S. Department of Defense [DoD], 2003).

A strength of this retrospective double cohort study was that the data to be analyzed had already been entered into an electronic health record (EHR) so that all eligible matched subjects could be followed over an elapsed 2-year time period (CY2015 through CY2016) to clarify outcome predictors. Being able to measure predictors prior to outcomes allowed establishment of an event sequence and control for measurement bias so that cause and effect inferences could be made while controlling for potential confounds. There were also advantages to the use of a randomized matching sampling strategy. First, confounding by subject characteristics that could be strong outcome determinants (e.g., age group, sex, service branch) was minimized. Second, unspecified differences that could not be measured, such as support staff at geographically different sites, were better controlled. Third, the precision of group comparison (i.e., the likelihood of finding a true association) and sampling convenience was improved by balancing the number of controls and cases (Hulley, Cummings, Browner, Grady, & Newman, 2013) that were treated by a single group of providers.

There were also disadvantages to this study design. For example, there was less control regarding the quality and nature of baseline and follow-up measurement than might have been the case in a prospective study. Similarly, there was less control over sampling. Adjusting the sampling procedure to accommodate feasibility concerns was necessary. The initial visit time period from which the TMH sample was drawn was extended through 12/31/2015 in order to include enough candidates to support adequate study power. The study design also risked including inaccurate or incomplete data that might have been collected in less than ideal ways. For example, GAD-7 outcome data were copied by providers from the Behavioral Health Data Platform (BHDP) to the electronic medical record and were then extracted for examination if they were deemed not to have been copied forward from one note to the next. This increased the

risk of both including scores that were not unique and excluding unique scores that happened to be numerically the same. Confounding concerns were also more prominent than they might have been in a single cohort study. The TMH cohort, drawn from different geographic areas, may have influenced outcomes in ways that could be difficult to measure, with results that could have been difficult to interpret (Hulley et al., 2013).

Drawbacks to the strategy of matching were additional time costs and the possibility of selecting incomparable groups (Creswell, 2009). This was of particular concern because the decision to match was irreversible. Another limitation was that analysis of the matched variables' effect on the outcome was precluded by the decision to use a matching strategy. Had a causal path intermediary been used as a matching variable, a serious error could have been built into the study design. In addition, subjects without a match could not be included. To analyze unmatched cases would have violated the assumption of independence. Finally, matching strategies carry the potential for overmatching, which could have occurred if a matched variable were to have been associated with a predictor but not the outcome. In other words, overly matched TMH-TAU subject pairs would have had the potential to increase exposure concordance and thereby reduce the study's power (Hulley et al., 2013).

The GAD-7 (see Appendix C) was developed prior to publication of the *DSM-5*. The primary *DSM-5* change to anxiety disorder categorization was that OCD and PTSD would no longer be considered anxiety disorders. Anxiety disorder criteria referenced in this dissertation were therefore limited to the more prevalent, non-phobia-specific disorders not attributed to a medical condition, with a 12-month prevalence in the general population above 2%. These included social anxiety disorder (SAD) (7%), generalized anxiety disorder (GAD) (3%), and panic disorder (PDO) (2-3%). To ensure that anxiety disorders with less diagnostic specificity

were not overlooked, unspecified anxiety disorders were also included (APA, 2013). Another consideration was that the GAD-7 scale referenced symptoms experienced by the patient over the most recent 2 weeks. Diagnostic criteria for generalized anxiety disorder, by contrast, required symptoms to have been present for ≥ 6 months. There is, however, reasonable evidence that patients with symptomatic episodes that last less than 6 months are not very different (Kroenke, Spitzer, Williams, & Löwe, 2010) and that there is little evidence to support a 6-month time discriminator (Kessler, Brandenburg, Lane, Roy-Byrne, Stang, Stein et al., 2005). Regardless, the GAD-7 was used in this study to measure anxiety symptom severity (lower scores indicated less severe symptoms) and not as a diagnostic tool.

Safety was also addressed. Because anxiety disorder sequelae can include suicide, and because little is known about VC TMH and suicide risk, this study conformed to the design of other studies and controlled for active suicidality.

1.5 POTENTIAL CONTRIBUTIONS TO KNOWLEDGE

This dissertation adds to current TMH knowledge by confirming TMH anxiety disorder treatment assumptions formed prior to publication of the *DSM-5*. This is important to TMH study because anxiety disorders have been more narrowly defined in the *DSM-5* (APA, 2013). The findings of this study, therefore, may help clinicians and researchers better inform research design and treatment planning decisions. By providing evidence as to whether one might expect outcomes to be significantly different when patients were treated via TMH or TAU, the study of TMH and the treatment of patients with anxiety disorders may continue to advance.

The first aim was to compare TMH and TAU treatment outcomes, with the null hypothesis being that there was no significant difference between VC and in-person treatment outcomes. The null hypothesis was retained, and this research supports assertions that VC TMH

care is a viable treatment delivery alternative for the treatment of anxiety disorders as they are categorized in the *DSM-5*. The second aim, to explore how patient characteristics relate to GAD-7 score outcomes, was consistent with the study site's organizational vision for patient-centered care (Madigan, 2015). Although zero-order correlations for potential predictors were, for the most part, not statistically significant, marital status was deemed likely to be a significant predictor of GAD-7 outcomes that could inform future TMH efforts and mental health referral decisions. Unmarried patients' symptom outcomes were predicted to be lower (better) than married patients, especially when initial GAD-7 scores were higher. Information like this could allow treatment to be tailored to patients likely to benefit from TMH and would help to avoid targeting patient groups in which TMH might not improve outcomes as much.

In addition to comparing regression slopes, a linear random intercept and slope mixed model was used to examine GAD-7 measurements at each visit. This allowed for visits to be evaluated as time points with measures at the first visit compared to those at the second visit, third visit, and so on. Analyzing the data this way provided some relatively simple but important additional context regarding treatment course. For example, TAU medication GAD-7 measurements were not available beyond the fifth visit. Although the overall linear mixed model decrease in symptoms was similar to regression model slopes, outcomes associated with each visit suggests some possible interruption in score decline at the fourth visit. This change was not significant and was not a signal of optimal treatment response. The symptom improvement, on average, resumed at the fifth visit.

Chapter 2. SURVEY OF RESEARCH

2.1 OVERVIEW OF EXTANT RESEARCH LITERATURE

A preparatory literature review of clinic-based VC TMH adult anxiety treatment literature was conducted to survey the extant evidence. Both primary literature and systematic reviews were considered.

2.1.1 Primary study literature.

Pilot studies have provided preliminary indications that use of VC TMH to facilitate treatment of anxiety disorders is feasible (Manfredi, Shupe, & Batki, 2005) and may improve access to care and promote engagement in mental health treatment (Thomas, Miller, Hartshorn, Speck, & Walker, 2005). One small randomized pilot study found > 50% pre-to-post improvement and suggested that further study of VC-enabled exposure response prevention psychotherapy is warranted (Vogel, Launes, Moen, Solem, Hansen, Håland et al., 2012). A larger, cross-sectional study indicated that some adult patients may be predisposed to find VC TMH acceptable. Correlates for VC TMH acceptance included younger patient age, reduced travel time, and higher education (Grubaugh, Cain, Elhai, Patrick, & Frueh, 2008).

A non-randomized effectiveness study of cognitive behavioral therapy (CBT) delivered via VC TMH compared to TAU found that both groups improved significantly, that therapeutic alliance was not negatively impacted (Germain, Marchand, Bouchard, Guay, & Drouin, 2010), and that there were no significant outcome differences (Germain, Marchand, Bouchard, Drouin, & Guay, 2009). Gros, Yoder, Tuerk, Lozano, and Acierno (2011) matched control demographic characteristics of veterans and compared VC-delivered prolonged exposure (PE) to PE delivered via TAU. Despite sampling limitations, these researchers found significant symptom

improvement with large effect sizes in both conditions and found that treatment completion predictors were older age and more remote exposure to traumatic experience.

In randomized trials, approaches to VC TMH study varied. For example, De las Cuevas, Arredondo, Cabrera, Sulzenbacher, and Meise (2006) demonstrated that one clinician could provide efficacious VC TMH treatment, inclusive of CBT and pharmacotherapy, to patients in a single clinic. Stubbings, Rees, Roberts, and Kane (2013) found that CBT delivered via VC with patients and providers located in the same building resulted in significant symptom improvement across time, without significant differences between TMH and TAU conditions. Similarly, no significant group differences in working alliance or treatment satisfaction were found. Fortney, Pyne, Edlund, Williams, Robinson, Mittal and colleagues (2007) suggested that a multisite collaborative stepped care model supported by the prospect of a VC TMH step evidenced symptom outcomes that were not significantly different from TAU. After controlling for PTSD, the only significant predictor of GAD persistence found at the 12-month follow-up point was major depression (Mittal, Fortney, Pyne, & Wetherell, 2011). These findings supported the need for further inquiry into VC TMH treatment of anxiety disorders that are often comorbid with depression. Another multisite study using a randomized pragmatic effectiveness design (Fortney, Pyne, Kimbrell, Hudson, Robinson, Schneider et al., 2015) suggested that even with more prominent use of VC TMH to provide cognitive processing therapy (CPT) (Monson, Schnurr, Resick, Friedman, Young-Xu, & Stevens, 2006) and pharmacotherapy there were no group differences in medication prescription or adherence. The VC TMH arm, however, evidenced greater symptom improvement, and at the 12-month point CPT fully mediated the intervention.

Large non-inferiority trials also found VC TMH outcomes to be without significant differences. They also found that outcomes were similar enough to determine that VC TMH was

not inferior to in-person care. O'Reilly, Bishop, Maddox, Hutchinson, Fisman, and Takhar (2007) found that when general psychiatric treatment was provided by four psychiatrists to a single location, overall distress, global symptom severity, mental health functioning, patient satisfaction, and hospitalization rates were not inferior to TAU. Morland, Mackintosh, Greene, Rosen, Chard, Resick et al. (2014) also found VC TMH process and clinical outcomes were not inferior to TAU. After 6 weeks of twice-weekly CPT sessions, symptoms were significantly reduced at both 3- and 6-month follow-up points. Most patients (95%) reported that they were likely to recommend this mode of treatment delivery to others.

More recently, Maieritsch, Smith, Hessinger, Ahearn, Eickhoff, and Zhao (2016) conducted a randomized equivalence trial of CPT treatment of PTSD delivered once or twice weekly either via VC TMH or TAU. This study described clinical and research challenges related to VC TMH use, and due to a 43% dropout rate across the study (no significant between-condition dropout rate differences were found), equivalence could not be determined. Nevertheless, two PTSD symptom outcome measures and therapeutic alliance scores indicated a trend toward equivalence between conditions. Maieritsch and colleagues (2016) suggested that their study warranted further inquiry into patient characteristics such as disability status change to determine how to best promote PTSD treatment engagement.

These primary studies included a range of literature for clinic-based VC TMH treatment that addressed anxiety disorders, including: pilot studies (Manfredi et al., 2005; Vogel et al., 2012) observational (Thomas et al., 2005) and cross-sectional (Grubaugh et al., 2008), secondary analyses (Germain et al., 2010; Mittal et al., 2011), non-randomized comparisons (Germain et al., 2009; Gros et al., 2011), traditional RCT comparison (De las Cuevas et al., 2006; Fortney, Pyne, Edlund, Robinson, Mittal, & Henderson, 2006; Fortney et al., 2015; Stubbings et al.,

2013), non-inferiority (Morland et al., 2014; O'Reilly et al., 2007), and an equivalence trial (Maieritsch et al., 2016). Interventions included general psychiatry with pharmacotherapy, collaborative care, and various psychotherapeutic approaches including CBT, CPT, and exposure therapies. PTSD and depression were the most studied diagnoses and no studies based on *DSM-5* anxiety disorder criteria were found. However, these studies strongly suggest that VC TMH is not inferior to TAU in the treatment of *DSM-IV* anxiety disorders. On the whole, this primary study literature indicates that a better understanding of outcomes related to patient characteristics may advance VC TMH literature.

2.1.2 Review literature.

Telemental health systematic review literature reinforced the importance of understanding subject characteristics. Berry, Lobban, Emsley, and Bucci (2016), for example, emphasized that participant characteristics had an impact on TMH acceptability. Batastini, King, Morgan, and McDaniel (2016) recommended further consideration of group-unique factors, and Gaebel, Grossimlinghaus, Kerst, Cohen, Hinsche-Bockenholz, Johnson and colleagues (2016) noted socioeconomic differences in TMH participation. Flodgren, Rachas, Farmer, Inzitari, and Shepperd (2015) considered study attrition as indicative of TMH unacceptability for some patients and noted that this may be an important consideration in future study. Pennant, Loucas, Whittington, Creswell, Fonagy, Fuggle and colleagues (2015) suggested that patient variables could contribute to the tailoring of TMH interventions to encourage subject participation. Vallury, Jones, and Oosterbroek (2015) added that subject characteristics are critical to designing TMH solutions that might address barriers to TMH care.

Subject characteristics also impact TMH intervention generalizability. The da Silva, Siegmund, and Bredemeier (2015) review noted that TMH study findings were limited by age

and were underexplored. This suggests that age group-specific TMH interventions might be tailored to individual preferences for an environment (virtual or in-person) in which to express their feelings. For example, the Goetter, Bui, Ojserkis, Zakarian, Brendel, and Simon (2015) review found that dropout rates were higher among patients treated via group therapy and that younger combat veteran age was the strongest correlate with treatment dropout. Perhaps more importantly, this meta-analysis found no TMH dropout correlation with gender, race/ethnicity or education, or treatment modality such as VC TMH. Meurk and colleagues (2016) found that in Australia, middle-to-high income, educated, English-speaking, young adult females tended to self-select for TMH study participation. This illustrates how some individuals may be prone to electing against TMH study participation and emphasizes the importance of using TMH to overcome health inequities and to avoid exacerbating health care disparity.

2.2 UNIQUENESS OF PRESENT RESEARCH

Based on extant primary studies (Gros et al., 2011; Maieritsch et al., 2016; Merry, Stasiak, Shepherd, Frampton, Fleming, & Lucassen, 2012; Morland et al., 2014; O'Reilly et al., 2007) and review literature (Flodgren et al., 2015; Gros, Price, Strachan, Yuen, Milanak, & Acierno, 2012; Totten et al., 2016), VC TMH outcomes may be equivalent or at least not inferior to in-person TAU, and further understanding of patient characteristics is warranted. There is an ongoing need to develop sustainable mental health interventions (Bashshur & Shannon, 2009; Bashshur, Shannon, Krupinski, & Grigsby, 2013). Failure to employ anxiety disorder treatment resources may perpetuate unnecessary suffering such as suicide attempts (Sareen, Cox, Afifi, de Graaf, Asmundson, ten Have et al., 2005) and disability on par with cancer (Olatunji et al., 2007).

The present study expands evaluation of treatment across four non-contiguous states inclusive of one state outside of the continental United States. The average distance between providers and TMH patients ($M > 1,370$ miles) was greater than reported in other relevant TMH studies. No previously published retrospective double-cohort inquiry on this topic was found. In addition, findings reported to date have been based on *DSM-IV* criteria (APA, 2000), which are substantially different than anxiety disorders in the *DSM-5* (APA, 2013). This dissertation study may therefore increase understanding of patient characteristics and VC TMH outcomes for the treatment of current anxiety disorders and thereby advance how future interventions may be tailored to meet the needs and preferences of mental health care participants.

Chapter 3. RESEARCH METHODOLOGY

3.1 CONCEPT DEVELOPMENT

The idea for this dissertation research emerged from the author's past clinical experience with VC TMH combined with his study of the Knowledge to Action (KTA) theoretical framework and its focus on overcoming treatment barriers. During a 2015 quality improvement project underpinned by the KTA framework, iterative weekly meetings with TMH providers included discussions of efforts to adapt to changes in mental health care (Tebbs, 2018). A prominent topic was how diagnostic category changes in the *DSM-5* might impact TMH. There was evidence that supported TMH treatment of depressed patients with concomitant anxiety; however, key assumptions about TMH anxiety disorder treatment were supported in large part by PTSD studies and to a lesser degree, OCD studies. Prior to 2013, these disorders represented 26% of the 12-month prevalence of non-phobia-specific anxiety disorders among adults in the United States (APA, 2013). TMH treatment outcome findings for PTSD and OCD were not significantly different from TAU outcomes, and TMH was considered a reasonable alternative platform to treat patients with anxiety disorders. However, without PTSD and OCD in the *DSM-5* anxiety disorder category there was a paucity of studies focused on TMH treatment of *DSM-5* anxiety disorders to support previously held assumptions. Reconsideration of TMH treatment of patients diagnosed with anxiety disorders was therefore warranted.

In accordance with the KTA emphasis on collaboration, the concept for this research was refined via discussion with mental health and telehealth academicians, military researchers, and expert clinicians. End user characteristics were deemed to be a central consideration for patient-centered program sustainability. Study feasibility and costs were also considered. An a priori power analysis determined that 62 subjects were required to adequately power linear regression

analysis ($\alpha = .05$, $\beta = 80\%$, $f^2 = .25$). Since we found no other retrospective double-cohort study on this topic, a proposal for the present study was developed and submitted to, and approved by, IRBs at both a doctoral research university (#00004336, 3/20/2018) and the consultant site's regional system of care (#218115, 8/13/2018). (See Appendix I).

3.1.1 Anxiety disorder construct.

Anxiety disorder definitions past and present have included overlapping components of anxiety and fear (APA, 2000, 2013), and anxiety disorders are highly comorbid with each other. Spitzer, Kroenke, Williams, and Lowe (2006) conducted a confirmatory factor analysis (CFA) and differentiated anxiety and depression as separate constructs. According to the *DSM-5*, the anxiety component of anxiety disorders is the sustained anticipation of future threat (Pine, 2009) that includes cautious avoidance, heightened arousal and physical tension (Shelton, 2008). The anxiety component was thereby understood as a combination of autonomic signs (Stein, Hollander, & Rothbaum, 2009). The fear component of anxiety disorders, on the other hand, was conceptualized as an emotional response to imminent threat (APA, 2013; Pine, 2009). The fear component refers to a more immediate, subjective response to sudden danger such as nervousness or worry. In other words, when a threat is proximal to a human individual, fear is a normal response. However, when the threat abates prolonged anxiety may indicate an abnormal response (Pine, 2009).

According to the *DSM-5*, in order to constitute an anxiety disorder, anxiety and fear must also be persistent, excessive, and different from culturally normal responses. Diagnostic criteria for some anxiety disorders in the past required patients to recognize their responses as excessive (APA, 2000). However, in the *DSM-5* this level of patient insight is no longer required. The excessiveness of a threat response may be determined by an observation-informed clinician

(APA, 2013). This change suggested that, in addition to categorical anxiety disorder changes, the diagnostic conceptualization shifted emphasis from subjective patient perception toward a greater reliance on clinician observation.

3.2 DATA COLLECTION

The study period was 1/1/2015 – 1/1/2017. The target population was military treatment-eligible patients who had received clinic-based mental health care delivered either via VC TMH or TAU with treatment encounters documented in the Military Health System (MHS) electronic record. All patients were offered TAU and voluntarily consented to behavioral health treatment. The treatment platform used was either TMH when patients were located at one of four possible remote Department of Defense (DoD) behavioral health clinic patient sites or in-person TAU when the provider and patient were physically collocated at the same DoD installation.

To control for outcome assessment bias, the standardized GAD-7 scale was selected to measure anxiety disorder symptoms. GAD-7 data were entered directly by patients into the standardized Behavioral Health Data Platform (BHDP) (Brown, 2013) via computer kiosk. These kiosks were available at each DoD behavioral health clinic patient site that hosted the treatment. GAD-7 data were entered prior to treatment visits when the interval between visits was at least 2 weeks. The MHS allowed patient data and provider documentation to be shared between the consulting and referring sites. Treatment was provided by the same group of eight specialized mental health providers assigned to the same specialty clinic. VC TMH connection was facilitated using Tandberg high definition, universal serial bus cameras, model CTS-PHD-USB (Cisco Systems Incorporated, 2012). These were used with Health Insurance Portability and Accountability Act (HIPAA) (United States, 1996) compliant, private office DoD office desktop computers. Cisco Jabber version 10.6 for Windows, encrypted videoconferencing software

(Cisco Systems Incorporated, 2015a, 2015b) facilitated network connectivity. The consultant clinic was located within the department of behavioral health at a single DoD medical center, in the Pacific Northwest of the United States. The treatment modalities provided by the consultant clinicians were psychotherapy or pharmacotherapy. Psychotherapy was provided by one of four doctoral-level psychologists. Pharmacotherapy was provided by either one of two psychiatrists, or one of two master's-level psychiatric-mental health nurse practitioners.

Eligible candidates were adults between 18 and 89 years of age and able to make care decisions independently. Initial encounters for each episode considered took place during the 2015 calendar year and had at least 2 follow-up visits associated with a GAD-7 score (first, mid-episode, last) prior to 1/1/2017. Eligibility required a diagnosis of at least one *DSM-5* non-phobia anxiety disorder to have been assigned prior to or during the treatment episode. Anxiety disorders were identified via International Classification of Disease ICD-9 (ICD-10) codes: SAD 300.23 (F40.1), GAD 300.02 (F41.1), PDO 300.01 (F41.0), and anxiety disorder, unspecified 300.0 (F41.9).

Candidate exclusion criteria were: (a) active substance abuse treatment, (b) terminal illness, (c) active suicidal thoughts within 1 month or suicidal actions within 3 months before the initial visit, (see Appendix D) defined as a Columbia Suicide Severity Rating Scale (C-SSRS) score > 2 (Madigan Army Medical Center, 2014; Youngstrom, Hameed, Mitchell, Van Meter, Freeman, Algorta et al., 2015), (d) pending legal problems and/or domestic violence concerns, (e) prescription of an antipsychotic, mood stabilizing agent (or concurrent diagnosis of bipolar disorder or psychotic disorder), and/or (f) mental function change due to a physical rather than psychiatric disease process. Confounding was also addressed by assembling cohorts matched on age group, sex, race, ethnicity, and service branch (Murphy, 2015). This allowed subject

inclusion based on the level of a predictor (Hulley et al., 2013) which, in this case, was exposure to the treatment platform: TMH or TAU.

Record identification was facilitated by the consultant clinic administrative coordinator who provided access to the 2015 consultant clinic referral tracking spreadsheet and a list encounters for the consultant clinic providers for that calendar year. Cases on these lists were examined to ensure that internal encounter coding did not inadvertently exclude eligible cases. The physical and electronic data collection environment was compliant with HIPAA regulation. Record review was supervised by a senior doctoral-level psychiatric nurse practitioner with expertise in military mental health record review and program evaluation. Data were accessed via the MHS Armed Forces Health Longitudinal Technology Application (AHLTA) electronic record and BHDP. Patient data were not collected from the psychotherapy portion of records. As stipulated by the clinical institution's IRB, a master key cross-referenced the unique, randomized 10-digit study identification numbers with DoD record identification numbers. Data were extracted in the same way for each candidate using a data collection spreadsheet tool. Candidates and subjects were identified only by their study number. The master key and data collection tool were stored in separate password-protected files on the study site's secure computer system.

Although a matching approach was not as generalizable as a fully randomized sampling design would have been, an advantage of criterion sampling was that it allowed for more in-depth study of the subjects (Grembowski, 2001). This approach also allowed for the maintenance of female sample representative of women (> 15.5%) across active DoD services in 2015 (Office of the Deputy Assistant Secretary of Defense for Military Community and Family Policy [DASD (MC&FP)], 2015). Randomization was employed when possible. For example, because the consultant clinic was focused on a relatively new TMH psychiatry and psychotherapy service

(Madigan, 2014), the number of eligible TAU candidates was smaller than the number of TMH candidates. Candidates were therefore matched in random order for subject cohort selection (see Appendix E).

3.2.1 Cohort selection.

Cohort selection took place in 2 phases: candidate outcome identification and subject matching. (See Figure 3.1.) Identification involved a review of cases for eligibility with a focus on outcome data availability. Duplicates and second treatment episodes in the same consultant clinic were removed. The EHR data were evaluated, exclusion criteria were applied, and records were removed from consideration accordingly. Data were then collected and prepared for the matching process. Candidate cases ($n = 109$) were sorted into TMH or TAU platform groups.

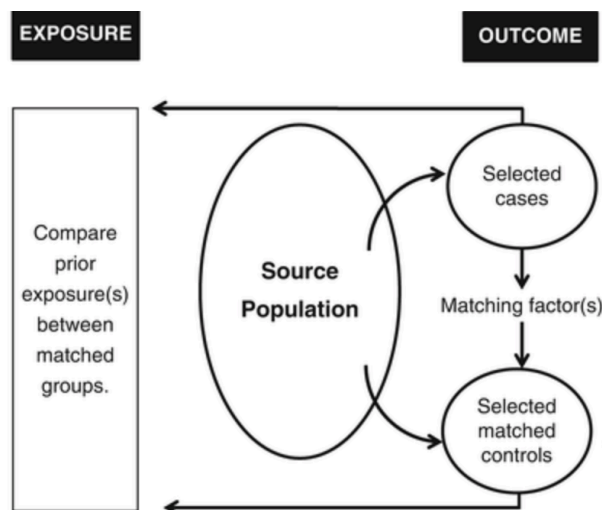


Figure 3.1. Selection and matching concept for cohort studies.

From “Longitudinal Studies 4: Matching Strategies to Evaluate Risk,” by M.T. James, in P. Parafrey, B. Barrett (Eds.), *Clinical Epidemiology. Methods in Molecular Biology* (p. 135), 2015, New York, NY: Humana Press. Copyright 2015 by Springer Nature. Reprinted with permission.

3.2.1.1 Matching Strategy.

The matching strategy approach adhered to formulation steps described by Murphy (2015). Candidate availability of > 40 eligible pairs and > 17% female representation in each

condition suggested that an 80% power to detect moderate effects was possible. Three lists were involved in the matching process: TAU candidate list, TMH candidate list, and the matched TAU-TMH subject list. Candidate comparison procedures were automated using a spreadsheet formula to determine if candidates matched on age group, sex, race, ethnicity and service branch. The criteria for each TAU candidate ($n = 68$) were compared to TMH candidates ($n = 41$) in random sequence. If matched, both candidates were removed from their respective candidate lists. The matched pair was then added to the TAU-TMH cohort subject list. This comparison process then resumed using the remaining TMH and TAU candidates with next lowest study numbers. The process was repeated until comparison possibilities were exhausted. Thirty-one matches were generated ($n = 62$).

During the matching process, the fidelity of ethnicity data was scrutinized. The proportion of people identifying as not Hispanic/Latino in the military population was 87.70% (DASD [MC&FP], 2015); however, the proportion observed among candidates was far lower at 14.7% ($\chi^2(1) = 538.79, p < .001$) and candidates identifying as unknown comprised 77.10% of the sample. Combining not Hispanic/Latino and unknown categories accounted for 91.74% of candidates. When evaluated in this way, population-candidate ethnicity differences were no longer significant. A methodologist was consulted, and, in collaboration with the clinician supervising data collection, we adjusted the matching strategy to better reflect total dichotomously categorized military population ethnicity demographics. To preserve exact matches, the matching process was then reengaged using cases remaining on the candidate lists. The unknown ethnicity category was allowed to match with the not Hispanic/Latino ethnicity category, and two additional candidate matches ($n = 4$) were found.

The result of the matching process was a TMH subject cohort ($n = 33$) equal to the number of TAU subject cohort ($n = 33$); however, female representation dropped below 15.5%. One male pair was therefore randomly selected for removal from the subject cohort list. Female representation in the subject sample increased to 15.6% ($n = 64$). After TMH and TAU cohort subjects were selected, a 12.5% ($n = 8$) fidelity check was conducted by a second doctoral-level clinician with electronic chart review and mental health treatment expertise ($r = 1.0$). Data de-identification was then reviewed on-site via the Safe Harbor method (Committee on Strategies for Responsible Sharing of Clinical Trial Data, 2015) and prepared for statistical analysis using IBM SPSS Statistics for Macintosh software, version 25 (IBM Corporation, 2017).

3.3 MEASUREMENT

Two measurement scales were involved in this dissertation research. First, the C-SSRS was used to define the active suicidality exclusion criterion. Second, the GAD-7 was used as the primary outcome measure for this study.

3.3.1 Columbia Suicide Severity Rating Scale.

The C-SSRS was approved by the United States Food and Drug Administration, with good validity and reliability (Youngstrom et al., 2015) and some predictive validity (Posner, Brown, Stanley, Brent, Yershova, Oquendo et al., 2011). Mundt, Greist, Jefferson, Federico, Mann, and Posner (2013) found that of patients reporting past suicidal ideation ($n = 3,776$) via the electronic version of the C-SSRS, 18.4% with both suicidal ideation and behavior were four- to nine-times more likely to indicate future suicidal behavior ($OR = 9.13$; 95% CI [6.47, 12.88]). For assessments that identified suicidal actions, C-SSRS sensitivity was .67 and specificity was .76 (Mundt et al., 2013).

The C-SSRS was uniformly administered to behavioral health patients via the BHDP prior to initial visits in both TMH and TAU conditions. Scores < 3 indicated an absence of active suicidality in the previous month and no suicidal behavior in the previous 3 months. TMH referrals with active suicidality were, as a matter of standard procedure, redirected to in-person care (Madigan, 2014). In addition to helping to control for potential safety concerns, C-SSRS was used to help determine similar treatment platform group eligibility between cohorts. It is noteworthy, however, that the suicidality exclusion criterion was applied prospectively (i.e., prior to treatment) to TMH candidates. For TAU candidates, active suicidality exclusion was applied retrospectively during the candidate selection process.

3.3.2 Generalized Anxiety Disorder 7-item Scale.

The GAD-7 scale was initially developed in English to screen for GAD in primary care settings (Beard & Bjorgvinsson, 2014). The GAD-7 was designed as a pragmatic, paper-pencil, non-proprietary, self-report instrument. The GAD-7 was intended to have diagnostic and symptom severity measure utility in clinical settings to measure GAD symptomology (APA, 2000; Spitzer, Kroenke, Williams, & Lowe, 2006). Response choices corresponded to a Likert-type 4-point scale. The GAD-7 was translated into several languages and widely used in research settings as a non-specific anxiety screening tool (Craske, Stein, Eley, Milad, Holmes, Rapee et al., 2017; Parkerson, Thibodeau, Brandt, Zvolensky, & Asmundson, 2015).

GAD-7 response items were based on the diagnostic criteria for GAD (APA, 2000), a review of extant anxiety scales, and patient interviews and questionnaires (Spitzer, Kroenke, Williams, & Lowe, 2006). Initial measurement validation work conducted by Spitzer et al. (2006) included developmental and replication samples ($n = 2,740$) that were 80% Caucasian (Parkerson, Thibodeau, Brandt, Zvolensky, & Asmundson, 2015). Selection of GAD-7 response

items was based on the highest correlations ($r > .75$). On the total item scale score, 6 items diverged from the Patient Health Questionnaire eight-item scale score with correlations ranging from .16 to .21 (Spitzer et al., 2006).

Consistent with anxiety and depression comorbidity (APA, 2013), both the Symptom Checklist-90 (SCL-90) and the GAD-7 correlated with Patient Health Questionnaire (PHQ-8) depression scale ($r_s = .75, .74$, respectively). Nevertheless, correlations between the GAD-7 the Beck Anxiety Inventory, and then the SCL-90 were also interpreted as having strong convergent validity ($r_s = .72, .74$, respectively). A Cronbach's α of .92 indicated excellent internal consistency. Spitzer, Kroenke, Williams, and Lowe (2006) found an optimal cut point of 10, with good sensitivity and specificity ($r_s = .89, .83$, respectively). Test-retest reliability and clinician-administered versions showed good consistency with an interclass correlation of .83. Principal component analysis combining GAD-7 and PHQ-8 items showed 2 emergent factors with a desirable eigenvalue > 1.0 . Anxiety items loaded to factor 2 (.69 – .81), and depression items loaded to factor 1 (.58 – .75). Parkerson and colleagues (2015) interpreted these findings as support for a GAD-7 single factor structure.

The GAD-7 was deemed reliable and valid to screen adults for anxiety symptoms in a clinical setting (Kroenke et al., 2007) as well as in the general population (Lowe, Decker, Muller, Brahler, Schellberg, Herzog et al., 2008). Use of the GAD-7 to measure anxiety symptom severity change was supported by good sensitivity (Beard & Bjorgvinsson, 2014). In addition, an online-version of the GAD-7 was found to be reliable (Cronbach's $\alpha = .86$), with sensitivity ($r = .82$) and convergent validity ($r = .83$) with the Hospital Anxiety and Depression Scale. The online GAD-7 version validation, however, evidenced lower specificity ($r = .65$) at a higher cut point of 12 (Donker, van Straten, Marks, & Cuijpers, 2011).

3.3.2.1 GAD-7 Concerns.

Although the GAD-7 has many strengths, factor structure concerns and cultural bias weaknesses were considered. First, the conceptualization of anxiety disorder factor may not yet be fully understood. As previously discussed, anxiety disorders were described as having two facets: anxiety and fear. On its face, the GAD-7 seemed to support a single factor conceptualization. For example, Portman, Starcevic, and Beck (2011) suggested two similar anxiety subtypes of worry and physical arousal. Building on the normative data provided by Lowe and colleagues (2008), Kertz, Bigda-Peyton, and Bjorgvinsson (2013) also hypothesized a unidimensional factor structure. They found, however, that this model did not fit well (root mean square error of approximation [$RMSEA$] = .14, $p < .001$). Their exploratory factor analysis suggested that allowing error terms for GAD-7 items 4 through 6 to covary would improve the model. Specified this way, the model fit improved, but it was still not optimal ($RMSEA = .09$). Parkerson and colleagues (2015) based CFA on the Kertz and colleagues (2013) revised model and found a better fit with shared variance between GAD-7 items 4 through 6. Subcategories of physical tension and autonomic arousal remained consistent with a single factor GAD-7 construct. Beard and Bjorgvinsson (2014) on the other hand, found that a two-factor structure accounted for 71% of variance. GAD-7 items 1, 2, 3 and 7 loaded to factor 1: emotional experience. Consistent with previous analyses GAD-7 items 4 through 6 loaded to factor 2: physical arousal. In addition, similar factor structure patterns for anxiety disorders other than generalized anxiety were found to support a 2-factor structure as the best fit for the GAD-7. On the whole, these analyses indicate that, just as the anxiety disorder category and diagnostic conceptualization changed in the *DSM-5*, the accepted understanding of how GAD-7 measures anxiety may be changing as well.

Second, because some subpopulations have greater representation in the military treatment-eligible population than in the general population (DoD, 2105; DASD [MC&FP], 2015; USCB, 2015) and foundational GAD-7 validation work was based on primarily Caucasian subjects (Spitzer, Kroenke, Williams, & Lowe, 2006), bias concerns were considered. For this dissertation research, which is focused on a military treatment-eligible sample, GAD-7 validity and reliability were revisited from the perspective of potential bias. Parkerson and colleagues (2015) found that although the GAD-7 has been used in various cultural contexts, there was little information about GAD-7 psychometric properties across different cultural groups. These researchers found that GAD-7 cultural measurement biases risked symptom severity underestimation in African Americans by 2 to 3 points. This raised a concern for cross-cultural measurement biases beyond cultural differences (Parkerson et al., 2015). This was relevant to the present dissertation research because African Americans ($n = 10$) accounted for 15.63% of the matched subject sample. Self-reported GAD-7 scores of African American subjects that tended to reflect a more conservative estimate of severity could have diminished how symptom severity was understood. This being the case, it was important that GAD-7 score severity had no bearing on candidate selection, and, as a matching variable, race was excluded from consideration as predictor in statistical models for this dissertation research.

3.4 METHODS

Univariate analysis of patient characteristics included measures of central tendency, variation, and frequency distributions (see Appendix F). Assumptions of independence were then assessed. No missing data value imputation was necessary. In accordance with the data analysis plan, a linear regression model with sequential predictor entry was fitted. The sequential predictor entry method was chosen because it allowed tests of incremental model fit improvement as predictors

were added to the model. Outcome data were then transposed in order to fit a linear random intercept mixed model and augment how multiple subject visit characteristics were understood.

3.4.1 Assumptions of independence.

Prior to fitting models, variable independence was assessed. Six assumptions were evaluated: (a) dependent variable level of measurement, (b) adequate independent variable categories, (c) observation independence, (d) data outliers, (e) homogeneity of variances, and (f) normality.

3.4.1.1 Dependent variable level of measurement.

A score of zero on the GAD-7 scale dependent variable was possible, so the GAD-7 outcome variable was treated as continuous. The dependent variable measurement assumption to support linear regression analysis was met.

3.4.1.2 Adequate independent variable categories.

Second, although the a priori power analysis allowed for six predictor variables, the sample size to predictor ratio target was 15:1. The sample of 64 subjects was sufficient support for four independent predictor variables. For this study, initial GAD-7 scores, treatment platform, and therapy type were essential predictors. After consultation with a statistician, inclusion of an additional predictor and related interaction term was deemed reasonable. Treatment platform included 2 matched levels: telemental health (TMH) or treatment as usual (TAU). Therapy type was composed of levels that were not matched: medication or psychotherapy. Similarly, marital status included 2 unmatched levels: married or not married. The assumption of independent variable adequacy was therefore met.

3.4.1.3 Observation independence.

Subjects were different between the levels of independent variables. Subjects were not included in more than one platform group during a treatment episode. For example, a single episode did not include patients treated in-person who then moved mid-episode and continued treatment remotely via TMH with the same provider. Similarly, subjects were included only in one therapy type group. Three subjects were exposed to both therapy types via TMH during an episode but were included only in the first therapy type group engaged. The marital status data element was fixed at intake. A mid-episode divorce, for example, did not allow a subject to be included in both married and unmarried groups. Small group dependence concerns for treatment platforms were further mitigated by drawing the entire matched subject sample from 100% of the 2015 treatment episodes engaged by providers assigned to a single consultant clinic. Nevertheless, to avoid residual dependence, dichotomous therapy type levels were controlled for as fixed effects. An assumption of independent observations was thereby deemed tenable.

3.4.1.4 Data outliers.

Potential dependent variable outliers were evaluated using standardized scores. With a sample size > 25 and < 75 , a dependent variable outlier was defined as exceeding ± 2 standard deviations from the mean. GAD-7 z-scores ranged from -1.35 to 1.72. No outliers were found. Platform and marital status variables were assessed for outliers using box-plots and did not indicate outliers. The therapy type variable, however, indicated 2 outliers (see Figure 3.2).

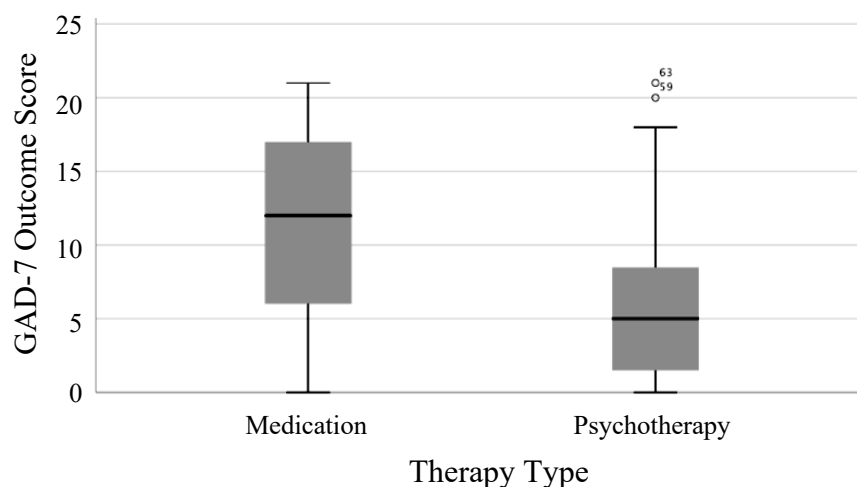


Figure 3.2. Simple box-plot of GAD-7 outcomes on therapy type.

To determine how to address these outliers, the initial data collection tool was reviewed to ensure there were no data entry errors (Parke, 2012). No data entry errors were found. The raw GAD-7 outcome scores of 20 and 21 points in individual therapy group cases 63 and 59 were examined more closely. These scores were deemed to be legitimate and within the 0 to 21-point GAD-7 score range. Because the GAD-7 outcome did not appear normally distributed, to ensure there was no significant difference between therapy group GAD-7 outcome scores, a Mann-Whitney U test was conducted with outliers and without outliers ($U_s = 222.50, 289.50, p_s < .01$, respectively). These tests indicated that therapy score outliers did not change dissimilarity significance between therapy type outcomes.

3.4.1.5 Homogeneity of variances.

Although by design, sample sizes of 32 subjects per TMH and TAU groups were equal, therapy type (medication: $n = 37$, psychotherapy: $n = 27$), and marital status (married: $n = 43$; not married: $n = 21$) were not. To initially assess homogeneity of variances (HOV), histograms were visually inspected for outcome score distribution. Spread ranged from 0 to 21 for both platform and therapy type. The marital status spread varied by 1-point. GAD-7 outcome data were then

evaluated for HOV using a Levene's test to compare initial and last GAD-7 scores on variables including initial GAD-7 scores, platform, therapy type and marital status. These tests confirmed that variances were significantly dissimilar and an assumption of HOV was tenable.

3.4.1.6 Normality.

Finally, the assumption of normality was considered. GAD-7 score frequency distribution histograms were visually evaluated for marked deviations in normality (Ghasemi & Zahediasl, 2012). The initial GAD-7 score appeared to be normally distributed with a left skew. The last GAD-7 score dependent variable, however, did not appear to be normally distributed. This was confirmed by Shapiro-Wilk's test ($W = .93, p < .01$). Despite the assumption of normality being considered robust to violation, when considering the use of independent t -tests, p -values could be inaccurate. A Shapiro-Wilk's test, however, indicated that GAD-7 change score distribution was normal ($W = .97, p > .05$) with a left skew. Based on this, change scores were used for additional t -tests to assess independence, and the normality assumption was deemed tenable.

3.5 OBSERVATION

Given the complexity of mental health treatment, examination of multiple variables related to GAD-7 outcomes was necessary. First, patient characteristic data used in the matching strategy were examined. Second, zero-order correlations were assessed for multicollinearity and then shared variance informed predictor selection. Third, preliminary paired t -tests or Wilcoxon signed rank sum tests, as appropriate, were conducted to indicate direction and significance of outcome changes. Fourth, the multiple linear regression and linear random intercept mixed effects models were fitted.

3.5.1 Multiple linear regression model data.

As expected, after candidates were matched to form subject groups, no matching variable differences between subject platform groups were found. Age ($M = 31.50$, $SD = 8.47$) was not significantly different between candidate and subject groups. The average age across DoD service branches in 2015 was 28.5 years (DASD [MC&FP], 2015). Population, candidate, and subject sample means were within the young-to-middle adult 26- to 35-year-old age group category. The average candidate time in service (TIS) was 9.42 ($SD = 6.99$) years. This was not significantly different among groups, with the exception of female subjects who had served an average of 7.83 years TIS ($SD = 4.26$) which was significantly lower than the 10.56 years TIS ($SD = 9.74$) female candidates had served ($z = -2.43$, $p < .05$). Interestingly, the proportion of female study candidates (29.36%) was significantly greater than the 15.5% female population ($\chi^2(1) = 15.98$, $p < .001$). Subject matching, however, controlled for this and female representation in the matched subject groups was 15.63%.

Race was also not proportionally different among minorities in the population, candidate, and subject groups. Caucasian candidates (77.98%) on the other hand, were overrepresented ($\chi^2(1) = 10.81$, $p < .001$) which was reflected in the subject sample (78.13%). The Hispanic/Latino candidate ethnicity proportion was not significantly different from that of the general population, and when non-Hispanic and unknown ethnicity categories were combined, no significant proportional difference was found.

Perhaps unsurprisingly, given that the consultant site was located in an Army facility, the Army branch of service was overrepresented at 74.31% in candidates ($\chi^2(1) = 200.94$, $p < .001$), and this difference was more pronounced (90.63%) among the subjects ultimately selected ($\chi^2(1) = 12.02$, $p < .001$). Conversely, the Navy, Marine and Veteran service branches among

candidates were represented at significantly lower proportions than the military population across services ($p < .001$). Education levels were not significantly different from expected population values. A greater proportion of candidates were married (65.14%) than in the larger population (54.30%), $\chi^2(1) = 5.16, p < .05$, and fewer candidates (22.94%) were not married than in the population (41.6%), $\chi^2(1) = 5.16, p < .001$. There were no significant proportional differences found between candidates and subjects. However, more candidates and subjects (11.93%, 17.74%, respectively) were divorced than in the population (4.60%), $\chi^2(1) = 14.26, p < .001$.

3.5.1.1 Zero-order correlations.

Predictor correlations with the GAD-7 outcome scores were evaluated for multicollinearity. To examine zero-order correlations for multicollinearity, potential data elements were separated into four categories of potential predictors: GAD-7, platform and therapy type, patient and treatment, and comorbidities. Multicollinearity concerns were initially identified as correlations with the GAD-7 dependent variable of $\geq .90$ (Tabachnick & Fidell, 2013).

The means of mid-episode GAD-7 scores as well as overall GAD-7 scores both indicated multicollinearity (variance inflation factors [VIFs] = 21.46, 21.21, respectively). To avoid an unstable matrix inverse, sensitive to data variations due to a near-zero determinant and large standard errors, these predictors were excluded from consideration as explanatory variables. Initial GAD-7 and GAD-7 change scores, on the other hand, did not evidence multicollinearity. Change scores were significantly positively correlated with the last GAD-7 score ($r = .55, p < .01$). Worse initial GAD-7 scores correlated with worse outcome scores. Platform ($r = -.28,$

$p < .05$) and therapy type ($r = .36, p = .01$) groups were also significantly correlated with GAD-7 outcome scores. The TMH platform was correlated with higher initial GAD-7 scores ($r = -.28, p < .05$), and psychotherapy was correlated with lower initial GAD-7 scores ($r = .36, p < .01$).

No multicollinearity concerns were observed for patient and treatment correlations. Education level did not significantly correlate with the GAD-7 outcomes but did significantly correlate both with being naive to psychotherapy ($r = -.34, p < .01$) and with medication change ($r = .27, p < .05$). Marital status ($r = .35, p < .01$) also correlated with GAD-7 outcomes. There were no multicollinearity concerns for comorbid diagnoses. As is often the case in clinical practice, the total number of comorbidities correlated with depression ($r = .50, p < .001$), sleep disorders ($r = .67, p < .001$), and PTSD ($r = .32, p < .05$). Depression also correlated with OCD ($r = .28, p < .05$) and GAD-7 outcome scores ($r = .26, p < .05$). Interestingly, treatment correlations such as specific provider type, encounter length, episode length, treatment interval, and time-to-treatment did not show significant correlations with the GAD-7 outcome. Similarly, patient correlations such as specific anxiety disorder diagnosis, TIS (career phase), and number of selected comorbidities were also not significantly correlated with the GAD-7 outcome.

3.5.1.2 Predictor selection.

Three explanatory variables were deemed to be predictors essential to the research, regardless of shared variance. First, the initial GAD-7 scores were needed to evaluate symptom change. Initial GAD-7 had a significant relationship with the GAD-7 outcome ($r = .67, 45.29\%, p < .001$). Initial GAD-7 scores also shared significant variance with other potential predictors: therapy type ($r = .35, 12.04\%, p < .01$), comorbid depression ($r = .29, 8.53\%, p < .05$) and treatment platform ($r = -.28, 7.84\%, p < .05$). Second, the platform variable was essential to the research question. Treatment platform had a significant relationship with GAD-7 outcome scores

($r = -.28$, 8.66%, $p < .05$) and in addition to shared variance with initial GAD-7 scores, treatment platform shared significant variance with comorbid depression ($r = -.31$, 9.49%, $p < .05$). Third, therapy type had a significant relationship with GAD-7 outcomes ($r = .36$, 12.60%, $p < .01$) and because therapy type included levels that needed to be controlled as fixed effects, it was also an essential model predictor. Therapy type shared significant variance with initial GAD-7 scores, comorbid depression ($r = .35$; 12.04%, $p < .01$), medication change ($r = .30$, 8.70%, $p < .05$), and marital status ($r = .28$, 2.18%, $p < .05$).

Marital status was included as a predictor because it was deemed likely to uniquely predict outcomes. Marital status had a significant relationship with GAD-7 outcomes ($r = .35$, 12.25%, $p < .01$). This was interesting because marriage has been considered to be a mental health protective factor mental in general populations (Gibb, Fergusson, & Horwood, 2011). The variance marital status shared with therapy group was relatively small (2.18%). Marital status was also relevant to all subjects regardless of platform or therapy type. Medication change on the other hand, while having a smaller significant relationship with the outcome ($r = .27$, 7.18%, $p < .05$), was deemed unlikely to uniquely predict outcomes for this sample. In addition to sharing significant variance with therapy type and depression, medication change data were relevant only to subjects in the medication level of the therapy type variable. Finally, comorbid depression had the smallest significant relationship with the outcomes ($r = .26$; 6.70%, $p < .05$) and it shared significant variance with initial GAD-7 scores, treatment platform, therapy type, and medication changes. Depression was therefore excluded as a potentially unique predictor (see Table 3.1).

Table 3.1
Descriptive Statistics, Zero-order Correlations, Potential Predictors

Measure	<i>M</i>	<i>(SD)</i>	1.	2.	3.	4.	5.	6.	7.
<i>Outcomes</i>									
1. GAD-7 Last	9.28	6.88	--						
<i>Potential Predictors</i>									
2. GAD-7 Initial	12.05	5.91	.67 ***	--					
3. Treatment Platform	.00	1.01	-.28 *	-.28 *	--				
4. Therapy Type	.16	1.00	.36 **	.35 **	-.22	--			
5. Marital Status	.34	.47	.35 **	.14	-.03	.28 *	--		
†6. Medication Change	-.06	.50	.27 *	.23	-.13	.30 *	.06	--	
†7. Depression	-.41	.46	.26 *	.29 *	-.31 *	.35 **	.02	.35 **	--

Note. $N = 64$. GAD-7 = Generalized Anxiety Disorder 7-item scale. Dichotomous predictors (3-7) were effect coded. Treatment Platform: 1 = telemental health. Therapy Type 1 = psychopharmacotherapy. Marital Status: 1 = married. Medication Change: 1 = psychiatric medication prior to episode, regimen changed. Depression: 1 = comorbid depression treated during an episode.

* $p < .05$, ** $p < .01$, *** $p < .001$, † excluded from model

3.5.1.3 Tests of independence.

The potential for patient site non-independence was considered. Because the GAD-7 outcome was not normally distributed and three of four possible TMH patient sites were included in the matched cohorts, a Kruskal Wallis test was conducted. It did not show significant differences in GAD-7 outcome scores among these TMH patient sites, $\chi^2(2) = 2.53, p > .05$. In addition, all patient sites including the TAU site were then evaluated using normally distributed GAD-7 change scores to conduct a one-way analysis of variance (ANOVA). No statistically significant difference was found ($F(3,60) = 1.82, p > .05$). This supported referral site independence and the decision not to control for individual patient sites beyond treatment delivery platform type.

Another concern was for provider type independence. Two provider types, medication prescribers and psychotherapists, participated in the study. These providers had been trained in one of three disciplines: psychiatry, psychiatric-mental health nursing, or clinical psychology. Provider disciplines were therefore evaluated for data clustering. A Kruskal Wallis test indicated

sufficient independence ($\chi^2(2) = .75, p > .05$). To check this finding further, provider disciplines were then evaluated using normally distributed GAD-7 change scores to conduct a one-way ANOVA. No statistically significant difference between provider disciplines was found ($F(2,61) = .57, p > .05$). This finding of independence was validated using a chi-square test of individual providers ($n = 8$) on GAD-7 outcome scores in 21 score categories. Sufficient independence was again supported ($\chi^2(84) = 79.19, p > .05$). Therefore, provider type with dichotomous levels (i.e., psychotherapy and pharmacotherapy) was deemed to be sufficient to control for types of providers in the regression model.

3.5.1.4 Outcome direction and significance.

To understand the direction and significance of GAD-7 outcomes in each platform condition, Wilcoxon signed rank sum tests were conducted. All GAD-7 outcome scores decreased significantly (improved) by -2.77 ($SD = 5.25$) points from first to last visit ($Z = -3.70, p < .001$). In the TMH ($Z = -2.83, p < .01$) and TAU ($Z = -2.42, p < .05$) conditions, GAD-7 scores significantly improved by -3.06 ($SD = 5.45$) and -2.47 ($SD = 5.11$) points, respectively. Also, in the medication ($Z = -2.70$) and psychotherapy treatment conditions ($Z = -2.63$), GAD-7 scores significantly improved by -2.43 ($SD = 5.05$) and -3.22 ($SD = 5.58$) points respectively ($p < .01$). These tests indicated that, consistent with extant literature, outcomes significantly improved in both treatment platform conditions and both therapy type groups. These findings were then validated using paired t -tests for the normally distributed GAD-7 change scores. As expected, GAD-7 change scores improved significantly ($t(63) = 6.50, p < .001$). TMH GAD-7 change scores improved ($t(31) = 4.21, p < .001$), as did TAU GAD-7 change scores ($t(31) = 4.95, p < .001$).

3.5.2 General multiple linear regression model.

$$y_i = (\beta_0 + \beta_1 x_{1i}) + (\beta_2 x_{2i} + \beta_3 x_{3i}) + (\beta_4 x_{4i} + \beta_5 x_{2i} x_{4i}) + e_i \quad (3.1)$$

Where:

y = GAD-7_{last}

i = subject: 1, 2, 3 . . . n

e_i = residual error

Block 1

β_0 = intercept

$\beta_1 x_{1i}$ = therapy type

Block 2

$\beta_2 x_{2i}$ = GAD-7_{initial}

$\beta_3 x_{3i}$ = platform

Block 3

$\beta_4 x_{4i}$ = marital status

$\beta_5 x_{4x_{2i}}$ = interaction GAD-7_{initial} * marital status

Squared semipartial correlation effect sizes were calculated using the formula:

$$f^2 = \frac{sr^2}{1 - R_{full}^2} \quad (3.2)$$

where the squared semipartial (part) correlation coefficient (sr^2) was the numerator, and the squared multiple correlation coefficient (R^2) for the *full* (total) model minus 1 was the denominator. Effect sizes of $f^2 \geq .02$, $f^2 \geq .15$, $f^2 \geq .35$ were interpreted as small, medium and large, respectively (Cohen, 1988).

3.5.3 Mixed effects model data.

Symptom changes over the course of treatment, in terms of multiple visits per subject, repeated GAD-7 measures, and unequal visit repetitions were then considered. To better understand correlated data, a linear random intercept and slope mixed model was chosen to accommodate random intercept and slope coefficients without affecting fixed effects variables of interest: treatment platform, therapy group, marital status. Beyond matched platform levels, predictor data were unbalanced. For example, counts for medication visit measures ($n = 220$) were greater than

psychotherapy visit measures ($n = 171$). Maximum likelihood estimation, as opposed to a method-of-moments approach, was therefore chosen because it produced estimates most consistent with observations (IBM Corporation, 2017). Visits were treated as time points in linear fashion to facilitate GAD-7 visit measurement comparisons.

In addition to the assumptions of independence (see section 3.4.1) and initial data evaluation (see section 3.5), the following linear mixed model assumptions were considered and deemed tenable: (a) the outcome had a linear relationship, (b) fixed effects expressed an outcome mean, (c) random effects represented the outcome's covariance structure, (d) random effects were independent, with separate covariance matrices, and (e) repeated measures reflected the residuals' covariance structure.

The initial frequencies assessment showed 42 visit-levels associated with 391 GAD-7 scores. Slopes and intercepts were identified as random-effects. A fixed effects model was then fitted in order to investigate the parameters: treatment platform, therapy group and marital status (fixed effects degrees of freedom [df] numerator = 45). Because the model was unbalanced, a type III sum of squares method was chosen to test fixed effects. Interpretation of sum of squares supported that treatment platform ($p < .001$), therapy group ($p < .01$) and marital status ($p < .05$) were potentially important for the prediction of GAD-7 scores. Estimates of fixed effects ($df = 346$) showed mean GAD-7 score at the first visit was substantially higher (worse) than the estimated GAD-7 mean for the third visit. The GAD-7 mean on the sixth visit, in turn, was lower (better) than it was for the third visit. This relationship supported an assumption that data behaved linearly.

GAD-7 score outliers were found after the seventh visit. (See Figure 3.3.) Evaluation of GAD-7 score frequencies by visit showed that the count of GAD-7 measurements per visit dropped from 64 at each of the first three visits, to 16 scores at the seventh visit.

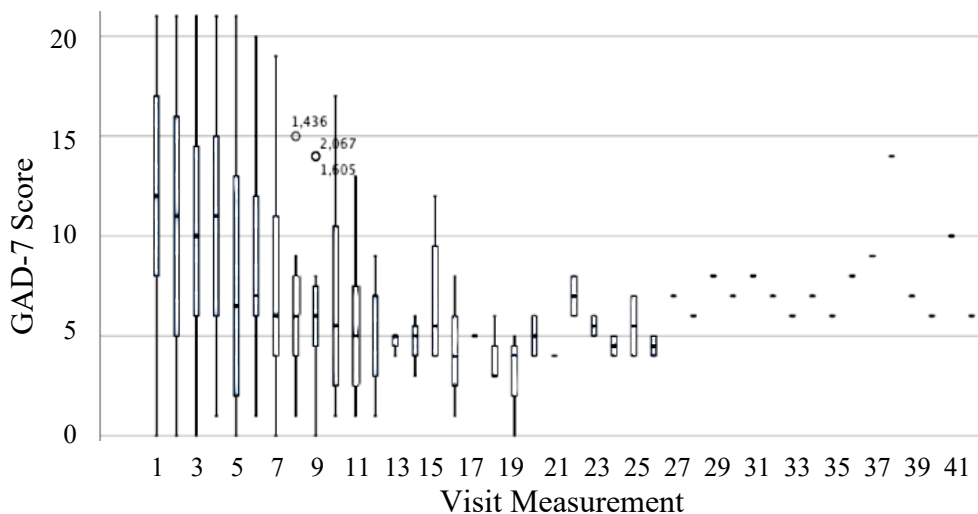


Figure 3.3. GAD-7 score by visit measurement.

Measurement frequencies were examined by treatment platform and therapy type groups. No TAU visit measure data existed at the sixth visit. (See Figure 3.4). Cases were therefore limited to five encounters ($n = 257$). This limitation included at least three scores from each of the 64 matched subjects.

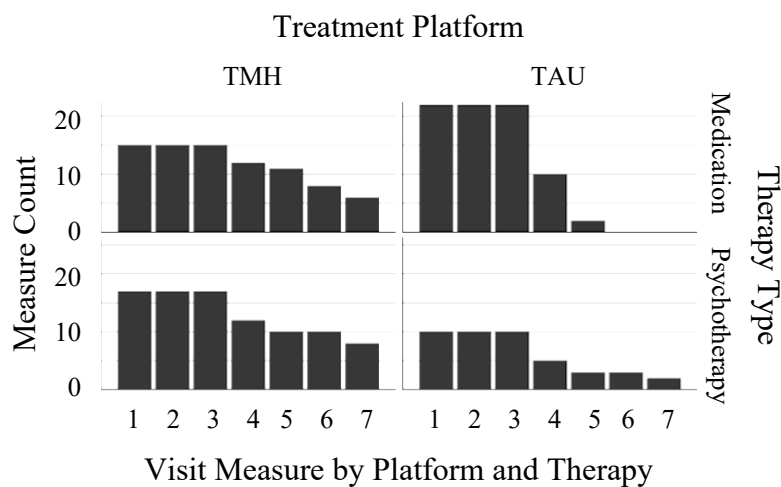


Figure 3.4. Visit-measure counts for delivery platform by therapy type.

The correlation parameter was relatively large ($\rho = .83$, Wald $Z = 27.07$, $p < .001$), indicating that an autoregressive covariance structure could better fit the data than the fixed factor model. Therefore, to evaluate for residual error covariance, a diagonal block matrix where each block was a first-order autoregressive covariance matrix was specified. The correlation parameter also provided further support for the use of the SPSS mixed-effects model procedure for this analysis (IBM Corporation, 2017) as opposed to general linear model or variance component approaches. These other procedures would have risked ignoring possible correlations that could lead to inaccurate conclusions (SPSS Incorporated, 2005).

3.5.3.1 Mixed effects model fit.

The null mixed effects model was $y_{ij} = \beta_0 + (u_j + e_{ij})$, where y was each GAD-7 score, β_0 was the overall mean across subjects and $(u_j + e_{ij})$ where $u_j + e_{ij}$ was the random subject + random visit measure on subject. The overall GAD-7 score across patients was estimated to be 10.92 ($SE = .70$). The mean outcome for patient j was estimated to be $10.92 + \hat{u}_{0j}$ where \hat{u}_{0j} was the subject residual. Residual confidence intervals determined whether overall mean differences were significant or attributable to chance. The estimated between-patient level-2 GAD-7 score covariance parameter was 27.78 ($SE = 5.42$), and the within-patient between-measure level-1 covariance parameter was estimated as 10.68 ($SE = 1.09$). The total variance (level-2 + level-1) was therefore 38.46 and the variance partition coefficient indicated that 72% of GAD-7 score variance was attributable to between-subject differences. However, first visits had not yet been accounted for so patient effects were not yet additive.

The null single-level mixed effects model ($y_{ij} = \beta_0$) was then fitted and random between-patient effects were evaluated. To test subject effects, a likelihood ratio (LR) test was used to compare the null mixed model with the single-level model. The difference on 1 df was 171.16.

Considering that $\chi^2(1)$ distribution is 3.84, this LR affirmed patient effects on the GAD-7 outcome and justified using a mixed effects model that included patient effects related to GAD-7 scores (see Figure 3.5).

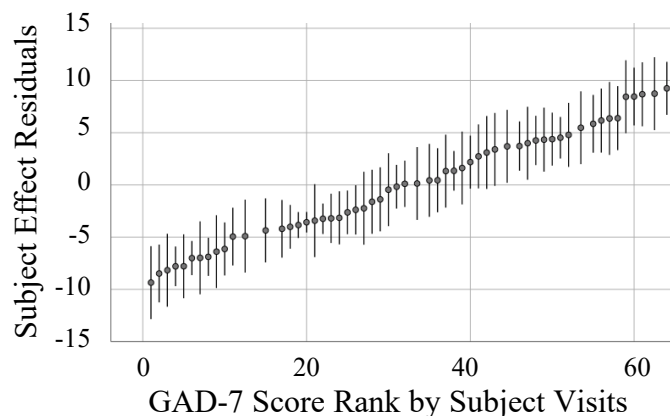


Figure 3.5. Caterpillar plot of patient effect residuals by GAD-7 score rank.

The subject ranked the lowest had an estimated residual of -9.68. The estimated mean for this subject was $10.92 + \hat{u}_0 = 1.24$. Likewise, the highest ranked subject's estimated residual was 8.80, so the estimated mean score for this patient was 19.72. Wider intervals indicated subjects with fewer observed measures during their treatment episodes. The confidence intervals for residuals of these estimates did not appear to be extremely different.

Next, the null single level mixed effects model was compared with the unconditional multilevel mixed effects mixed model that included visit measure ($y_{ij} = \beta_0 + \beta_1 x_{ij} + (u_j + e_{ij})$) where $\beta_1 x_{ij}$ was the fixed effect visit measure for each patient. Subject variance was estimated. The LR was $\chi^2(2) = 183.22$ and indicated strong evidence that visit measures differed across platforms. This model predicted a .63-point decrease (improvement) on the GAD-7 visit measure between platforms. The 95% coverage interval for GAD-7 slopes was estimated to be between -1.48 and 1.64. The estimated covariance between visit intercepts and slopes of -1.96 meant that subjects with above average GAD-7 scores (i.e. high intercept value) were associated with

average slopes that were flatter. The intercept-slope correlation was -.30 and suggested that GAD-7 scores would decrease at successive visits. (See Figure 3.6.)

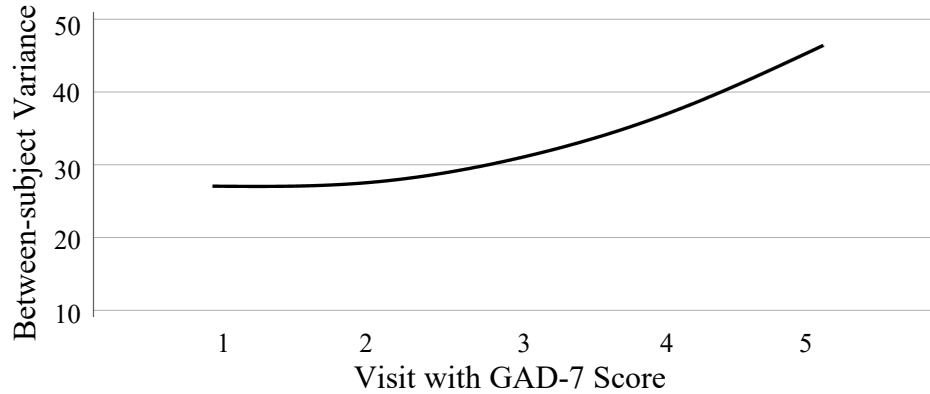


Figure 3.6. Between-subject visit measurement variance.

3.5.4 General linear random intercept and slope mixed effects model.

$$y_{ij} = \beta_0 + \beta_1 x_{ij} + \beta_2 x_{ij} + \beta_3 x_{ij} + \beta_4 x_{ij} + (u_j + u_j x_{ij} + e_{ij}) \quad (3.3)$$

Where:

- y = GAD-7_{score}
- i = visit measure: 1, 2, 3 . . . n
- j = subject
- ij = measure on subject

Fixed Part:

- β_0 = mean across subjects
- $\beta_1 x_{ij}$ = platform by visit for each subject
- $\beta_2 x_{ij}$ = therapy type by visit for each subject
- $\beta_3 x_{ij}$ = marital status by visit for each subject
- $\beta_4 x_{ij}$ = treatment platform by visit for each subject

Random Part:

- u_j = subject random effect
- $u_j x_{ij}$ = visit measure slope for each subject random effect
- e_{ij} = measure on subject random effect

Mixed effect model effect local sizes were calculated using a variation of Cohen's global effect size (1988). This variation isolates the local effects of fixed effects (f^2) relevant to this data analysis:

$$f^2 = \frac{(R_{AB}^2 - R_A^2)}{1 - R_{AB}^2} \quad (3.4)$$

where A represents all variables in the model except B , and B represents the variable to which the effect size applies. The variance accounted for by regressors in the mixed effects model (R^2) was not computed by SPSS, and was calculated using model variants that included only *full* model and *null* model fixed effects and that held constant random effects variance for the *null* and the A model variants:

$$R^2 = \frac{(null - full)}{null} \quad (3.5)$$

where *null* was the residual variance for the null model and *full* was the residual variance for the full models. Local effect sizes of $f^2 \geq .02$, $f^2 \geq .15$, $f^2 \geq .35$, are interpreted as small, medium and large, respectively (Cohen, 1988; Selya, Rose, Dierker, Hedeker, & Mermelstein, 2012).

After data element univariate analysis, model assumption review, method selection, fitting multiple linear regression and linear random intercept and slope mixed models, data preparation for the experiment was complete. Next, the conceptual framework is revisited before reporting observations and findings.

Chapter 4. RESEARCH RESULTS AND ANALYSIS

4.1 CONCEPTUAL FRAMEWORK

TMH intervention success may hinge on telehealth adoption and sustainment themes inherent in Knowledge to Action (KTA) theoretical framework assumptions. The KTA framework is an amalgamation of planned action theories (Graham & Tetroe, 2010; Moodie et al., 2011) that presupposes a systems outlook stemming from social constructivism and focuses on overcoming treatment barriers (Cabassa & Baumann, 2013; Mitchell et al., 2010; Moodie et al., 2011; Ward, Ringold, Metz, Archbold, Lentz, Wallace et al., 2011). KTA integrates evidence and practice by fostering development of adaptable interventions that privilege the needs of end users. Process accessibility, an important component of this framework, fosters stakeholder engagement from project conception through intervention adoption and sustainment (Graham & Tetroe, 2010; Mitchell et al., 2010).

There are two main, collaborative, co-occurring processes within the KTA framework (Moodie et al., 2011). The first is problem identification (Ward et al., 2011), which is necessary to tailor interventions to meet end user needs. The second is implementation via a bidirectional cycle of adaptation, assessment, selection, intervention, monitoring, and sustainment (Moodie et al., 2011). While evidence and intervention development both emerge from information gleaned from stakeholders (Graham & Tetroe, 2010), this framework's primary usefulness hinges on organizing systems of thought, interpreting observations (Mitchell et al., 2010) and focusing on actions important to meaningful change. In other words, in order to develop interventions that are meaningful to the care end user (i.e., patients and care providers), KTA conceptualizes collaborative data exploration.

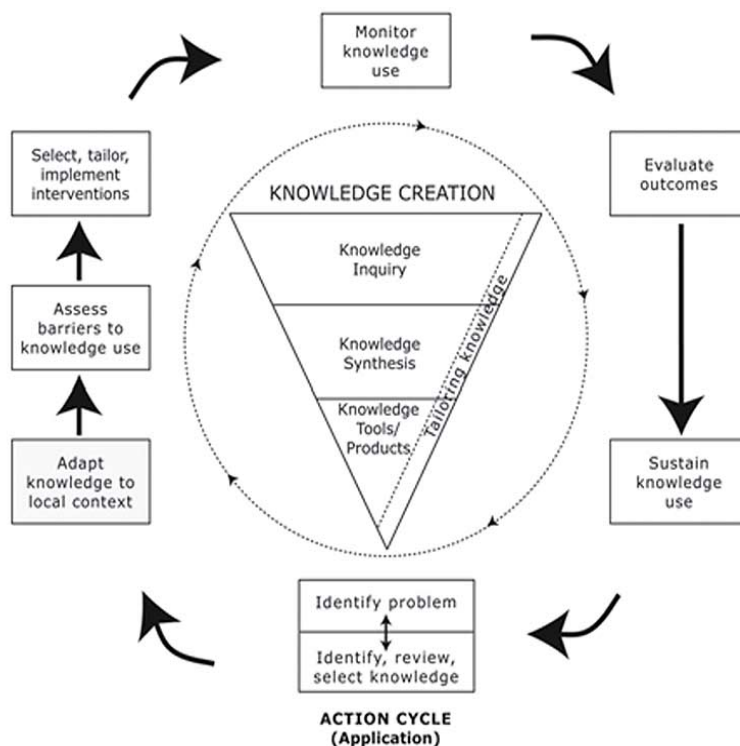


Figure 4.1. The Knowledge to Action theoretical framework.

From “The Knowledge to Action Framework,” by J. Rycroft-Malone & T. Bucknall (Eds.), *Models and Frameworks for Implementing Evidence-based Practice: Linking Evidence to Action* (p. 208), 2010, West Sussex, England: Wiley-Blackwell. Copyright 2010 by John Wiley and Sons. Reprinted with permission.

For this dissertation research, KTA provided a framework in which to conceive of the knowledge gained not as the end product but rather as a means to provide user-focused evidence on which to base, and tailor, future treatment approaches (Graham & Tetroe, 2010) in the emerging multidisciplinary practice environment of VC TMH. KTA assumptions most applicable to this research, therefore, were twofold. First, understanding patient characteristics (e.g., marital status) is critical to effectively tailor future TMH interventions (Batterham et al., 2015; Meurk et al., 2016). Second, TMH participants exist in dynamic, iterative, complex systems, so a better understanding of TMH treatment context (e.g., treatment course) is essential to anxiety disorder treatment improvement sustainability (Graham, Logan, Harrison, Straus, Tetroe, Caswell et al., 2006; Totten et al., 2016).

4.2 DATA PRESENTATION AND REPORTING

Results were interpreted in two phases for each model. First, assumptions for data included in the model were reviewed. Then, results were examined to gain a better understanding of how individual characteristics related to GAD-7 outcomes and how scores changed over the course of treatment.

4.2.1 Multiple linear regression model results

Multiple linear regression (MLR) with sequential predictor entry ($n = 64$) was used to predict GAD-7 outcomes for four predictor variables and one interaction term. Block 1 included therapy type which was treated as a fixed effect to provide control for provider type. Block 2 added the effects of initial GAD-7 scores and treatment platform condition. The third block included all model predictors including marital status and the interaction term of marital status with the initial GAD-7 score.

Table 4.2
Descriptive Statistics and Zero-order Correlations

Measure	<i>M</i>	<i>(SD)</i>	1.	2.	3.	4.	5.	6.
<i>Outcomes</i>								
1. GAD-7 Last	9.28	6.88	--					
<i>Block 1 Predictor</i>								
2. Therapy Type	.16	1.00	.36 **	--				
<i>Block 2 Predictors</i>								
3. GAD-7 Initial	.00	1.00	.67 **	.35 **	--			
4. Treatment Platform	.00	1.01	-.28 *	-.22	-.28 *			
<i>Block 3 Predictors</i>								
5. Marital Status	.34	.95	.35 **	.28 *	.14	-.03	--	
6. GAD-7 Initial * Marital Status	.13	.99	.29 *	.06	.15	-.41 **	-.05	--

Note. $N = 64$. GAD-7 = Generalized Anxiety Disorder 7-item scale. Dichotomous predictors (2-5) were effect coded. Treatment Platform: 1 = telemental health. Therapy Type 1 = pharmacotherapy. Marital Status: 1 = married. GAD-7 Initial scores were coded as standardized z -scores.

* $p < .05$, ** $p < .01$, *** $p < .001$

Assumptions were reviewed using the final model. Regression GAD-7 residuals were normally distributed with a slight left skew for GAD-7 outcome standardized residuals (see Figure 4.2).

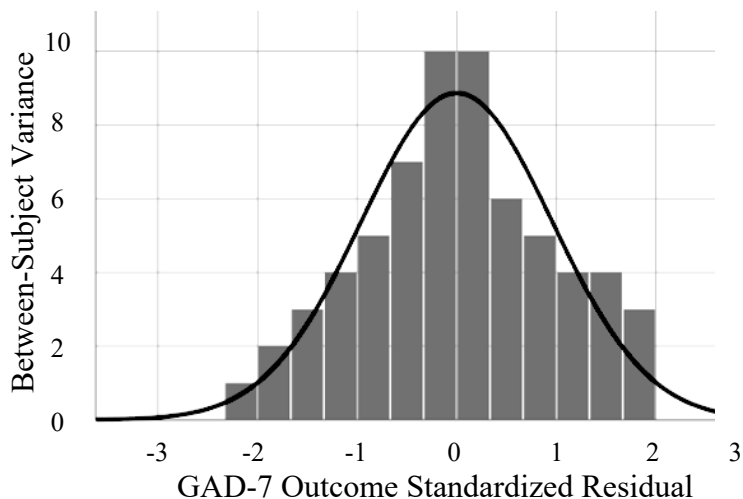


Figure 4.2. Histogram of multiple linear regression standardized residuals.

Inspection of the probability-probability plot of standardized regression residuals revealed no S-shaped or U-shaped patterns. (See Figure 4.3.) The assumption of linearity remained tenable.

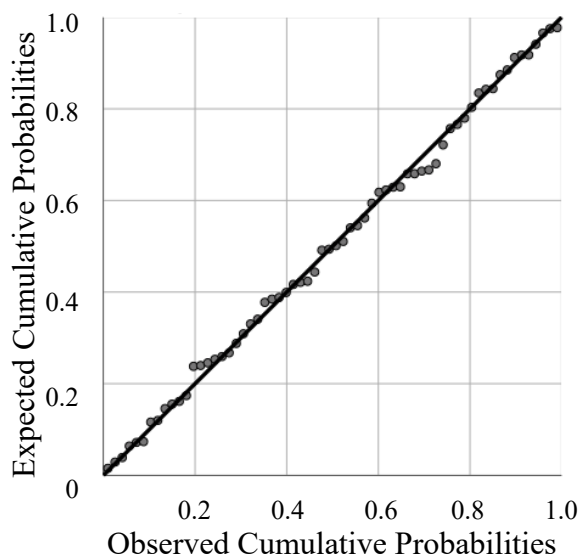


Figure 4.3. Probability plot of multiple linear regression residuals.

A scatterplot of GAD-7 regression residuals showed relatively even dispersion between low and high predicted values. Data fan spread was not observed (see Figure 4.4).

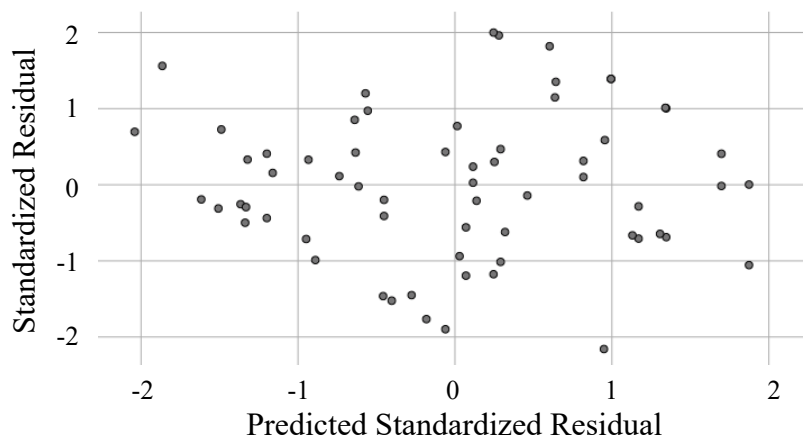


Figure 4.4. Scatterplot of multiple linear regression residuals.

Finally, residual independence was evaluated. As previously discussed, treatment was individually implemented and therapy type, a potential source of clustering, was included in the model. The assumption of independence therefore remained tenable.

Results showed that the main effects of therapy type which comprised the first block, accounted for significant variation $R^2 = .13$ ($R^2_{\text{adjusted}} = .11$), $F(1,62) = 8.93$, $p < .01$. Controlling for therapy type, the main effects group including initial GAD-7 scores and treatment platform together (Block 2), also accounted for significant variance in GAD-7 outcome scores: $R^2_{\text{change}} = .35$, $F_{\text{change}}(2,60) = 20.07$, $p < .001$ ($R^2_{\text{total}} = .48$, $R^2_{\text{adjusted}} = .45$). In the third block, marital status and marital status-by-initial GAD-7 score interaction accounted for an additional 9% of the variance in GAD-7 outcomes, $R^2_{\text{change}} = .09$, $F_{\text{change}}(2, 58) = 6.03$, $p < .01$ ($R^2_{\text{total}} = .57$, $R^2_{\text{adjusted}} = .53$). (See Table 4.3.)

Results from the final block, with all the predictors entered in the model, showed that the average subject's GAD-7 outcome score was 8.37 ($SE = .64$), holding all other variables constant ($t(58) = 13.08$, $p < .001$). Although Block 1 was significant, in the third block therapy type did

not significantly predict GAD-7 outcomes. Similarly, Block 2 was significant and treatment platform did not significantly predict GAD-7 outcomes. Holding all else constant, initial GAD-7 scores uniquely predicted GAD-7 outcome scores, $b = 3.97$, $SE = .65$, $t(58) = 6.08$, $p < .001$, $sr^2 = .28$. Specifically, for every standard deviation increase in initial GAD-7 scores, GAD-7 outcomes were predicted to be 3.97 points greater than average.

Table 4.3
Multiple Linear Regression with Sequential Predictor Entry

	Block 1				Block 2				Block 3					
	R^2_{total}	R^2_{adj}	b	sr^2	R^2_{change}	R^2_{total}	R^2_{adj}	b	sr^2	R^2_{change}	R^2_{total}	R^2_{adj}	b	sr^2
Model Fit	.13 **	.11			.35 ***	.48	.45			.09 **	.57	.53		
<i>Coefficients</i>														
Intercept			8.90 ***					9.15 ***					8.37 ***	
Therapy Type			2.45 **	.13				.87	.01				.97	<.01
GAD-7 Initial								4.16 ***	.31				3.97 ***	.28
Treatment Platform								-.59	.01				-.10	<.01
Marital Status													1.89 **	.06
GAD * Marital													1.41 *	.03

Note. $N = 64$. Block 1 F -change test $df = 1,62$. Block 2 $df = 2,60$. Block 3 $df = 2,58$. GAD-7 Initial: The first Generalized Anxiety Disorder 7-item scale in each treatment episode, coded as standardized z -scores. Dichotomous predictors were effect coded. Therapy Type: 1 = pharmacotherapy. Treatment Platform: 1 = telemental health. Marital Status: 1 = married. GAD * Marital: interaction between GAD-7 Initial and Marital Status.

* $p < .05$, ** $p < .01$, *** $p < .001$.

Marital status also uniquely predicted GAD-7 outcome improvement with subjects who were not married outperforming married subjects by an average of 3.78 points (marital status was effect coded), $b = 1.89$, $SE = .66$, $t(58) = 2.87$, $p < .01$, $sr^2 = .06$. (See Figure 4.5.)

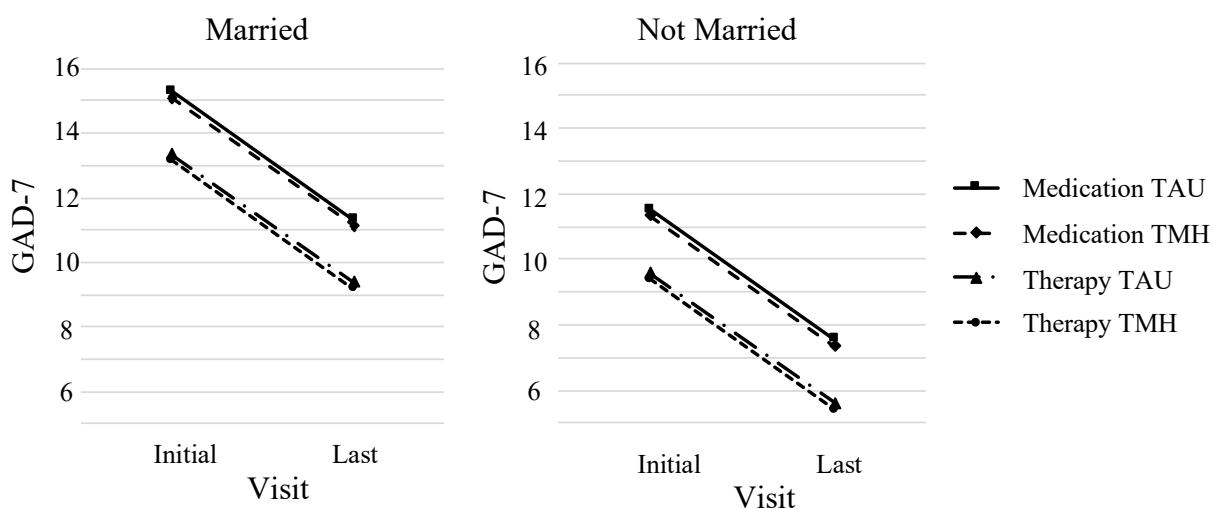


Figure 4.5. Multiple linear regression GAD-7 predicted outcomes by marital status.

Finally, there was also a significant interaction between marital status and initial GAD-7 scores on GAD-7 outcome scores, $b = 1.41$, $SE = .66$, $t(58) = 2.14$, $p < .05$, $sr^2 = .03$. To understand the nature of this interaction, predicted values were plotted for marital status by initial GAD-7 levels (low = -1 SD , high = +1 SD). As illustrated in Figure 4.5, GAD-7 outcomes were elevated (worse) when subjects had relatively higher (worse) initial GAD-7 scores, holding all else constant. Specifically, subjects who were not married, at +1 SD above average on initial GAD-7 score, had a predicted advantage over married subjects with relatively higher initial GAD-7 scores by 6.60 points on the GAD-7 outcome. In contrast, for subjects with relatively lower initial GAD-7 scores, there was < 1-point advantage for subjects who were not married, holding all else constant (see Figure 4.6).

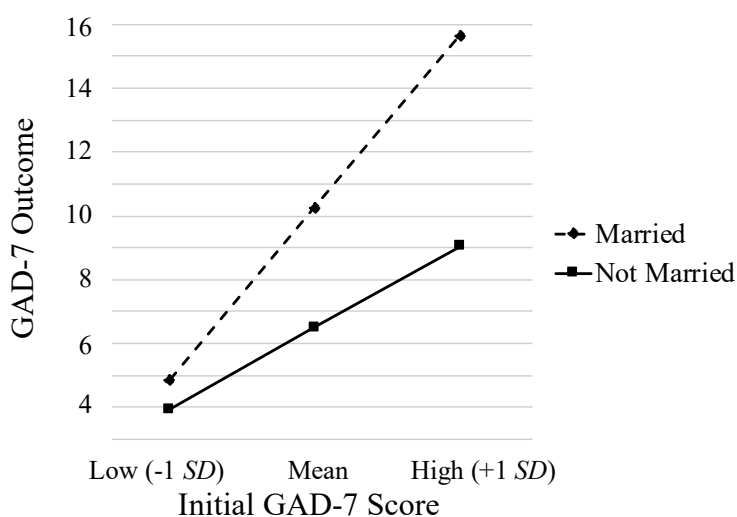


Figure 4.6. Predicted interaction between initial GAD-7 score by marital status.

4.2.2 Linear random intercept and slope mixed effects model results.

Model Assumptions were reviewed for the random intercept and slope mixed effects model, with data limited to five visits ($v = 257$). This roughly approximated the sample's average episode length of approximately 4 months with an average visit interval of 1 month (see Table

4.10). All 64 subjects were included (see Table 4.4). A review of functional form affirmed that predictors were linearly related to the outcome and to other predictors. Ordinary least squares (OLS) estimates plotted on predictors indicated that the relationship between GAD-7 and visit appeared to be linear. The assumption of linearity therefore remained tenable (see Figure 4.7).

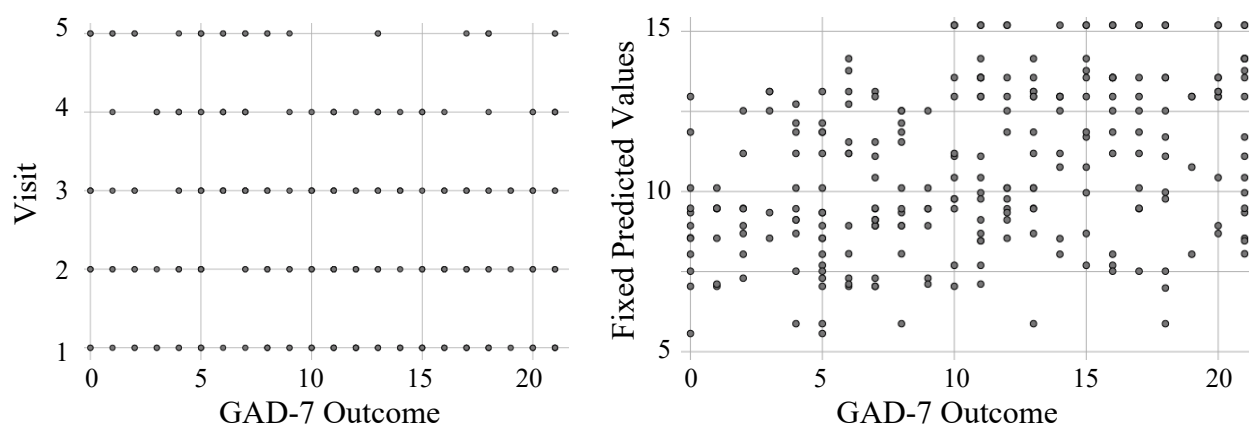


Figure 4.7. OLS estimates and fixed, predicted values on outcomes.

Homogeneity was evaluated using a scatter plot of fixed, predicted values on outcome scores. The variance appeared to be smaller for lower-outcome values and homogeneity was tenable (see Figure 4.7). Finally, a histogram of residuals indicated an approximately normal distribution (see Figure 4.8). The assumption of normality remained tenable.

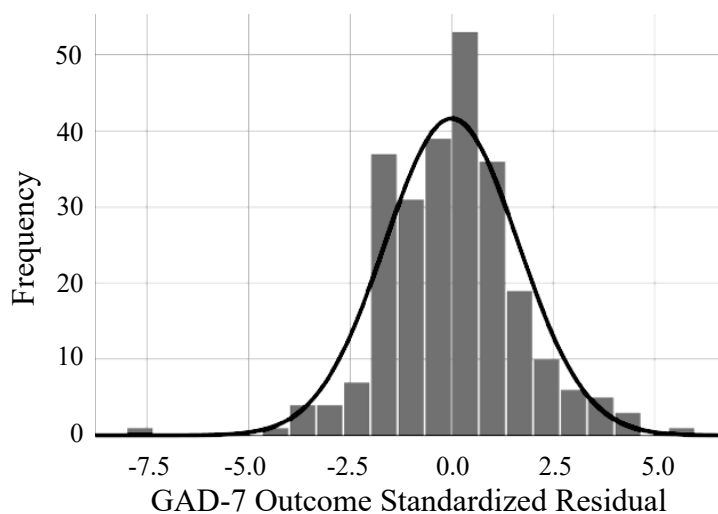


Figure 4.8. Histogram of linear mixed effects model standardized residuals.

The random intercept and slope mixed effects model including visits ($y_{ij} = \beta_0 + \beta_1 x_{ij} + (u_j + e_{ij})$), where $\beta_1 x_{ij}$ = subject fixed effect, was then plotted (see Figure 4.8). On this plot, \hat{u}_{0j} is the estimated GAD-7 intercept for subject j , and \hat{u}_{1j} is the estimated visit measure-change slope. Higher intercepts indicated worse GAD-7 scores and higher negative slopes denoted a greater rate of symptom improvement. For example, subjects with lower GAD-7 scores, but flatter than average between-visit GAD-7 improvements were found in the left upper quadrant of the plot. (See Figure 4.9.)

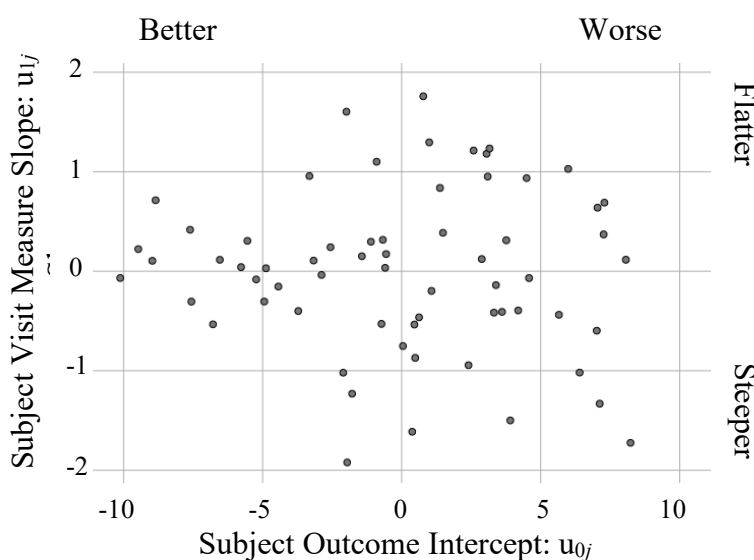


Figure 4.9. Linear mixed effects model subject intercepts on slopes.

The null model showed that the GAD-7 intercept changed significantly ($F(1,63.72) = 249.84, p < .001$). The unconditional model showed level 1 fixed effects with significant average GAD-7 changes at successive visits ($F(4,293.08) = 7.57, p < .001$). (See Table 4.4.) The level-2 predictors considered for construction of the basic mixed effects model were treatment platform, therapy type and marital status. These predictor variables were binary and dummy coded (TMH = 1, medication = 1, married = 1) in the mixed effects models (see Table 4.5). Category proportions of GAD-7 visit measures were reviewed. Visits with measures by psychotherapy

($v = 111, 43.2\%$) and by medication ($v = 146, 56.8\%$) group sizes were different from each other ($\chi^2(1) = 9.53, p < .01$) but reflected overall sample therapy type proportions of 42.2% for psychotherapy and 57.8% for medication groups.

Table 4.4
Null and Unconditional Linear Mixed Effects Models

Parameters	Null Model					Unconditional Model by Visit					R^2
	Est.	(SE)	(df)	t	95% CI	Est.	(SE)	(df)	t	95% CI	
Intercept	10.93	(0.68)	(63.72)	16.02 ***	9.57 - 12.29	8.34	(0.88)	(286.85)	9.48 ***	6.61 - 10.07	0.12
Level 1											
Visit 1						3.70	(0.84)	(289.14)	4.39 ***	2.04 - 5.36	
Visit 2						2.80	(0.82)	(289.51)	3.39 ***	1.18 - 4.22	
Visit 3						1.86	(0.79)	(290.28)	2.37 *	0.31 - 3.41	
Visit 4						2.85	(0.70)	(294.18)	4.10 ***	4.22 - 4.22	

Tests of Main Effects:

Null Model: $F(1,63.72) = 249.84^{***}$

Unconditional Model: visit, $F(4,293.08) = 7.57^{***}, f^2 = .14$

Note. $N = 64$ subjects, $V = 257$ visit measures over 5 encounters. Covariance matrix specified: first-order autoregressive (null default: identity). $R^2 = (\text{residual variance null model} - \text{residual variance model}) / \text{residual variance null model}$, used to calculate local effect size. Est.: estimate. Visit: visit with Generalized Anxiety Disorder 7-item scale score. Visit 5 was the reference category.

$f^2 \geq .02, f^2 \geq .15$ indicate small, medium local effect sizes.

* $p < .05$, ** $p < .01$, *** $p \leq .001$

Similarly, marital status levels' visits with measures for married ($v = 169, 65.8\%$) and not married subjects ($v = 88, 34.2\%$) group sizes were different from each other ($\chi^2(1) = 51.06, p < .001$), but reflected subject marital status proportions in the full sample: 67.2% married and 32.8% not married, respectively. For treatment platform visits with measures, TMH ($v = 141, 56.8\%$) and TAU ($v = 116, 43.2\%$) group sizes were different from each other as well ($\chi^2(1) = 4.86, p < .05$) as well; however, the proportional difference from 50% proportions in the full sample was not significant.

The basic model with random intercept and slopes included treatment platform and specified a first-order autoregressive covariance matrix structure. (See Table 4.5.) The estimated main effects (i.e., marginal mean differences) of GAD-7 scores at successive visits again showed significant change ($F(4,194) = 6.60, p < .001$). When therapy type was included in the model, visit measure changes remained significant ($F(4,164.20) = 6.21, p < .001$), as did the average

GAD-7 difference between therapy type ($F(1,53.01) = 6.45, p < .05$). In the final full model with all predictors included, the tests of fixed main effects indicated that visit measure changes ($F(4,176.42) = 5.82, p < .001, f^2 = .33$) and marital status ($F(1,52.07) = 5.23, p < .05, f^2 = .29$) were significant with medium to large local effect sizes. While the estimated effect of one variable within a level of another (i.e., fixed simple effects) for marital status was not significant, the first visit average GAD-7 scores ($t(224.35) = 2.11, p < .05$) and fourth visit ($t(152.47) = 2.03, p < .05$) average GAD-7 scores were significantly higher (worse) than those of other visits. Between visit change estimates for visits 2 and 3 were no longer significant whereas visits 1 and 4 were associated with significant GAD-7 score change. (See Figure 4.10.) On the whole, GAD-7 scores trended lower, toward improvement.

Table 4.5
Basic and Full Linear Random Intercept and Slope Mixed Effects Models

Parameters	Basic Model by Visit and Platform						Full Model by Visit, Platform and Marital Status					
	Est.	(SE)	(df)	t	95% CI	R ²	Est.	(SE)	(df)	t	95% CI	R ²
Intercept	7.43	(1.21)	(102.47)	6.15 ***	5.03 - 9.64		7.74	(1.72)	(92.63)	4.50 ***	4.33 - 11.15	
Level 1						0.12						0.25
Visit 1	2.98	(0.97)	(239.72)	3.07 ***	1.06 - 5.18		2.96	(1.41)	(224.35)	2.11 *	0.19 - 5.73	
Visit 2	2.32	(0.95)	(224.51)	2.45 **	0.45 - 4.25		1.76	(1.40)	(222.68)	1.26	-0.99 - 4.51	
Visit 3	1.73	(0.90)	(208.24)	1.91	-0.05 - 3.50		1.56	(1.37)	(205.66)	1.14	-1.14 - 4.26	
Visit 4	2.79	(0.80)	(155.68)	3.49 **	1.36 - 4.37		2.68	(1.32)	(152.47)	2.03 *	0.07 - 5.29	
Level 2												
Platform	1.62	(2.22)	(172.57)	0.73	-2.77 - 6.01		6.82	(3.75)	(252.26)	1.82	-0.56 - 14.21	
Therapy							-2.76	(2.58)	(114.22)	-1.07	-7.87 - 2.36	
Marital Status							2.46	(3.20)	(101.86)	0.77	-3.89 - 8.81	0.71

Tests of Main Effects:

Basic Model: visit, $F(4,194.60) = 6.60^{***}, f^2 = .14$

Full Model: visit, $F(4,176.42) = 5.82^{***}, f^2 = .33$; marital status, $F(1,52.07) = 5.23^*, f^2 = .29$

Note. $N = 64$ subjects. $V = 257$ visit measures over 5 encounters. Covariance matrix specified: first-order autoregressive. $R^2 = (\text{residual variance null model} - \text{residual variance model}) / \text{residual variance null model}$, used to calculate local effect sizes.

Est.: estimate. Visit: visit with Generalized Anxiety Disorder 7-item scale score. Visit 5 was the reference category. Level 2 variables were dummy coded. Therapy (therapy type) 1 = pharmacotherapy ($v = 146$). Platform (treatment platform) 1 = telemental health ($v = 141$). Marital status 1 = married ($v = 169$).

$f^2 \geq .02, f^2 \geq .15, f^2 \geq .35$ indicate small, medium, and large local effect sizes.

* $p < .05$, ** $p < .01$, *** $p < .001$

To better understand these relationships, we graphed the estimated marginal means of the basic linear mixed model and evaluated pairwise comparisons with Bonferroni adjustments. As illustrated in Figure 4.9, patients with the most severe symptoms were treated with psychotropic

medications. Rates of symptom improvement appeared to be similar; however, no significant group mean differences between visits 1 and 5 were found. The apparent increases in scores at visit 4 were not significant. Although the mean 3.65-point decrease within the TMH medication group from visit 4 to visit 5 was significant ($SE = 1.17, p < .05$), the decreases from visit 3 to 5 for both TMH and TAU medication groups were not significant.

We then examined mean GAD-7 visit scores between groups and compared therapy type groups by platform (e.g., medication TAU group vs medication TMH group) and treatment platform groups by therapy type (e.g., TAU medication vs TAU psychotherapy). A graph of these data (see Figure 4.10) showed that GAD-7 measure change progressions for psychotherapy between platforms are strikingly similar. Univariate tests of linearly independent pairwise comparisons indicated a significant GAD-7 score difference in visit level combinations within the TMH medication group, $F(4,160.97) = 2.93, p < .05$. Therapy type GAD-7 score differences between TAU groups at visit 1 ($M = -5.07, SE = 2.32$), visit 3 ($M = -5.15, SE = 2.23$), and visit 4 ($M = -6.22, SE = 2.63$) were significant ($ps < .05$).

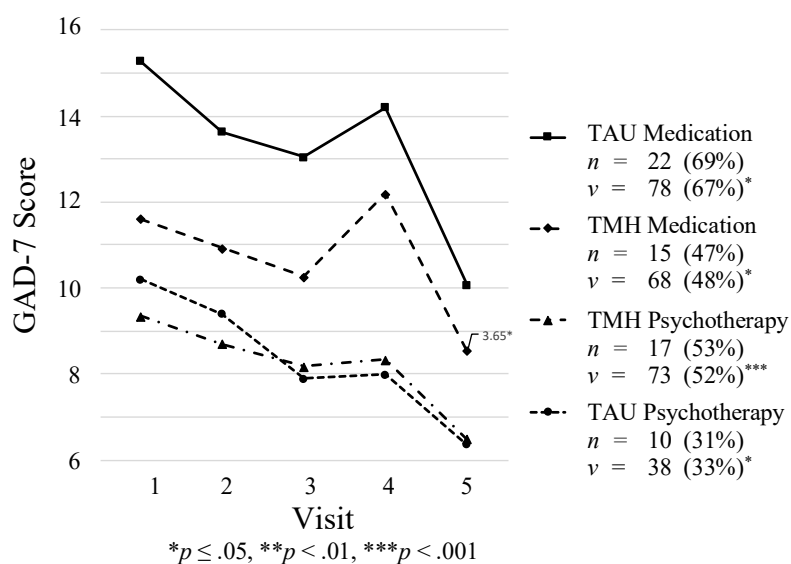


Figure 4.10. Mixed effects visit measure on therapy type and treatment platform.

To test for cross-level interactions and help further explain GAD-7 score change trends, interactions between visit-measure (level-1) and the level-2 predictors were explored. The differences between therapy type on visit measure estimates and treatment platform on visit measure estimates were not statistically significant. There was, however, an interaction between marital status and visit measures ($t(164.83) = -2.04, p < .05$). To further explore this interaction, we graphed the estimated marginal means of marital status and treatment platform and interpreted pairwise comparisons with Bonferroni adjustments.

When the mean GAD-7 score differences within each group were examined, the TAU married group had the highest initial GAD-7 score. Although this group's outcomes appeared to worsen after visit 3, anxiety score change was not significant for this group. The increase in the anxiety mean scores for the TMH not married and TAU married groups from visit 3 to visit 4 were not significant. Additionally, the apparent continued increase in the TAU married group's mean anxiety scores from both visit 4 to visit 5, as well as visit 3 to visit 5, was also not significant. Similar to the therapy type comparisons, the mean 4.03-point decrease between the TMH not married group's visits 4 and 5 was significant ($SE = 1.39, df = 147.64, p < .05$), the GAD-7 score differences between visits 1 and 5, as well as visits 3 and 5 for this group were not significant. The largest significant improvement in mean GAD-7 was scores found in the TAU not married group from visit 1 to visit 2 ($M = 4.67, SE = 1.31, df = 148.30, p < .01$).

Mean treatment platform group GAD-7 visit scores were then compared by marital status (e.g., TAU married group vs TAU not married group) and marital status group mean scores were compared by platform (e.g., married TAU group vs married TMH group). When mean GAD-7 scores on treatment platforms at each visit were compared by marital status groups, no significant differences between GAD-7 scores at visit 1 for either TAU or TMH marital status

groups were found. As illustrated in Figure 4.10, the only significantly different TMH not married group mean score was at visit 4 ($M = 4.73$ points, $SE = 2.11$, $p = .05$). The TAU not married group GAD-7 score mean differences, on the other hand, decreased from -9.09 points at visit 2 ($SE = 2.41$, $p < .001$) to -16.36 points at visit 5 ($SE = 3.63$, $p < .001$).

Not married group GAD-7 scores at visit 1 were not significantly different between platforms. The not married TAU group otherwise significantly outperformed the not married TMH group. Mean score differences ranged from -5.83 ($SE = 2.43$) at visit 2 to -8.73 ($SE = 2.95$) at visit 5 ($ps \leq .05$). Married TMH group GAD-7 score mean differences ranged from -6.11 ($SE = 2.01$) at visit 1, to -10.72 ($SE = 2.95$) at visit 5. The married TMH group outperformed the married TAU group mean anxiety scores at visits 1 to 3 ($ps < .01$) and visits 4 to 5 ($ps < .05$).

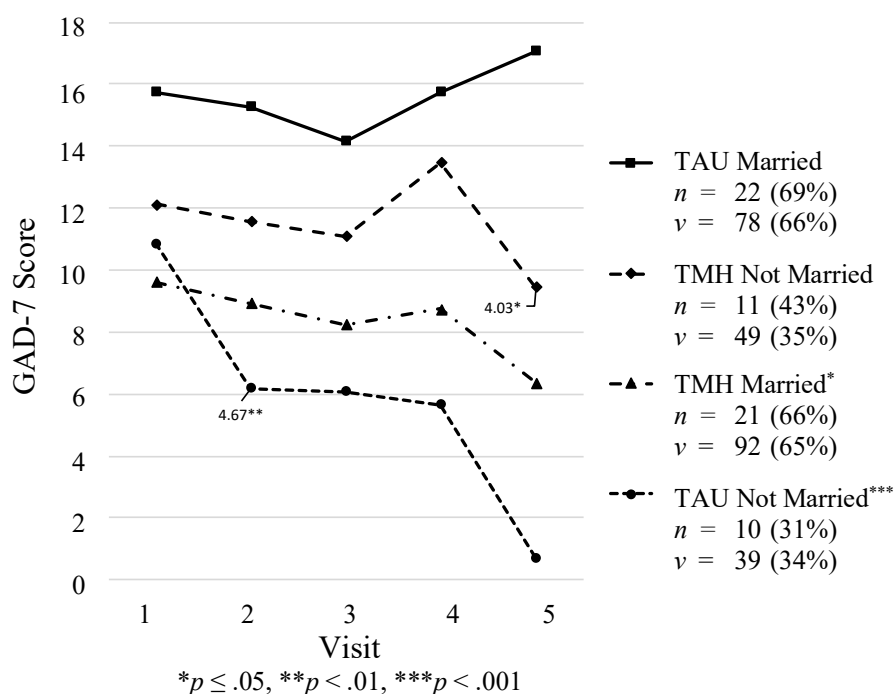


Figure 4.11. Mixed effects visit measure on marital status and treatment platform.

No significant TMH therapy type group differences were found. Between group comparisons of platform and therapy type groups showed TAU psychotherapy group GAD-7

scores were significantly lower (better) than the TAU medication group at visit 1, visit 3, and visit 4 ($ps < .05$). This reflected the MLR finding that initial GAD-7 scores predicted outcomes and an overall impression that lower initial anxiety scores preceded lower subsequent scores for visits 1 to 5. The TAU not married group outperformed the TMH not married group from visit 2 to visit 5 ($ps \leq .05$). Conversely, the married TMH group outperformed the married TAU group at all visits (1 to 3 [$ps < .01$], 4 to 5 [$ps < .05$]). Overall, GAD-7 visit score changes from visit 1 to 5 were significant for two groups: the TAU not married ($M = -10.14$, $SE = 2.17$, $df = 222.07$, $p < .001$) and TMH married groups, $M = -3.26$, $SE = 1.08$, $df = 224.79$, $p < .05$ (see Figure 4.11).

4.3 OBSERVATION CATEGORIES

Data elements comprising observation categories were based on National Institutes of Health (2017) common data elements. In Chapter 3, we evaluated category correlations in the process of selecting model predictors. To better understand the context of regression results, we then evaluated observation categories with an emphasis on treatment platform, marital status and therapy type. To do this, data elements were organized into three main treatment categories: (a) patient, (b) clinician and (c) process-related.

4.3.1 Patient characteristics.

4.3.1.1 Marital status and visit dose.

Given the relationship of marital status to symptom outcomes, closer evaluation of marital status characteristics was warranted. Married individuals in the active duty military population (54%) included candidates separated from their spouses, and individuals who were not married included widowed and divorced persons (46%) (see Appendix F). Marital status proportions in the smaller ($n = 27$) psychotherapy group reflected the population; however, 78%

of the subjects in the larger medication group ($n = 37$) were married compared to both the population at large ($\chi^2(1) = 8.85, p < .01$) and the psychotherapy group ($\chi^2(1) = 4.98, p < .05$).

Over the first five encounters with GAD-7 scores, visit by therapy type (i.e., treatment visit dose) proportions were not significantly different from the sample inclusive of all 42 encounter points. (See Figure 3.3.) The larger medication group accounted for significantly more visits ($v = 146$) than the smaller psychotherapy group ($v = 111$), $\chi^2(1) = 9.53, p < .01$, and the larger married group accounted for more visits ($v = 169$) than the smaller not married group ($v = 88$), $\chi^2(1) = 51.06, p < .001$. Between therapy types, married medication subjects engaged more visits than the married ($\chi^2(1) = 20.34, p < .001$) or the not married psychotherapy subjects ($\chi^2(1) = 21.60, p < .001$). In the psychotherapy group, the number of visits engaged was not significantly different between marital status; however, in the medication group, married subjects engaged in more visits than subjects who were not married ($\chi^2(1) = 20.34, p < .001$).

In addition to study treatment episodes, most subjects engaged a concurrent therapy episode with a different therapy type provider. For example, 97.30% of medication subjects engaged separate psychotherapy concurrent with proportionally more related visits than in the sample ($\chi^2(1) = 16.35, p < .001$). Conversely, the smaller, less frequently married psychotherapy group included proportionally fewer subjects with concurrent medication treatment episodes ($\chi^2(1) = 4.22, p < .05$) and fewer associated visits overall ($\chi^2(1) = 14.40, p < .001$). Between treatment platforms, TAU psychotherapy subjects engaged concurrent medication treatment less frequently than the TAU medication group engaged concurrent psychotherapy (Fisher's Exact test, $p < .01$) and less frequently than the sample overall ($\chi^2(1) = 8.97, p < .001$).

Treatment platform was a criterion used to match candidates. As expected, platform group subjects and visits were relatively balanced. One exception was that TAU medication not

married subgroup included relatively few subjects ($n = 3$) compared to married TAU medication ($n = 19$) and to married TMH psychotherapy ($n = 11$) subgroup groups, Fisher's Exact test, $p < .001$. Similarly, the married TAU psychotherapy subgroup ($n = 3$) was significantly smaller than the not married TAU medication subgroup ($n = 19$), Fisher's Exact test, $p < .01$. Another difference was that married TAU psychotherapy subjects engaged fewer visits than both married subjects in the sample ($\chi^2(1) = 5.29, p < .05$) and TMH married psychotherapy subjects ($\chi^2(1) = 15.38, p < .001$).

4.3.1.2 Marital status and visit observations related to outcomes.

Understanding these dynamics may add context to two significant outcome changes in the first five visits. Married TMH group symptoms improved significantly ($p < .05$) and not married TAU group symptoms improved significantly ($p < .001$). (See Figure 4.10.) Marital status by therapy type and platform subgroups were therefore examined further.

One way to understand the treatment course was to consider treatment visit doses engaged voluntarily by platform-therapy type groups with specific marital status characteristics. Total visits (i.e., regardless of an associated visit measure) were not significantly correlated with outcomes and were therefore not included in the regression models. The visit doses considered here included only visits with GAD-7 measurements within the first five encounters. Post hoc, these encounters with measures, limited to the first five visits ($v = 257$), were significantly correlated with symptom improvement ($r = -.272, p < .001$). When considered in this way, the married TMH group ($n = 21$) showed significant improvement with a larger visit dose ($v = 92, 65.35\%$). By contrast, married TAU subjects ($n = 22, v = 77, 66.38\%$) did not show significant outcome change. On the other hand, TAU subjects who were not married ($n = 10$) reported

significant outcome improvement with proportionally fewer visits ($v = 39, 33.62\%$) than other groups.

The married TMH psychotherapy subgroup engaged larger visit doses than both the not married TMH psychotherapy ($\chi^2(1) = 7.92, p < .001$) and the married TAU psychotherapy subgroup ($\chi^2(1) = 10.69, p < .001$). Similarly, the married TMH medication subgroup engaged significantly greater visit doses than the not married TMH medication subgroup ($\chi^2(1) = 19.88, p < .001$). The married TMH medication subgroup visit dose, however, was proportionally smaller than the average visit dose engaged in the married TAU medication subgroup ($\chi^2(1) = 4.99, p < .001$). The married TAU group engaged the greatest visit doses but did not show significant outcome improvement. This dynamic may argue against considering outcome improvement to be a direct function of visit dose as opposed to further consideration of visit dose as an indicator of treatment desirability. Another example was that within the not married TAU group, a group that showed significant outcome improvement, the not married TAU psychotherapy subgroup engaged more visits than both the not married TMH ($\chi^2(1) = 10.69, p < .01$) and the married TAU psychotherapy ($\chi^2(1) = 13.47, p < .001$) subgroups. Conversely, the not married TAU medication subgroup engaged significantly fewer visits than the not married TMH ($\chi^2(1) = 4.99, p < .05$) and the married TAU medication subgroups ($\chi^2(1) = 4.99, p < .001$). (See Table 4.6.) This subgroup analysis suggests that married TMH subjects, with improved symptom outcomes, engaged visit doses indicative of a greater participation in medication treatment. In similar fashion, the not married TAU subjects, with significant symptom outcome improvement, engaged greater psychotherapy visit doses suggesting that this subgroup had a greater participation in psychotherapy.

Table 4.6
Marital Status and Subject Therapy Type by Platform and Visit

Marital Status Characteristics	Subjects		Visits		Subject by Platform [†]				Visit by Platform			
	<i>N</i> = 64		<i>V</i> = 257		TMH <i>n</i> = 32		TAU <i>n</i> = 32		TMH <i>v</i> = 141		TAU <i>v</i> = 116	
	No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.	(%)
<i>Marital Status</i>	64	(100.00)	257	(100.00)	32	(50.00)	32	(50.00)	141	(54.86)	116	(45.14)
Married	43	(67.19)	169	(65.76)	21	(65.63)	22	(68.75)	92	(65.25)	77	(66.38)
Not Married	21	(32.81)	88	(34.24)	11	(34.38)	10	(31.25)	49	(34.75)	39	(33.62)
<i>Concurrent Therapy</i>	53	(82.81)	213	(82.88)	26	(81.25)	27	(84.38)	116	(82.27)	97	(83.62)
<i>Therapy Type</i>												
Medication	37	(57.81)	146	(56.81) **	15	(46.88)	22	(68.75)	68	(48.23)	78	(67.24)
Married	29	(78.38)	113	(77.40) *	10	(66.67)	19	(86.36)	47	(69.12)	66	(84.62)
Not Married	8	(21.62)	33	(22.60) *	5	(33.33)	3	(13.64)	21	(30.88)	12	(15.38)
Concurrent Psychotherapy	36	(97.30)	141	(96.58) ***	14	(93.33)	22	(100.00)	63	(92.65)	78	(100.00)
<i>Psychotherapy</i>	27	(42.19)	111	(43.19) **	17	(53.13)	10	(31.25)	73	(51.77)	38	(32.76)
Married	14	(51.85)	56	(50.45) **	11	(64.71)	3	(30.00)	45	(61.64)	11	(28.95) *
Not Married	13	(48.15)	55	(49.55) **	6	(35.29)	7	(70.00)	28	(38.36)	27	(71.05) *
Concurrent Medication	17	(62.96) *	72	(64.86) ***	12	(70.59)	5	(50.00)	53	(72.60)	19	(50.00)

Note. *N* = 64 subjects. *V* = 257 visits with Generalized Anxiety Disorder 7-item (GAD-7) scale score scores. TMH: telemental health. TAU: treatment as usual. Visits: first five treatment encounters associated with a GAD-7 scale score. Goodness of Fit: determined using chi-square; when frequencies were < 5, significance was determined via Fisher's Exact test. Concurrent therapy visits: visits within study cases that had additional therapy during the studied episode. Additional visits were not counted. Medication: psychotropic pharmacotherapy. Subjects by therapy type values were compared to sample marital status values to determine significance. Subjects by platform and visits by platform values were compared to subject column values and visit column values respectively in order to determine significance.

[†] Three subjects engaged both therapy types via TMH and were included only in the first therapy type group identified.

* *p* < .05, ** *p* < .01, *** *p* < .001

4.3.1.3 Diagnostic characteristics.

Although study candidates were not matched on specific anxiety disorder diagnoses, proportionally, the anxiety disorder diagnoses that met inclusion criteria were not significantly different between treatment platforms or therapy type. (See Table 4.7.) There were also no significant proportional differences in diagnoses between platforms compared to the sample. The most frequently diagnosed anxiety disorder was unspecified anxiety disorder (82.81%). No SAD diagnoses were found and the *DSM-IV* (former) anxiety disorders (i.e., PTSD and OCD) represented less than 15% of sample comorbidity.

significant differences between individual comorbidities and comorbidities in the sample for each diagnosis; however, there were significantly fewer comorbid *DSM-5* anxiety disorder diagnoses in the TAU cohort (Fisher's Exact test, $p > .05$).

4.3.1.4 History characteristics.

Subject history may be useful in identifying the characteristics of subjects that may have benefitted from using one treatment platform or the other to engage treatment. However, in this sample, subject history may be most useful in providing the context necessary to compare this study to others. In the study sample, most subjects (75.56%) had engaged previous psychotropic medication therapy, but more subjects (90.63%) had previously engaged psychotherapy ($\chi^2(1) = 4.61, p < .05$). This proportion was not significantly different among platform groups. As expected, given that psychotherapy was generally engaged before pharmacotherapy in this system of care, fewer psychotherapy subjects (62.96%) than medication subjects (86.49%) had previously engaged psychotropic medication treatment, $\chi^2(1) = 4.81, p < .05$. Similarly, there were fewer subjects who were naive to psychotherapy (9.38%) than there were subjects who had no history of psychotropic medication at all (23.44%), $\chi^2(1) = 4.61, p < .05$. In addition, more psychotherapy subjects were naive to psychotherapy (22.22%) than there were for the overall sample ($\chi^2(1) = 7.15, p < .01$) or in the medication subject group (Fisher's Exact test, $p < .01$). Between therapy types, psychotherapy subjects were naive to medication therapy more frequently (37.04%) than were medication subjects (13.51%), $\chi^2(1) = 4.81, p < .05$ (see Table 4.8).

Most subjects (89.06%) re-engaged or continued psychotherapy started prior to the treatment episode. All medication subjects with a history of psychotherapy continued psychotherapy (Fisher's Exact test, $p < .05$). This was significantly greater than for

psychotherapy subjects (74.07%) with a history of psychotherapy who continued psychotherapy (Fisher's Exact test, $p < .001$). By contrast, significantly fewer subjects with a history of medication therapy (17.19%) continued a previous medication regimen, $\chi^2(1) = 66.38, p < .001$. More subjects with previous medication therapy engaged medication change (46.88%) than did subjects with previous psychotherapy engaged psychotherapy change (e.g., transitioned from group to individual therapy) (1.56%), Fisher's Exact test, $p < .01$. Between therapy type groups, medication subjects with previous medication therapy changed medications more frequently (59.46%) than psychotherapy patients (29.63%), $\chi^2(1) = 5.58, p < .05$.

Table 4.8
Relevant Subject History Characteristics

Subject History Characteristics	All Subjects		Subjects by Platform				Subjects by Marital Status				Subjects by Therapy Type			
	<i>N</i> = 64		TMH <i>n</i> = 32		TAU <i>n</i> = 32		Mar <i>n</i> = 43		NM <i>n</i> = 21		Med <i>n</i> = 37		Ther <i>n</i> = 27	
	No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.	(%)
<i>Previous Psychotropic</i>	49	(76.56)	23	(71.88)	26	(81.25)	32	(74.42)	17	(80.95)	32	(86.49)	17	(62.96)
Not Continued	8	(12.50)	5	(15.63)	3	(9.38)	4	(9.30)	4	(19.05)	2	(5.41)	6	(22.22)
Continued	11	(17.19)	5	(15.63)	6	(18.75)	7	(16.28)	4	(19.05)	8	(21.62)	3	(11.11)
Medication Changed	30	(46.88)	13	(40.63)	17	(53.13)	21	(48.84)	9	(42.86)	22	(59.46)	8	(29.63)
None Found	15	(23.44)	9	(28.13)	6	(18.75)	11	(25.58)	4	(19.05)	5	(13.51)	10	(37.04)
<i>Previous Psychotherapy</i>	58	(90.63)	28	(87.50)	30	(93.75)	40	(93.02)	18	(85.71)	37	(100.00)	27	(100.00)
Continued/Re-engaged	57	(89.06)	27	(84.38)	30	(93.75)	39	(90.70)	18	(85.71)	37	(100.00)*	20	(74.07)
Mode Changed	1	(1.56)	1	(3.13)	0	(0.00)	1	(2.33)	0	(0.00)	0	(0.00)	1	(3.70)
None Found	6	(9.38)	4	(12.50)	2	(6.25)	3	(6.98)	3	(14.29)	0	(0.00)	6	(22.22)*
<i>TIS: Career Phase</i>														
None/Unknown	4	(6.25)	2	(6.25)	2	(6.25)	4	(9.30)	0	(0.00)	2	(5.41)	2	(7.41)
Early (< 5 years)	18	(28.13)	10	(31.25)	8	(25.00)	12	(27.91)	6	(28.57)	12	(32.43)	6	(22.22)
Mid (5-15 years)	32	(50.00)	16	(50.00)	16	(50.00)	22	(51.16)	10	(47.62)	18	(48.65)	14	(51.85)
Late (> 15 years)	10	(15.63)	4	(12.50)	6	(18.75)	5	(11.63)	5	(23.81)	5	(13.51)	5	(18.52)
<i>Wartime Service</i>	57	(89.06)	29	(90.63)	28	(87.50)	36	(83.72)	21	(100.00)	33	(89.19)	24	(88.89)
OIF/OEF/OND	56	(87.50)	29	(90.63)	27	(84.38)	36	(83.72)	20	(95.24)	32	(86.49)	24	(88.89)
Vietnam	1	(1.56)	0	(0.00)	1	(3.13)	0	(0.00)	1	(2.33)	1	(2.70)	0	(0.00)
None/Unknown	7	(10.94)	3	(9.38)	4	(12.50)	7	(16.28)	0	(0.00)	4	(10.81)	3	(11.11)
<i>Employment</i>	58	(90.63)	29	(90.63)	29	(90.63)	39	(90.70)	19	(90.48)	33	(89.19)	25	(92.59)
Unknown	6	(9.38)	3	(9.38)	3	(9.38)	4	(9.30)	2	(9.52)	4	(10.81)	2	(7.41)

Note. *N* = 64 subjects. Goodness of Fit: determined using chi-square; when frequencies were < 5, significance was determined via Fisher's Exact test. Mar: married. NM: not married. OIF: Operation Iraqi Freedom. OEF: Operation Enduring Freedom. OND: Operation New Dawn.

Employment: full-time equivalent. TIS: time in service (years).

* $p < .05$

The most prevalent career phase was mid-career (5 to 15 years' time-in-service (TIS)) (50.00%), and the least prevalent was late-career (> 15 years TIS). Subjects were matched on career phase. As expected, TIS proportions among and between groups were not significantly

different and TIS was not significantly correlated with outcomes. Contrary to expectations, TIS was not deemed likely to uniquely predict outcomes. Consistent with service branch data and the treatment timeframe studied, most subjects (87.50%) had wartime military service during the Iraq and Afghanistan conflicts, and full-time employment was 90.63%.

4.3.2 Clinician characteristics

Clinicians assigned to a single hub clinic provided voluntary clinic-based care either via TMH to patients remote to the medical center ($M = 1,376.45$, $SD = 313.71$ miles) or TAU to patients engaging care in-person at the consultant clinician's DoD clinic site. All providers engaged care episodes with patients in both platform treatment conditions but did not treat subjects in a combination of platform conditions during a study episode. Clinicians met weekly to discuss both TMH and TAU cases. Of the eight independent providers in the clinic during the intake period (1/1/2015 – 1/1/2016) that engaged patient care in both conditions, seven engaged treatment with TMH subjects, and six engaged treatment with TAU subjects (see Table 4.8). Differences were not significant between the proportions of clinician types by platform; however, the proportion of female (50%) providers was greater than the 15.63% of females in the sample $\chi^2(1) = 7.17$, $p < .01$. There were proportionally fewer active duty Army providers (37.50%) than active duty Army subjects (90.63%), $\chi^2(1) = 26.59$, $p < .001$, and more providers who were military veterans (25.00%) than there were veteran subjects (3.25%) $\chi^2(1) = 14.27$, $p < .001$. This indicated that TMH clinicians with active duty military service experience (71.36%), which was not significantly different from subjects (93.88%) with military experience (Fisher's Exact test = .10, $p > .05$) may have played a role in significant outcome improvement for married TMH group. On the other hand, in the TAU group, subjects were treated by fewer

clinicians with military experience and significantly more civilian clinicians (50.00%) compared to civilian subjects in the sample (6.25%), $p < .05$. (See Table 4.9.)

Table 4.9
Clinician Characteristics by Platform

Clinician Characteristics	Clinicians		Clinician by Platform			
	$N = 8$		TMH $n = 7$	TAU $n = 6$		
	No.	(%)	No.	(%)		
<i>Therapy Type</i>	8	(100.00)	7	(87.50)	6	(75.00)
Medication	4	(50.00)	4	(57.14)	2	(33.33)
<i>Psychiatric ARNP</i>	2	(25.00)	2	(28.57)	1	(16.67)
<i>Psychiatrist</i>	2	(25.00)	2	(28.57)	1	(16.67)
Psychotherapy	4	(50.00)	3	(42.86)	4	(66.67)
<i>Psychologist</i>	4	(50.00)	3	(42.86)	4	(66.67)
<i>Sex</i>						
Male	4	(50.00) **	4	(57.14)	3	(50.00)
Female	4	(50.00) **	3	(42.86)	3	(50.00)
<i>Service Branch</i>						
Active Army	3	(37.50) **	3	(42.86)	2	(33.33)
Civilian	3	(37.50)	2	(28.57)	3	(50.00)
Veteran	2	(25.00) ***	2	(28.57)	1	(16.67)

Note. $N = 8$ clinicians. TMH: telemental health. TAU: treatment as usual. All clinicians engaged treatment episodes via each platform during the study period. Goodness of fit: determined using Fisher's Exact test. Significance of sex and service branch in the clinician column were calculated using subject sample values for comparison. Psychiatric ARNP (advanced registered nurse practitioner): master's level, psychiatric-mental health nurse practitioner. Psychiatrist: medical doctor or doctor of osteopathic medicine. Psychologist: doctor of philosophy or doctor of psychology.

* $p < .05$, ** $p < .01$, *** $p < .001$

4.3.3 Process characteristics

The process characteristics considered here focus on anxiety symptom measurements and treatment course. To facilitate a better contextual understanding of findings based on the first five encounters ($v = 257$) discussed previously, treatment course data were considered using all visits in the episode regardless of association with GAD-7 score ($v = 490$). Measurement data were considered using all eligible visits with GAD-7 scores ($v = 391$).

4.3.3.1 Measurement data.

The mean of all GAD-7 scores (i.e., overall case acuity) was not significantly different from platform, marital status, or TMH marital status acuity means (see Appendix G). As expected, the average initial GAD-7 score was significantly higher than overall acuity ($z = 2.12$, $p < .05$) and the average last GAD-7 score (i.e., episode outcome) was significantly lower than the average initial score, $z = -3.75$, $p < .001$. The average z-score improved -2.77 points. Average scores by treatment platform were not significantly different from the sample mean. Outcome improvement was also not significantly different for married subjects, but subjects who were not married had lower than average acuity ($z = -2.54$, $p < .05$), with better than average mid-treatment ($z = -2.84$, $p < .05$) and end-of-episode ($z = -2.56$, $p < .05$) improvement.

TMH by marital status group GAD-7 scores were not significantly different from sample averages. Consistent with regression analyses, the married TAU group showed significantly greater initial acuity than the sample ($z = 3.77$, $p < .001$) and higher than average scores over the course of the episode through the last visit ($z = 3.65$, $p < .001$). By contrast, TAU subjects who were not married had significantly lower than average acuity ($z = -2.54$, $p < .05$) and greater than average mid-treatment ($z = -2.84$, $p < .05$) and end-of-episode improvement ($z = -2.56$, $p < .05$).

Medication subjects had significantly greater than average acuity ($z = 2.12$, $p < .05$) and episode outcome scores that were significantly higher than initial scores in that group ($z = 2.90$, $p < .01$). Medication subjects who were not married had significantly greater than average symptom improvement ($z = -2.07$, $p < .05$). The married TAU medication subgroup had greater than average acuity ($z = 2.06$, $p < .05$) and mid-treatment scores ($z = 2.27$, $p < .05$). TAU medication subjects who were not married, on the other hand, had lower than average mid-treatment scores ($z = -2.38$, $p < .05$) and greater symptom improvement ($z = -2.37$, $p < .05$).

The acuity for the psychotherapy group was significantly lower than average ($z = -2.47$,

$p < .05$). Mid-treatment scores ($z = -2.01, p < .05$) and the end-of-episode outcome scores ($z = -2.47, p < .05$) were lower than the average initial GAD-7 scores for this group. Married TAU psychotherapy subjects had greater than average acuity ($z = -2.07, p < .01$), initial ($z = 2.11, p < .05$), mid-treatment ($z = 2.45, p < .05$), and end-of-episode ($z = 2.95, p < .05$) scores. In general, GAD-7 scores for this sample improved significantly, $t(63) = 4.21, p < .001$. Consistent with findings in the extant literature, outcome improvements were not significantly different in either treatment platform ($t(62) = .66, p > .05$) or either therapy type ($t(62) = .59, p > .05$). In addition, the treatment platform by therapy type outcome improvement was not significantly different between TAU groups ($t(30) = .37, p > .05$) or TMH groups ($t(30) = .71, p > .05$).

Marital status provided some additional context. While outcome changes by marital status were not significantly different from the mean, subjects who were not married improved significantly more than married subjects ($t(62) = 2.47, p < .05$). This difference was not balanced between treatment platforms by marital status groups. TAU subjects who were not married improved significantly more than married TAU subjects, $t(30) = 2.84, p < .01$. This was consistent with mixed effects regression findings that compared measurements by successive visit to the fifth visit. The difference between TMH marital status groups' outcome improvement without accounting for successive visits, on the other hand, was not significant. Therefore, without MLR and mixed effects model analyses, the significance of the married TMH group improvement may not have been identified (see Appendix G).

4.3.3.2 Treatment course.

The treatment process characteristics of treatment course included four main data elements: (a) Time-to-treatment: for the TMH cohort, this was the difference in days between referral date and the initial encounter in the episode. For the TAU cohort, time-to-treatment was

the estimated difference between the most recent encounter likely to have generated a mental health referral (e.g. medical visit or mental health provider) and the initial encounter. (b) Episode length: the difference in days between the initial visit and the last visit in the episode. (c) Encounter interval: days per visit per episode. (d) Visit dose: encounters per episode. These characteristics were evaluated by medication groups, platform groups, marital status groups, and platform by marital status groups.

Among sample subjects, the average time-to-treatment ($M = 16.02$, $SD = 18.33$) was not significantly different from respective treatment platform means or therapy type means. The average time-to-treatment was also not significantly different between treatment platform, therapy type, or marital status. In addition, no significant difference was found between TMH by marital status groups ($t(35) = 1.03$, $p > .05$) or between TAU by marital status groups ($t(15.54) = -1.78$, $p > .05$).

The average episode length was 166.45 days ($SD = 137.94$), and the interval between visits was 26.03 days ($SD = 15.21$). The average episode dose (i.e., number of visits per episode) was 7.66 ($SD = 9.88$) when all visits regardless of GAD-7 measurement were counted. Platform by marital status group means for these characteristics were not significantly different from respective sample means. (See Table 4.10.) There were, however, some significant episode treatment dose differences. When we compared therapy type groups, the mean psychotherapy group's visit dose was significantly greater than the mean medication group's visit dose, $t(27.302) = -2.04$, $p < .05$. This was similar to the visit count where encounters limited to the first five visits with GAD-7 scores ($\chi^2(1) = 9.53$, $p < .01$). (See Section 4.3.1.1.) When all visits were considered, TMH medication subjects had, on average, a significantly greater visit dose than the average medication subject ($z = 6.93$, $p < .05$) and TAU medication subjects had lower than

average visit doses than the average medication subject ($z = -2.03, p < .05$). The difference between platform groups on visit dose was also significant, $t(35) = 3.72, p < .001$.

Table 4.10
All Visit Treatment Course by Platform and Marital Status.

Process Characteristics	All Subjects <i>N</i> = 64		Platform				Marital Status			
			TMH <i>n</i> = 32		TAU <i>n</i> = 32		Married <i>n</i> = 43		NM <i>n</i> = 21	
	<i>M</i>	(<i>SD</i>)	<i>M</i>	(<i>SD</i>)	<i>M</i>	(<i>SD</i>)	<i>M</i>	(<i>SD</i>)	<i>M</i>	(<i>SD</i>)
<i>Time-to-Treatment</i>	16.02	(18.33)	14.31	(13.11)	17.72	(22.46)	15.72	(19.10)	16.62	(17.07)
<i>Episode Length</i>	166.45	(137.94)	203.09	(149.91)	129.81	(115.88)	152.35	(108.58)	195.33	(184.06)
<i>Encounter Interval</i>	26.03	(15.21)	28.40	(16.39)	23.66	(13.78)	26.93	(15.17)	24.19	(15.49)
<i>Visit Dose</i>	7.66	(9.88)	8.56	(10.00)	6.75	(9.83)	6.81	(8.71)	9.38	(11.98)

Therapy Type Medication	Subjects _{Med} <i>k</i> = 37		Platform				Medication by Marital Status			
			TMH <i>k</i> = 15		TAU <i>k</i> = 22		Married <i>k</i> = 29		NM <i>k</i> = 8	
	<i>M</i>	(<i>SD</i>)	<i>M</i>	(<i>SD</i>)	<i>M</i>	(<i>SD</i>)	<i>M</i>	(<i>SD</i>)	<i>M</i>	(<i>SD</i>)
<i>Time-to-Treatment</i>	16.92	(20.01)	15.80	(12.43)	17.68	(24.13)	18.69	(22.09)	10.50	(6.97)
<i>Episode Length</i>	148.16	(99.27)	190.93	(127.77)	119.00	(61.73)	134.28	(85.61)	198.50	(132.92)
<i>Encounter Interval</i>	28.69	(14.16)	28.56	(15.52)	28.77	(13.53)	26.68	(13.43)	35.95	(15.27)
<i>Visit Dose</i>	5.24	(2.66)	6.93	(3.35)*	4.09	(1.11)*	5.21	(2.76)	5.38	(2.45)

Psychotherapy	Subjects _{Ther} <i>k</i> = 27		Platform				Psychotherapy by Marital Status			
			TMH <i>k</i> = 17		TAU <i>k</i> = 10		Married <i>k</i> = 14		NM <i>k</i> = 13	
	<i>M</i>	(<i>SD</i>)	<i>M</i>	(<i>SD</i>)	<i>M</i>	(<i>SD</i>)	<i>M</i>	(<i>SD</i>)	<i>M</i>	(<i>SD</i>)
<i>Time-to-Treatment</i>	14.78	(16.02)	13.00	(13.93)	17.80	(19.49)	9.57	(8.20)	20.38	(20.43)
<i>Episode Length</i>	191.52	(177.02)	213.82	(170.28)	153.60	(190.90)	189.79	(141.67)	193.38	(214.82)
<i>Encounter Interval</i>	22.39	(16.10)	28.26	(17.60)	12.42	(4.73)	27.44	(18.84)	16.95	(10.73)
<i>Visit Dose</i>	10.96	(14.39)	10.00	(13.39)	12.60	(16.57)	10.14	(14.52)	11.85	(14.78)

Note. *N* = 64 subjects. Data reflects treatment visits regardless of measurement (*V* = 490 visits: $v_{TMH} = 274, v_{TAU} = 216, v_{Med} = 194, v_{Ther} = 296$. *k* = subjects by therapy type. Goodness of fit (GoF): z-scores, two-tailed ($\alpha = .05$). GAD-7: Generalized Anxiety Disorder 7-item scale. TMH: telemental health. TAU: treatment as usual. Mar: married. NM: Not married. Med: medication. Ther: psychotherapy. Therapy type group subject column GoF was calculated using all subject comparator values. GoF for all other values used the respective values in the subject column for comparator values. Time-to-treatment: for TMH, the days difference between referral date and the initial encounter; for TAU, the days difference between the most recent encounter likely to have generated a mental health referral (e.g. medical visit or mental health provider) and initial encounter. Because TAU encounters may have been generated by self-referral, TAU time-to-treatment is estimated. Episode: the period from initial treatment visit that occurred between 1/1/2015 - 1/31/2016, until last treatment visit prior to 1/1/2017. Episode length: the difference in days between the initial visit and the last visit in the episode. Encounter interval: days per encounter per episode. Visit dose: encounters per episode.

* $p < .05$

The married TMH medication subject group had a mean visit dose ($M = 7.40, SD = 3.57$) that was greater than average, $z = 2.57, p < .05$. While this difference between TMH marital status groups was not significant, it was significant when compared to visit dose for married TAU subjects, $t(30) = 3.85, p < .001$. Episode length for the not married TMH subject group ($M = 241.00, SD = 156.56$) was greater than average, $z = 2.09, p < .05$. Although this was

significantly greater than TAU medication subjects, $t(25) = 2.92, p < .01$, the not married TMH group episode length was not significantly different from the married TMH group, $t(13) = .75, p > .05$. Finally, the not married TAU psychotherapy subject episode dose ($M = 14.29, SD = 20.00$) was significantly greater than the sample mean for psychotherapy subjects, $z = -2.05, p < .05$. This was not significantly different from the married TAU psychotherapy group, $t(8) = -.47, p > .05$, or from the TMH psychotherapy group, $t(22) = .617, p > .05$. (See Table 4.11.)

Table 4.11

All Visit Treatment Course by Platform by Therapy by Marital Status.

Process Characteristics	All Subjects		Platform by Marital Status							
	$N = 64$		TMH _{Mar} $n = 21$		TMH _{NM} $n = 11$		TAU _{Mar} $n = 22$		TAU _{NM} $n = 10$	
	<i>M</i>	<i>(SD)</i>	<i>(SD)</i>		<i>M</i>	<i>(SD)</i>	<i>M</i>	<i>(SD)</i>	<i>M</i>	<i>(SD)</i>
<i>Time-to-Treatment</i>	16.02	(18.33)	13.81	(11.29)	15.27	(16.63)	17.55	(24.51)	18.10	(18.33)
<i>Episode Length</i>	166.45	(137.94)	186.57	(135.20)	234.64	(177.30)	119.68	(62.31)	152.10	(190.76)
<i>Encounter Interval</i>	26.03	(15.21)	27.08	(16.51)	30.92	(16.64)	26.79	(14.17)	16.78	(10.46)
<i>Visit Dose</i>	7.66	(9.88)	9.05	(12.03)	7.64	(4.37)	4.68	(2.01)	11.30	(17.02)
Therapy Type	Subjects _{Med}		Medication by Platform by Marital Status							
	$k = 37$		TMH _{Mar} $k = 10$		TMH _{NM} $k = 5$		TAU _{Mar} $k = 19$		TAU _{NM} $k = 3$	
<i>Medication</i>	<i>M</i>	<i>(SD)</i>	<i>(SD)</i>		<i>M</i>	<i>(SD)</i>	<i>M</i>	<i>(SD)</i>	<i>M</i>	<i>(SD)</i>
<i>Time-to-Treatment</i>	16.92	(20.01)	19.30	(13.19)	8.80	(7.56)	18.37	(25.91)	13.33	(6.03)
<i>Episode Length</i>	148.16	(99.27)	165.90	(111.41)	241.00	(156.56) *	117.63	(65.93)	127.67	(27.75)
<i>Encounter Interval</i>	28.69	(14.16)	23.00	(11.10)	39.69	(18.26)	28.62	(14.40)	29.72	(7.45)
<i>Visit Dose</i>	5.24	(2.66)	7.40	(3.57) *	6.00	(3.00)	4.05	(1.18)	4.33	(0.58)
	Subjects _{Ther}		Psychotherapy by Platform by Marital Status							
	$k = 27$		TMH _{Mar} $k = 11$		TMH _{NM} $k = 6$		TAU _{Mar} $k = 3$		TAU _{NM} $k = 7$	
<i>Psychotherapy</i>	<i>M</i>	<i>(SD)</i>	<i>M</i>	<i>(SD)</i>	<i>M</i>	<i>(SD)</i>	<i>M</i>	<i>(SD)</i>	<i>M</i>	<i>(SD)</i>
<i>Time-to-Treatment</i>	14.78	(16.02)	8.82	(6.40)	20.67	(20.74)	12.33	(14.74)	20.14	(21.81)
<i>Episode Length</i>	191.52	(177.02)	205.36	(156.76)	229.33	(207.82)	132.67	(36.86)	162.57	(232.16)
<i>Encounter Interval</i>	22.39	(16.10)	30.79	(20.07)	23.61	(12.09)	15.16	(2.49)	11.24	(5.10)
<i>Visit Dose</i>	10.96	(14.39)	10.55	(16.52)	9.00	(5.10)	8.67	(1.53)	14.29	(20.00) *

Note. $N = 64$ subjects. Data reflects treatment visits regardless of measurement ($V = 490$ visits: $v_{TMH} = 274, v_{TAU} = 216, v_{Med} = 194, v_{Ther} = 296$). $k =$ subjects by therapy type. Goodness of fit (GoF): z -scores, two-tailed ($\alpha = .05$).

GAD-7: Generalized Anxiety Disorder 7-item scale. TMH: telemental health. TAU: treatment as usual. Mar: married. NM: Not married. Med: medication. Ther: psychotherapy. Therapy type group subject column GoF was calculated using all subject comparator values. GoF for all other values used the respective values in the subject column for comparator values. Time-to-treatment: for TMH, the days difference between referral date and the initial encounter; for TAU, the days difference between the most recent encounter likely to have generated a mental health referral (e.g. medical visit or mental health provider) and initial encounter. Because TAU encounters may have been generated by self-referral, TAU time-to-treatment is estimated. Episode: the period from initial treatment visit that occurred between 1/1/2015 - 1/31/2016, until last treatment visit prior to 1/1/2017. Episode length: the difference in days between the initial visit and the last visit in the episode. Encounter interval: days per encounter per episode. Visit dose: encounters per episode.

* $p < .05$

Examination of the treatment course inclusive of all visits by subject showed that the married TMH and not married TAU groups, with significantly improved outcomes, engaged greater overall visit doses. The not married TAU group also had longer than average treatment episodes.

4.4 RELEVANT COMPARATIVE STUDIES

An overview of relevant literature was presented in Section 2.1.1. In order to draw parallels and contrasts between extant literature and the present research, two exemplar studies involving military treatment-eligible adult subjects treated for *DSM-IV* anxiety disorders (i.e., PTSD) are discussed here. These studies were selected because they represented high-quality research at the vanguard of contemporary TMH study: a noninferiority comparison and a randomized multisite program comparison. Symptom outcomes in these studies aligned with TMH anxiety disorder treatment assumptions. The noninferiority comparative study found that VC TMH psychotherapy was not inferior to in-person TAU (Morland et al., 2014). The second study was a pragmatic randomized clinical trial of a TMH-based collaborative PTSD-focused care approach that compared to usual care (Fortney et al., 2015). The latter study centered on improving care using a variety of TMH interventions inclusive of VC TMH. The former study directly compared platform conditions to detect whether group therapy delivered via TMH produced outcomes that were inferior to TAU.

Moreland and colleagues' (2014) non-inferiority study ($n = 125$) compared VC TMH ($n = 61$) to in-person TAU $n = 64$. Symptoms were measured at five prospective time-points using a mixed effects statistical analysis approach to estimate differences. Patients were seen in twice-weekly group sessions, over a 6-week period by conducted by members of a group of nine psychologists and one social worker who provided treatment in both TMH and TAU conditions.

Beyond the prospective design, other differences from the present research were apparent. (a) The non-inferiority research question did not reject or retain a traditional null hypothesis (i.e., that conditions were not significantly dissimilar); rather, the difference between conditions did not exceed the upper limit of a 95% confidence interval (i.e., worse TMH outcomes were not found). (b) Medication stability was required for 45 days prior to the study which may not be reflective of pragmatic practice. In military behavioral health care psychotherapy is frequently engaged as a first-line treatment, with psychopharmacotherapy added when necessary. (c) A reliable and valid instrument, the 136-point Clinician Administered PTSD Scale (CAPS) (Blake, Weathers, Nagy, Kaloupek, Gusman, Charney et al., 1995) was used to determine diagnostic eligibility and measure symptom change (i.e., frequency score + intensity score). (d) Measurements were not monitored at five time-points during the study; rather, symptoms were monitored pre-, mid-, and post-treatment and then at 3- and 6-month follow-up. (e) The study sites were all within a single state, the Hawaiian Islands. (f) Patient characteristics of subjects were different, with no female subjects included. The sample was older ($M = 55.3$ years, $SD = 12.5$), with fewer Caucasians (44%), more Asian subjects (15%), and the category of other (16%) included Hispanic ethnicity as well as the African American, and Native American races.

There were proportionally fewer married subjects (59%), compared to 67% married subjects in the present study. Fewer comorbidities were considered. Major depression (29%) was more prevalent than it was the present study (17%). Concurrent anxiety disorders that more prevalent (19%) than they were in the present study (12%). The overlap with other potentially confounding anxiety disorders was 19% compared to potentially confounding former anxiety disorders in the present study (17%). Finally, active substance use disorders included in the

Morland and colleagues' (2014) sample was 23%. Candidates with substance abuse treatment during the eligible treatment episode were excluded from the present study.

There were also some prominent differences in treatment. At the third measured visit in Morland and colleagues' (2014) study, 14% of the TAU and 18% of the TMH groups had been lost to follow-up. The present research, by design, lost no patients to follow-up at the third visit. However, at the fifth follow-up measurement in Morland and colleagues (2014) study, 30% of the TAU subjects and 33% of the TMH subjects had been lost to follow-up. The present study showed a far greater difference between platforms in treatment continuation. At the fifth visit measure, 84% of TAU subjects were no longer active. Similar to the Morland and colleagues (2014) study, on the other hand, treatment discontinuation in the TMH group was 34%. Therefore, TMH acceptability and engagement between these studies appears to be similar to the dropout rate reported by Morland and colleagues (2014).

Mean CAPS scores for study TMH completers in the Morland and colleagues (2014) study improved by 14.6 points (10.74 percentage points on the CAPS). In contrast, the present study's multiple linear regression results, inclusive of all visit measures showed a TMH 3.95-point improvement (18.81 percentage points on the GAD-7 scale) and liner mixed effects results for TMH showed a 2.97-point improvement at visit 5 (14.14 percentage point improvement on the GAD-7 scale). This comparison was imperfect, because it contrasted group psychotherapy with individual psychotherapy and medication management; nevertheless, the direction of outcomes toward symptom improvement was similar. Therefore, findings in the present study, compared to a study that found TMH not to be inferior (i.e., a more stringent standard than a traditional null hypothesis test), do not contradict previously held assumptions that TMH care is a viable alternative to TAU.

In the Fortney and colleagues (2015) pragmatic multisite RCT ($n = 265$) inclusive of sites in Louisiana and California (TMH $n = 133$, TAU $n = 132$) subjects were prospectively assessed at baseline and then at and follow-up at 6 and 12 months. Fortney and colleagues (2015) used CAPS to determine PTSD diagnoses for study inclusion and the Posttraumatic Diagnostic Scale (PDS) (Foa, Cashman, Jaycox, & Perry, 1997) to measure symptom change. This study emphasized treatment context and patient characteristics (Fortney et al., 2015), and its exclusion criteria were similar to the present study. For example, Fortney and colleagues (2015) excluded candidates with active substance abuse, bipolar disorder and psychosis. They did not, however, exclude for domestic violence concerns as was the case in the present research.

There were some similar sample characteristics. For example, in the study by Fortney and colleagues (2015), the sample included females (10.2%), which was much closer to the 15.6% female sample in the present study. Most subjects (90.9%) of subjects had engaged prior psychotherapy compared to 90.6% in the present study. Most patients had engaged previous psychotropic treatment (89.9%) in the Fortney colleagues (2015) study as was the case 76.6% in the present study. Another similarity was that most subjects had wartime service; however, in the study conducted by Fortney and colleagues (2015), subjects with Afghanistan and Iraq wartime service represented 29.1% of the subjects (70.9% of subject's was categorized as "other"). On the other hand, most of the primarily active duty sample in the present study had Afghanistan and Iraq wartime service (87.5%).

Although the Fortney colleagues (2015) clinic sites were located in two non-adjacent states, the average distance to a Veterans medical center with a supporting TMH consultant team was 57 miles (91 km) compared to 1,377miles (2216 km) in the present study. One important difference between these studies may be that treatment across noncontiguous states was engaged

much more frequently in the present study. In the Fortney and colleagues (2015) study, 78.9% of participants met criteria for a major depressive disorder (compared to 17% in the present study), 67.2% GAD (compared to 15.6% in the present study), and 44.2% panic disorder (compared to 1.6% panic disorder as primary diagnosis, and 1.8% of comorbidities). It is noteworthy that the most prevalent diagnosis in the present study was anxiety disorder, unspecified (82.8%). This difference may be reflective of the timeframes in which treatment was delivered. In the Fortney and colleagues (2015) study, subjects were enrolled 2009 – 2011, prior to the publication of the *DSM-5*, a timeframe in which clinicians may have greater diagnostic confidence regarding the current and accepted criteria. In the present study, however, treatment occurred 2015 through 2018 after publication of the *DSM-5*, so greater uncertainty about diagnostic changes may have been a factor.

The Fortney and colleagues (2015) study sample was older ($M = 52.2$ years, $SD = 13.8$), with fewer Caucasians (63.8%, compared to 78.0% in the present study) and more African Americans (19.6%, compared to 13.8% in the present study). Hispanic subjects comprised 7.6% of the sample and 9.0% were categorized as “other” (Fortney et al., 2015). In the present study, 8.3% of subjects identified as Hispanic, and 5.5% were categorized as “unknown”. Seventy percent of subjects were married subjects in the Fortney and colleagues (2015) study, compared to 67% in the present study.

Visit dose was addressed in the study by Fortney and colleagues (2015). In the telemedicine outreach for PTSD (TOP) condition, the mean psychotherapy visit dose for patients who engaged CPT psychotherapy was 7.6 visits. The overall visit dose in the present study was 7.7 visits, and 11 visits for the psychotherapy group. In the study by Fortney and colleagues (2015), loss to follow-up was minimal (TOP: 16.5%, TAU: 13.6%) compared to Morland et al.

(2014) and the present study. Comparison to the Fortney and colleagues (2015) study, however, should be considered in conjunction with a clear understanding of the study design differences. TOP was an enhanced multimodal program with additional outreach and support that included VC TMH and was compared to TAU. The present study provided no additional services compared to TAU. Nevertheless, the current research sought to emulate Fortney and colleagues' (2015) emphasis on the characteristics of pragmatic treatment. Use of the VC platform to deliver 55% of the psychotherapy was only one component of TOP. For example, the TOP condition included telephonic nurse case management follow-up every 2 weeks and aimed at supporting in-person providers (i.e., decision support). Rather than a single team treating patients at several referring locations, the consulting clinicians in the Fortney and colleagues (2015) study formed into three PTSD teams, each composed of a psychologist, a psychiatrist and a "telephone pharmacist" (a total of six independent providers per team, all focused on a single diagnosis) with an additional "registered nurse care manager" (Fortney et al., 2015, p. 61) at each of 3 consultant team sites.

Outcomes in the study by Fortney and colleagues (2015) showed significant improvement (change score) for the TOP group at 12 months ($p < .05$) and outcomes improved 2.49 points (4.88 percentage points on the 51-point PDS). This was smaller than the TMH 3.95-point improvement overall (18.81 percentage points) on the GAD-7 scale ($p < .001$) as well as the linear mixed effects TMH results that showed a 2.97-point improvement at visit 5 (14.14 percentage points) on the GAD-7 scale in the present study. In the present study, no significant score change differences between TMH and TAU platform scores was found between the 3.06-point improvement in the TMH group (14.57 percentage points) on the GAD-7 scale and the 2.47-point improvement in the TAU group (11.76 percentage points) on the GAD-7 scale.

Fortney and colleagues (2015), on the other hand, showed that TOP outperformed TAU with unadjusted TOP scores that improved 2.85 points (5.59 percentage points) more on the PDS scale more than the TAU scores, $t = 2.30$, $p < .05$, $d = .31$. Fortney and colleagues (2015) found outcome improvements when they focused resources that included VC TMH to specifically target PTSD. As Fortney and colleagues identified in a previous collaborative care study (Fortney et al., 2007), telephonic nurse case management was a likely active treatment component in collaborative care. Elements of the collaborative, multifaceted TMH approach facilitated by TMH, such as reviews of shared records, regimen evaluation and telephone outreach, were echoed by the grounded research of Solli, Hvalvik, Bjork, and Helleso (2015), who explored the value of distance in multimodal therapeutic TMH relationships (Tebbs, 2016). The present study did not augment resources for the TMH group. This comparison therefore supports the assumption that subjects with *DSM-5* anxiety disorders may respond at least as well to TMH treatment as did subjects who were treated more intensively for PTSD.

4.5 DISCUSSION

It may seem counterintuitive that, in the present study, GAD-7 outcomes improved significantly for the not married TAU group while the married TAU group outcomes did not. It is therefore important to understand that the military lifestyle involves some unique challenges that may impact marriages. These include preparation for deployment, frequent geographical partner separation, and reintegration stress. Leach, Butterworth, Olesen, and Mackinnon (2013) suggested that the use of marital status as a proxy for marital quality in epidemiological research has led to a misperception that marriage itself is a protective factor for mental health. These researchers conducted a large population-based study in Australia ($n = 3,820$) and found that depressed or anxious men and women (49.2%, 42.1.2%, respectively) were more likely to be

involved in poor-quality partnered relationships than were those who were not in a de-facto marriage (29.5%, 24.9%). Allen, Rhoades, Stanley, and Markman (2011) found that military spouses ($n = 300$) experienced greater levels of emotional distress than service members themselves. Service member stress ($r = .28$) and spouse stress ($r = .27$) were correlated with combat exposure ($r = -.27$), marital satisfaction ($r = -.31$), as well as value of the military service mission for both the service members ($r = -.26$) and their spouses ($r = -.23, ps < .01$). Interestingly, time together since deployment significantly related to increased stress for military spouses ($r = -.20, p < .05$).

Lambert, Engh, Hasbun, and Holzer (2012), conducted a meta-analysis of the associations among relationship quality, psychological distress of intimate partners, and PTSD ($n = 3,421$). Symptoms were associated with moderate detrimental effects to patients' intimate partners. Of these effects, the impact on relationship quality was significant, with small-to-moderate effect. Military service was identified as a relationship quality moderator ($r = .33, p < .01$). Bergmann, Renshaw, Allen, Markman, and Stanley (2014) conducted path analysis of married military couples ($n = 606$) to help understand the relationship between the perceived meaningfulness of military service and marital satisfaction, while accounting for service members' PTSD. Military spouses' positive perceptions of meaningful military service significantly predicted marital satisfaction ($+1 SD: \lambda = .17, p < .01$). Interestingly, service members' perception of the meaningfulness of their service was only significantly linked to marital satisfaction when their spouses also perceived their military service as meaningful. Renshaw and Campbell (2017) emphasized the importance of marital satisfaction (i.e., benefit finding) in PTSD symptom improvement among married military couples ($n = 66$). Military spouses' perception of benefit was positively associated with marital satisfaction as well as the

service members' symptom improvement on marital satisfaction ($r = .34, p < .05$), with a medium effect. This demonstrated the importance of service member spouses' benefit perception as it related to improvement of the patients' psychiatric symptoms.

Leach and colleagues (2013) pointed out that clinic-based research on patients seeking mental health treatment is likely to be biased. Married patients in this dissertation research sample were seeking treatment for anxiety disorder symptoms, suggesting an increase in psychiatric symptoms compared to the larger military population. It may therefore be important to distinguish between marital status and relationship satisfaction for military treatment-eligible patients being treated for anxiety disorders. Marital relationship satisfaction has been positively linked with symptom improvement. The converse may also be true. If increased psychiatric symptoms correlate with marital dissatisfaction in spouses of patients with PTSD, this dynamic may also be reflected in married subjects with *DSM-5* anxiety disorders. Marital status of subjects treated for anxiety disorders, then, may be understood as a possible indicator of marital dissatisfaction.

Because married patients with anxiety disorders are more vulnerable to marital dissatisfaction, relationship dissatisfaction may, in turn, precede worse anxiety symptom outcomes in patients prone to anxiety. The present research findings are consistent with extant literature that suggests that marital status for patients with anxiety disorders may predict symptom outcomes in some conditions. This dynamic may strengthen the finding that married patients with anxiety disorders who were treated via VC TMH experienced significant symptom improvement, where married patients treated in-person did not. Married patients may therefore be more likely to benefit from treatment for anxiety disorders delivered via TMH.

4.5.1 Theoretical implications

This study's findings have theoretical implications within the KTA framework. KTA integrates practical evidence that incorporates the needs of end users in order to encourage engagement in successful interventions in a way that fosters their adoption and sustainment (Graham & Tetroe, 2010; Mitchell et al., 2010). Evidence in the present study may be useful for this purpose in four ways. First, married patients treated via TMH improved significantly over five visits, with treatment retention rates similar to those found in a prospective noninferiority study. Therefore, future TMH intervention designs may focus TMH efforts on married subjects and marital satisfaction. Second, not married patients' symptoms improved significantly and more quickly when treated in person. This supports further incorporation of user-focused referral decisions that may best support symptom improvement. In addition to safety concerns that may be better managed in-person being part of the referral decision, referral guidelines for behavioral health treatment via TMH or TAU may take into account marital status. Third, future program iterations may include the study of other potential contextual factors (Batterham et al., 2015; Meurk et al., 2016) such as marital satisfaction and the value of distance in a therapeutic relationship (Solli et al., 2015). Fourth, clinician characteristics warrant further consideration beyond discipline and the type of therapy offered. A mental health provider's personal experiences with active duty service might also be a factor in how patients respond to treatment. It may therefore be worthwhile to consider the military experience of providers treating married military patients as well as the civilian expertise of providers treating patients who are not married. The value stakeholders place on providers' proximity to the workplace and/or to military service may be a meaningful component to treatment success in this population. By

connecting treatment approaches to patients most likely to benefit from them, anxiety treatment quality outcomes as well as TMH program improvements, may advance.

Chapter 5. SUMMARY OF CONCLUSIONS

Although visit measurement changes were significant overall, rates of change were not significantly different between treatment platforms or therapy types. There was, however, a significant interaction between marital status and GAD-7 scores. Not married patients outperformed married patients and pharmacotherapy predicted the greatest anxiety improvements for patients in the TAU group who were not married. So, in-person treatment of patients who were not married was supported. However, when considering mental health treatment modalities for the majority of military treatment-eligible patients with anxiety disorders (i.e., married patients), TMH care predicted significantly lower GAD-7 scores at the fifth visit compared to TAU.

5.1 RESULT EMPHASIS

The assumption that outcomes of treatment delivered to military treatment-eligible patients via TAU and TMH for anxiety disorders are not significantly different between platforms was supported by findings in this dissertation research. This assumption was consistent with findings based on PTSD-focused anxiety disorder treatment prior to 2013. Anxiety symptom improvement in GAD-7 scale percentage points, juxtaposed with PTSD symptom improvement on PTSD rating scales' percentage points in other research suggests that *DSM-5* anxiety disorders treatment response may, at the least, reflect symptom improvement found in PTSD that had been diagnosed per the *DSM-IV*.

In the present study, married TMH subjects improved significantly by the fifth visit. This was interesting not only because GAD-7 improvement of 3.26 points on average was significant, this group also retained 13 subjects (61.90%) in treatment at the fifth visit for psychotherapy

($n = 5$) and medication ($n = 8$) therapy groups. The 30% retention of not married TAU subjects, ($n = 3$) at the fifth visit, on the other hand, balanced between psychotherapy ($n = 1$) and medication ($n = 2$) therapy groups. The retention rate for married TMH subjects was nearly double that of not married TAU subjects. So, although the TAU not married group showed the most pronounced improvement at visit 5, this finding must be considered in the context of this group's size at the fifth visit.

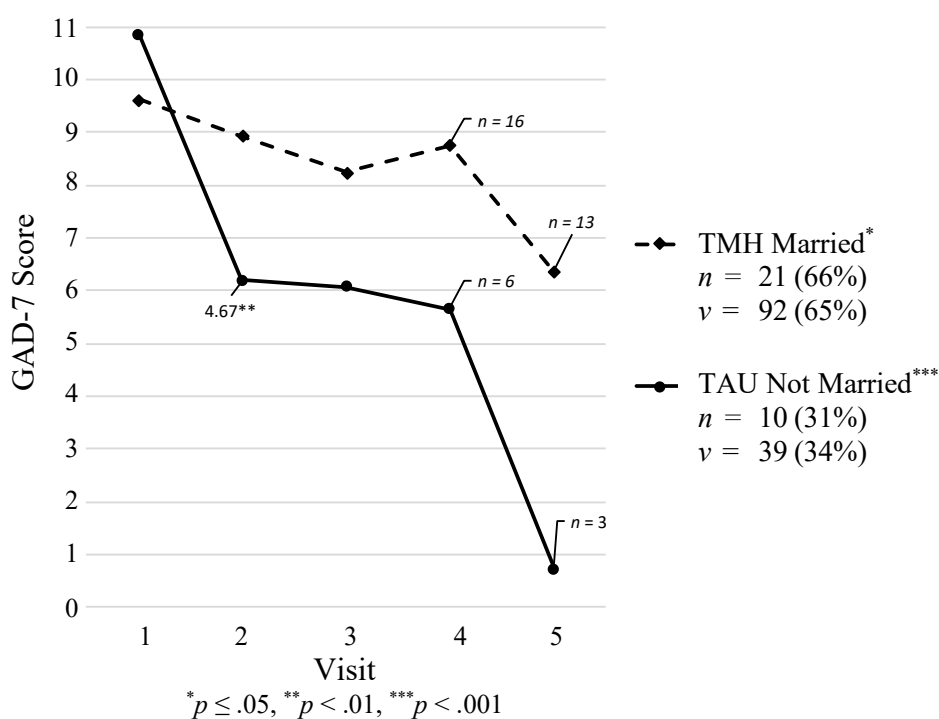


Figure 5.1. Visit measure change on marital status and treatment platform.

The TAU not married group also showed dramatic improvement at visits 2 ($M = 4.67$) and 3, when the group had 100% participation ($n = 10$) (see Figure 4.11). The reason TAU subjects did not continue treatment after the third visit is not known; however, one explanation may be that once symptoms improved to a GAD-7 score of 6, well below the diagnostic threshold of 10, treatment was no longer deemed necessary by the provider or patient. Another

way to state outcome findings is that married TMH patients who had better treatment retention over five visits, showed a significant, 19-percentage point improvement on the GAD-7 scale ($\cong 3$ points). The TAU not married group, on the other hand, reached a similar level of improvement sooner with proportionally fewer visits, at visit 3.

5.2 FUTURE RESEARCH

Future directions for research may be guided by considering ways in which the current work might be extended and improved, considering literature gaps and, finally, revisiting the theoretical framework that has underpinned this research. First, results of this research should be replicated. For many subjects in the present study, at the time treatment episodes took place the *DSM-5* had been in publication less than 2 years. Given that few patients were naive to treatment, anxiety disorder diagnoses may have been established with even closer time-proximity to categorical diagnostic changes in May of 2013 (APA, 2013). Secondly, the Structured Clinical Interview for the *DSM-5* Diagnoses (SCID-5) reference-standard (Williams & First, 2016) could be used improve diagnostic fidelity and perhaps allow for greater diagnostic differentiation beyond unspecified anxiety disorders. Thirdly, the research design should be a fully randomized prospective study using a larger sample size. In addition, a longer study period with post-treatment follow-up could further elucidate findings and increase power to detect differences.

Tailoring interventions to accommodate patient characteristics and address the needs of dissimilar patients (e.g., married and not married patients) may improve TMH effectiveness as well as uptake and sustainment. Additional study, therefore, may provide important clues useful in potentiating future intervention effectiveness while helping to solidify TMH effectiveness evidence. For example, a study could incorporate a TMH marital satisfaction component to

treatment, as well as marital satisfaction measurements in future anxiety disorder treatment intervention iterations. Another way to improve TMH evidence in future research would be to increase the number of study sites and expand treatment to DoD sites beyond the Pacific region. Cooperation between agencies such as the Veterans Administration and joint military systems of care, could both expand site variation and expand care continuity into older age groups by to helping bridge care for active service members and older veterans. Doing so could improve the generalizability of findings, provide care continuity insights, and address patient aging concerns. In addition, post-intervention follow-up should also be considered in order to have a better understanding of how treatment gains might be retained.

Next, gaps in recent literature might also help to direct future TMH research. One possibility would be to increase focus on decision support to include clinician-to-clinician consultation. This could be a central feature of TMH as part of stepped care (Fortney et al., 2007) that focuses on maximizing the least invasive, most cost-effective interventions (Wootton, 2016). Given the potential to both increase efficiency and to limit some access, careful attention to this TMH approach is warranted. In addition, VC TMH treatment of other prominent psychiatric disorders that might co-occur with anxiety disorders should be considered. Study of symptoms common to multiple mental health disorders may have more pragmatic utility than studying individual disorders. These may include insomnia and parasomnias, adult attention deficit hyperactivity disorders (ADHD) and/or autism spectrum disorders in adults. Expanding TMH knowledge in this regard could conceivably be leveraged to inform intervention adaptation in the treatment of several disorders.

Finally, KTA theoretical framework assumptions may be helpful in guiding future research endeavors. Stakeholder feedback, system complexity and role clarification are also

aspects of TMH important to remotely located patients with mental health needs. Incorporation of mobile devices may help to empower remotely located patients. Interventions enhanced by the judicious use of mobile devices could allow for virtual aggregation of low-density population treatment concerns to be less limited by location so that they may warrant the attention and resources of larger systems of care. Mobile devices may thereby have an equalizing effect when considering the relative power of other TMH stakeholders such as insurers, professional organizations, legal systems and intervention developers to target care delivery. Considerations that may require additional considerations when studying clinic-based VC TMH treatment should include greater attention to environment of care, therapeutic alliance, confidentiality, and end-user trust. A collaborative care approach (Fortney et al., 2015) could conceivably include a voluntary mobile device VC option for some patients (e.g., those not actively suicidal) at some visits (e.g., post-stabilization follow-up when substance abuse is not a confounding factor), in certain circumstances (e.g., with end-to-end encryption and other privacy arrangements in place) may be especially well suited to expanding the use of mobile devices beyond appointment reminders and telephonic case management.

Also, because remote populations may be more isolated, addressing the complexities of social support may be a way to strengthen future interventions in a way that these populations may value (e.g., marital/relationship resources). An example of this might be to engage family caregivers in a way that promotes access to currently available resources. Conversely, a patient's desire for distance from others may also be a valid cultural norm and/or preference, so interventions may consider matching patients with an appropriate level of therapeutic intensity (Wootton, 2016). Future TMH study may consider accommodating patients in this way by offering a range of adjunctive TMH modalities that could include self-help resources, professionally

curated closed-group message boards, therapist correspondence via secure e-mail (Solli et al., 2015) and self-guided mobile applications that incorporate user-centered design principles.

Finally, for remote populations, role negotiation and clarification may be especially important. Should an emergency arise in the course of TMH care delivery, the nearest resource may not be a mental health professional. Identifying and partnering with local resources may be critical to tailoring future TMH endeavors to populations within the communities the intervention is intended to help. Role clarity, therefore, in addition to improving end user confidence in TMH, may also help to foster uptake and sustainment of mental health intervention improvements that could include videoconferencing.

5.3 CONCLUSION

Consistent with previous research, the current dissertation research showed that, independent of therapy type, overall GAD-7 symptoms improved significantly among treatment platform cohorts with a large effect size. Marital status predicted an outcome advantage for patients who were not married with a significant small-to-medium effect. Subjects who were not married and had lower initial anxiety demonstrated a significantly greater treatment outcome advantage. This outcome was pronounced over the first five visits if subjects who were not married were treated in-person. Most patients in the sample, however, were married. The comparatively robust married subject group improved significantly over the first five visits when treatment was provided via VC TMH. In addition to supporting assumptions of anxiety disorder treatment outcome improvement based on a previously held diagnostic conceptualization, findings in this dissertation research will inform future treatment interventions focused on treatment of anxiety disorders as they are currently categorized in the *DSM-5*. These efforts would aim to improve access to, and engagement in, high quality care for patients in locations with limited resources.

Tailoring VC-enabled TMH treatment to the characteristics (e.g., marital status) of patients with *DSM-5* anxiety disorders may thereby help to overcome barriers, advance treatment options, and improve outcomes for military service members and their families.

APPENDIX A

DA Form 8001, Limits of Confidentiality (U.S. Department of the Army, 2010)

LIMITS OF CONFIDENTIALITY		
<small>For use of this form, see AR 40-66; the proponent agency is the Office of The Surgeon General.</small>		
<p>As part of your healthcare team, our goal is to provide you with quality care and to protect the privacy of your personal information. The care we provide you may include, but is not limited to: assessment, referral, individual therapy, couples therapy, family therapy, group therapy, substance abuse treatment, psychiatric evaluation and medications.</p> <p>As your providers, we will document information about your visits in your military health record (written and electronic) to ensure continuity of care. Your health record is maintained as the property of the U.S. Government. In the majority of cases, we will not disclose any of your personal information nor confirm/deny that we have met with you unless you provide us with written authorization to disclose your personal information. There are a few exceptions, under which we may be required to release your personal information without obtaining your prior authorization. However, we will discuss these with you at the beginning of treatment and throughout treatment, whenever possible. For example:</p>		
<ol style="list-style-type: none"> 1. Safety: If you threaten to harm yourself, we may seek hospitalization and/or contact others to ensure your safety. If you threaten serious bodily harm to another, we are required to take protective actions, such as contacting the potential victim, police, chain of command, or seeking hospitalization. 2. Abuse: If we believe that a child, spouse, or vulnerable adult is being abused, we will be required to file a report. 3. Legal: If you are involved in legal actions/proceedings, your records may be subject to subpoena or lawful directive from a court. Under the Uniform Code of Military Justice (UCMJ), we have a limited "privileged communication" that may prevent your records from being disclosed in legal proceedings. This privilege is not absolute and there may be situations involving violations of the UCMJ or civil law where we may be required to divulge that information to the chain of command and/or other authorities. If you have any concerns related to this, please contact an attorney. 4. Self Referrals: In accordance with DoDI 6490.08, healthcare providers will notify commanders if it is determined that your mental health condition represents a risk of harm to self, others or mission; impairs you in performing potentially sensitive or urgent requirements; is likely to impair your judgment or reliability to protect classified information; requires inpatient care; interferes with ability to perform duties; or requires substance abuse treatment. 5. Substance Abuse: If you are a Service member, records related to any treatment for substance abuse will be released to individuals within the Armed Forces who have an official need to know. If you are a Service member and information is released to someone outside of the Armed Forces or you are a civilian, all releases of information related to any treatment for substance abuse are subject to additional federal regulations under Code of Federal Regulation, Title 42, Part 2, Chapter 1. 6. Fitness for Duty/Command-Directed Referrals: If you are command-referred, your chain of command will not be authorized to view your medical record, but is entitled to limited information pertinent to any duty limitation or restriction, security clearance, or treatment that might affect duty performance or jeopardize the safety of yourself or co-workers. 7. Care Coordination: Because we operate as a team with other healthcare staff to provide you the best possible services, other members of the military medical system are permitted access to your record. In most cases, your information will not be disclosed outside the clinic/hospital setting without your written permission. If you are in treatment for substance abuse, access to your individual records can only be disclosed between the rehabilitation staff members and personnel involved in your rehabilitation, and to those required to determine compliance with AR 600-85, The Army Substance Abuse Program. 8. Quality Care Review: Quality assurance personnel may review your record to ensure that care standards are being met. If this occurs, the reviewer is required to keep your identity confidential. 		
If you have any questions or concerns, please feel free to discuss it with us.		
STATEMENT OF UNDERSTANDING/CONSENT TO ASSESSMENT and/or TREATMENT		
Patient's Statement: I have read the above and understand that clinical information about me will be safeguarded within the limitations mentioned above and under the provisions of the Privacy Act - DD Form 2005 and the Health Insurance Portability and Accountability Act (HIPAA) of 1996.		
PATIENT/CAREGIVER NAME	PATIENT/CAREGIVER SIGNATURE	DATE (YYYYMMDD)
Provider's Statement: I have explained the nature of the assessment and treatment(s) including benefits and risks of proposed and alternatives treatments.		
PROVIDER NAME	PROVIDER TITLE	
DEPARTMENT/SERVICE/CLINIC/MTF CODE	PROVIDER SIGNATURE	DATE (YYYYMMDD)
PATIENT'S IDENTIFICATION (For typed or written entries give: Name/last, first, middle; grade; SSN; date; hospital or medical facility)		

APPENDIX B

DD Form 2005, Privacy Act Statement
(U.S. Department of the Army, 2010)

PRIVACY ACT STATEMENT - HEALTH CARE RECORDS		
<i>THIS FORM IS NOT A CONSENT FORM TO RELEASE OR USE HEALTH CARE INFORMATION PERTAINING TO YOU.</i>		
<p>1. AUTHORITY FOR COLLECTION OF INFORMATION INCLUDING SOCIAL SECURITY NUMBER (SSN)</p> <p style="padding-left: 40px;">Sections 133, 1071-87, 3012, 5031 and 8012, title 10, United States Code and Executive Order 9397.</p>		
<p>2. PRINCIPAL PURPOSES FOR WHICH INFORMATION IS INTENDED TO BE USED</p> <p style="padding-left: 40px;">This form provides you the advice required by The Privacy Act of 1974. The personal information will facilitate and document your health care. The Social Security Number (SSN) of member or sponsor is required to identify and retrieve health care records.</p>		
<p>3. ROUTINE USES</p> <p style="padding-left: 40px;">The primary use of this information is to provide, plan and coordinate health care. As prior to enactment of the Privacy Act, other possible uses are to: Aid in preventive health and communicable disease control programs and report medical conditions required by law to federal, state and local agencies; compile statistical data; conduct research; teach; determine suitability of persons for service or assignments; adjudicate claims and determine benefits; other lawful purposes, including law enforcement and litigation; conduct authorized investigations; evaluate care rendered; determine professional certification and hospital accreditation; provide physical qualifications of patients to agencies of federal, state, or local government upon request in the pursuit of their official duties.</p>		
<p>4. WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION</p> <p style="padding-left: 40px;">In the case of military personnel, the requested information is mandatory because of the need to document all active duty medical incidents in view of future rights and benefits. In the case of all other personnel/beneficiaries, the requested information is voluntary. If the requested information is not furnished, comprehensive health care may not be possible, but CARE WILL NOT BE DENIED.</p> <p style="padding-left: 40px;">This all inclusive Privacy Act Statement will apply to all requests for personal information made by health care treatment personnel or for medical/dental treatment purposes and will become a permanent part of your health care record.</p> <p style="padding-left: 40px;">Your signature merely acknowledges that you have been advised of the foregoing. If requested, a copy of this form will be furnished to you.</p>		
SIGNATURE OF PATIENT OR SPONSOR	SSN OF MEMBER OR SPONSOR	DATE

APPENDIX C
 Generalized Anxiety Disorder 7-item Inventory
 (Spitzer, Kroenke, Williams, & Löwe, 2006)

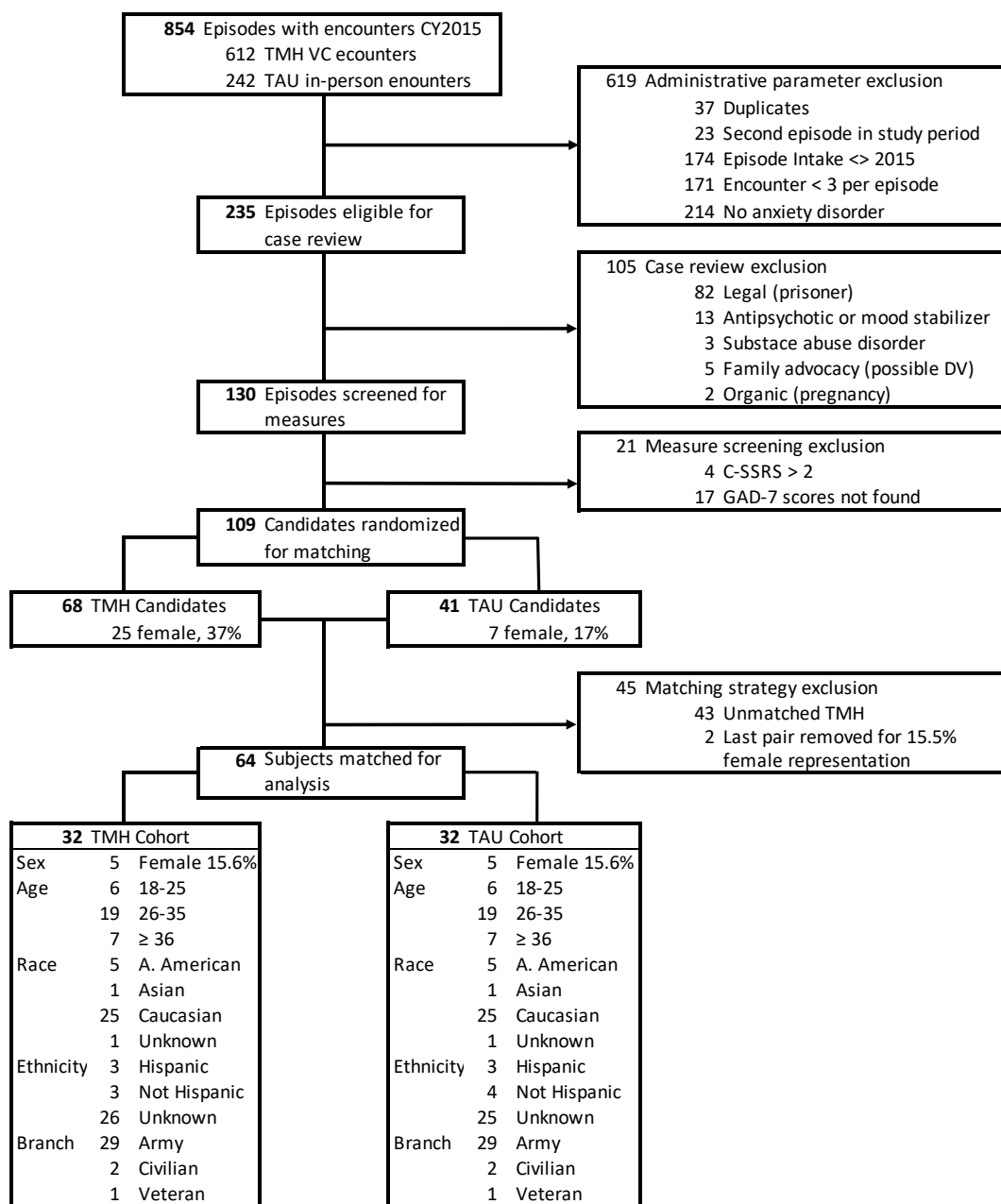
GAD-7				
Over the last 2 weeks, how often have you been bothered by the following problems? <i>(Use "✓" to indicate your answer)</i>	Not at all	Several days	More than half the days	Nearly every day
1. Feeling nervous, anxious or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	3
4. Trouble relaxing	0	1	2	3
5. Being so restless that it is hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritable	0	1	2	3
7. Feeling afraid as if something awful might happen	0	1	2	3
<i>(For office coding: Total Score T ____ = ____ + ____ + ____)</i>				
<small>Developed by Drs. Robert L. Spitzer, Janet B.W. Williams, Kurt Kroenke and colleagues, with an educational grant from Pfizer Inc. No permission required to reproduce, translate, display or distribute.</small>				

Columbia Suicide Severity Risk Assessment Scale (continued)
(Posner, 2009)

SUICIDAL BEHAVIOR (Check all that apply, so long as these are separate events; must ask about all types)	Lifetime		Past 3 months				
<p>Actual Attempt: A potentially self-injurious act committed with at least some wish to die, as a result of act. Behavior was in part thought of as method to kill oneself. Intent does not have to be 100%. If there is any intent/desire to die associated with the act, then it can be considered an actual suicide attempt. There does not have to be any injury or harm, just the potential for injury or harm. If person pulls trigger while gun is in mouth but gun is broken so no injury results, this is considered an attempt. Inferring Intent: Even if an individual denies intent/wish to die, it may be inferred clinically from the behavior or circumstances. For example, a highly lethal act that is clearly not an accident so no other intent but suicide can be inferred (e.g., gunshot to head, jumping from window of a high floor/story). Also, if someone denies intent to die, but they thought that what they did could be lethal, intent may be inferred. Have you made a suicide attempt? Have you done anything to harm yourself? Have you done anything dangerous where you could have died? <i>What did you do?</i> <i>Did you _____ as a way to end your life?</i> <i>Did you want to die (even a little) when you _____?</i> <i>Were you trying to end your life when you _____?</i> <i>Or Did you think it was possible you could have died from _____?</i> Or did you do it purely for other reasons / without ANY intention of killing yourself (like to relieve stress, feel better, get sympathy, or get something else to happen)? (Self-Injurious Behavior without suicidal intent) If yes, describe:</p>	<p>Yes No <input type="checkbox"/> <input type="checkbox"/></p>	<p>Yes No <input type="checkbox"/> <input type="checkbox"/></p>	<p>Total # of Attempts _____</p>	<p>Total # of Attempts _____</p>			
<p>Has subject engaged in Non-Suicidal Self-Injurious Behavior?</p>	<p>Yes No <input type="checkbox"/> <input type="checkbox"/></p>	<p>Yes No <input type="checkbox"/> <input type="checkbox"/></p>	<p>Interrupted Attempt: When the person is interrupted (by an outside circumstance) from starting the potentially self-injurious act (if not for that, actual attempt would have occurred). Overdose: Person has pills in hand but is stopped from ingesting. Once they ingest any pills, this becomes an attempt rather than an interrupted attempt. Shooting: Person has gun pointed toward self, gun is taken away by someone else, or is somehow prevented from pulling trigger. Once they pull the trigger, even if the gun fails to fire, it is an attempt. Jumping: Person is poised to jump, is grabbed and taken down from ledge. Hanging: Person has noose around neck but has not yet started to hang - is stopped from doing so. Has there been a time when you started to do something to end your life but someone or something stopped you before you actually did anything? If yes, describe:</p>	<p>Yes No <input type="checkbox"/> <input type="checkbox"/></p>	<p>Yes No <input type="checkbox"/> <input type="checkbox"/></p>	<p>Total # of interrupted _____</p>	<p>Total # of interrupted _____</p>
<p>Aborted or Self-Interrupted Attempt: When person begins to take steps toward making a suicide attempt, but stops themselves before they actually have engaged in any self-destructive behavior. Examples are similar to interrupted attempts, except that the individual stops him/herself, instead of being stopped by something else. Has there been a time when you started to do something to try to end your life but you stopped yourself before you actually did anything? If yes, describe:</p>	<p>Yes No <input type="checkbox"/> <input type="checkbox"/></p>	<p>Yes No <input type="checkbox"/> <input type="checkbox"/></p>	<p>Preparatory Acts or Behavior: Acts or preparation towards imminently making a suicide attempt. This can include anything beyond a verbalization or thought, such as assembling a specific method (e.g., buying pills, purchasing a gun) or preparing for one's death by suicide (e.g., giving things away, writing a suicide note). Have you taken any steps towards making a suicide attempt or preparing to kill yourself (such as collecting pills, getting a gun, giving valuables away or writing a suicide note)? If yes, describe:</p>	<p>Yes No <input type="checkbox"/> <input type="checkbox"/></p>	<p>Yes No <input type="checkbox"/> <input type="checkbox"/></p>	<p>Total # of preparatory acts _____</p>	<p>Total # of preparatory acts _____</p>
<p>Actual Lethality/Medical Damage: 0. No physical damage or very minor physical damage (e.g., surface scratches). 1. Minor physical damage (e.g., lethargic speech; first-degree burns; mild bleeding; sprains). 2. Moderate physical damage; medical attention needed (e.g., conscious but sleepy, somewhat responsive; second-degree burns; bleeding of major vessel). 3. Moderately severe physical damage; medical hospitalization and likely intensive care required (e.g., comatose with reflexes intact; third-degree burns less than 20% of body; extensive blood loss but can recover; major fractures). 4. Severe physical damage; medical hospitalization with intensive care required (e.g., comatose without reflexes; third-degree burns over 20% of body; extensive blood loss with unstable vital signs; major damage to a vital area). 5. Death</p>	<p>Most Recent Attempt Date: Enter Code _____</p>	<p>Most Lethal Attempt Date: Enter Code _____</p>	<p>Initial/First Attempt Date: Enter Code _____</p>				
<p>Potential Lethality: Only Answer if Actual Lethality=0 Likely lethality of actual attempt if no medical damage (the following examples, while having no actual medical damage, had potential for very serious lethality: put gun in mouth and pulled the trigger but gun fails to fire so no medical damage; laying on train tracks with oncoming train but pulled away before run over). 0 = Behavior not likely to result in injury 1 = Behavior likely to result in injury but not likely to cause death 2 = Behavior likely to result in death despite available medical care</p>	<p>Enter Code _____</p>	<p>Enter Code _____</p>	<p>Enter Code _____</p>				

APPENDIX E

STROBE Depiction of Sorting, Randomization and Matching (Vandenbroucke, von Elm, Altman, Gotzsche, Mulrow, Pocock et al., 2007)



Note. STROBE: Strengthening the Reporting of Observational Studies in Epidemiology recommendations based on a 22 item checklist used to guide cohort studies in order to foster critical appraisal of study results. C-SSRS: Columbia Suicide Severity Rating Scale. Candidate: Episode within administrative parameters, appropriate for case review, with ≥ 3 encounters, CSSRS < 3, and at least x3 Generalized Anxiety Disorder 7-item Scale (GAD-7) scores available in the electronic medical record. Subjects: matched candidates included while maintaining >15.5% female representation in each cohort. Matching Strategy: Randomized candidates were matched on sex, age group, race, ethnicity (when possible), and branch. Once all fully matched candidate pairs were exhausted, two candidate pairs matched on all criteria except ethnicity were considered, of these, one was included. The last pair was excluded in order to maintain 15.5% female representation in each cohort. TMH: telemental health. VC: video conference. TAU: treatment as usual.

APPENDIX F

Characteristics of Candidates and Subjects

Characteristics [†]	Population μ	Candidates by Platform				Subjects by Platform							
		All Candidates <i>n</i> = 109		TMH <i>n</i> = 68		TAU <i>n</i> = 41		All Subjects <i>n</i> = 64		TMH <i>n</i> = 32		TAU <i>n</i> = 32	
		<i>M</i>	(<i>SD</i>)	<i>M</i>	(<i>SD</i>)	<i>M</i>	(<i>SD</i>)	<i>M</i>	(<i>SD</i>)	<i>M</i>	(<i>SD</i>)	<i>M</i>	(<i>SD</i>)
<i>Age (years)</i>													
All	28.5	31.50	(8.47)	30.90	(8.44)	32.51	(8.51)	31.70	(8.18)	31.09	(7.26)	32.31	(9.09)
Male		31.35	(7.97)	30.28	(7.28)	32.71	(8.67)	31.98	(8.19)	31.19	(6.75)	32.78	(9.48)
Female		31.88	(9.69)	31.96	(10.22)	31.57	(8.22)	30.20	(8.43)	30.60	(10.60)	29.80	(6.87)
<i>Time in Service (years)</i>													
All		9.42	(6.99)	8.76	(7.60)	10.37	(5.96)	9.40	(6.26)	9.00	(6.82)	9.80	(5.74)
Male		9.15	(6.21)	8.14	(6.58)	10.42	(5.53)	9.57	(6.45)	9.07	(7.07)	10.07	(5.87)
Female		10.56	(9.74)	10.77	(10.30)	10.00	(9.17)	7.83	(4.26) [*]	8.33	(4.93)	7.33	(4.51)
<i>Distance to Provider (miles)</i>													
		829.28	(698.35)	1329.28	(334.01)	-	-	688.45	(727.95)	1376.91	(313.71)	-	-
<i>Sex</i>													
	%	No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.	(%)
Male	84.50	77	(70.64) ^{***}	43	(63.24)	34	(82.93)	54	(84.38) [*]	27	(84.38)	27	(84.38)
Female	15.50	32	(29.36) ^{***}	25	(36.76)	7	(17.07)	10	(15.63) [*]	5	(15.63)	5	(15.63)
<i>Race</i>													
African American	17.30	15	(13.76)	10	(14.71)	5	(12.20)	10	(15.63)	5	(15.63)	5	(15.63)
Asian	4.20	3	(2.75)	2	(2.94)	1	(2.44)	2	(3.13)	1	(3.13)	1	(3.13)
Caucasian	68.70	85	(77.98) ^{***}	53	(77.94)	32	(78.05)	50	(78.13)	25	(78.13)	25	(78.13)
Unknown	3.80	6	(5.50)	3	(4.41)	3	(7.32)	2	(3.13)	1	(3.13)	1	(3.13)
<i>Ethnicity</i>													
Hispanic/Latino	12.30	9	(8.26)	3	(4.41)	6	(14.63)	6	(9.38)	3	(9.38)	3	(9.38)
Not Hispanic Combined	87.70	100		65		35		58		29		29	
<i>Not Hispanic/Latino</i>		16	(14.68) ^{***}	10	(14.71)	6	(14.63)	8	(12.50)	4	(12.50)	4	(12.50)
<i>Unknown</i>		84	(77.06)	55	(80.88)	29	(70.73)	50	(78.13)	25	(78.13)	25	(78.13)
<i>Branch, Service</i>													
Active Army	20.00	81	(74.31) ^{***}	46	(67.65)	35	(85.37)	58	(90.63) ^{***}	29	(90.63)	29	(90.63)
Active Navy & Coast Guard	14.80	4	(3.67) [*]	2	(2.94)	2	(4.88)	-		-		-	
Civilian [‡]	24.50	18	(16.51)	15	(22.06)	3	(7.32)	4	(6.25)	2	(6.25)	2	(6.25)
Army Guard and Reserve	27.00	1	(0.92) ^{***}	1	(1.47)	0	(0.00)	-		-		-	
Active Marine Corps	7.50	2	(1.83) ^{***}	2	(2.94)	0	(0.00)	-		-		-	
Veteran	6.10	3	(2.75) ^{***}	2	(2.94)	1	(2.44)	2	(3.13)	1	(3.13)	1	(3.13)
<i>Income</i>													
≥ \$19,000		107	(98.17)	66	(97.06)	41	(100.00)	64	(100.00)	32	(100.00)	32	(100.00)
<i>Education</i>													
Less than Bachelor	76.50	86	(78.90)	55	(80.88)	31	(75.61)	52	(81.25)	26	(81.25)	26	(81.25)
<i>GED</i>		5	(4.59)	3	(4.41)	2	(4.88)	1	(1.56)	1	(3.13)	0	(0.00)
<i>High School Grad.</i>		42	(38.53)	26	(38.24)	16	(39.02)	27	(42.19)	12	(37.50)	15	(46.88)
<i>Some College</i>		16	(14.68)	13	(19.12)	3	(7.32)	9	(14.06)	6	(18.75)	3	(9.38)
<i>Associate Degree</i>		23	(21.10)	13	(19.12)	10	(24.39)	15	(23.44)	7	(21.88)	8	(25.00)
Bachelor Degree	12.90	19	(17.43)	10	(14.71)	9	(21.95)	11	(17.19)	5	(15.63)	6	(18.75)
Master Degree or Higher	8.20	4	(3.67)	3	(4.41)	1	(2.44)	1	(1.56)	1	(3.13)	0	(0.00)
<i>Marital Status</i>													
Married Category	54.30	71	(65.14) [*]	43	(63.24)	28	(68.29)	43	(67.19)	21	(65.63)	22	(68.75)
<i>Married</i>		70	(64.22)	43	(63.24)	27	(65.85)	42	(65.63)	21	(65.63)	21	(65.63)
<i>Separated</i>		1	(0.92)	0	(0.00)	1	(2.44)	1	(1.56)	0	(0.00)	1	(3.13)
Not Married Category	41.60	25	(22.94) ^{***}	19	(27.94)	6	(14.63)	10	(15.63)	6	(18.75)	4	(12.50)
<i>Not Married</i>		24	(22.02)	19	(27.94)	5	(12.20)	9	(14.06)	6	(18.75)	3	(9.38)
<i>Widowed</i>		1	(0.92)	0	(0.00)	1	(2.44)	1	(1.56)	0	(0.00)	1	(3.13)
Divorced	4.60	13	(11.93) ^{***}	6	(8.82) [*]	7	(17.07)	11	(17.19)	5	(15.63)	6	(18.75)

Note. *N* = 3,533,174 military and civilian personnel, *n* = 1,301,443 active duty, *n* = 109 study candidates, *n* = 64 subjects. Goodness of Fit: Age and time in service (TIS) significance was determined using Z-scores two-tailed ($\alpha = .05$). Categorical variable significance was determined using chi-square; when frequencies were < 5, significance was determined via Fisher's Exact test. GED: general education diploma or equivalent. TIS: calculations included patients with TIS (candidates: *n* = 93, male = 75, female = 18; subjects: *n* = 60, male = 54, female = 6). Income: based on rank; if unknown, the candidate was excluded from this calculation. Ethnicity: after all exact matches were exhausted, matches between Not Hispanic/Latino (*n* = 2) and Unknown (*n* = 2) candidates were allowed.

[†]Unless otherwise specified, population references relate to total Department of Defense active duty demographics

[‡]Relates to both military and civilian demographics

Population data: from 2015 *Demographics: Profile of the Military Community*, by Office of the Deputy Assistant Secretary of Defense for Military Community and Family Policy, 2015. Retrieved from <http://www.militaryonesource.mil/12038/MOS/Reports/2015-Demographics-Report.pdf>

p* < .05, *p* < .01, ****p* < .001

APPENDIX G

Characteristics of GAD-7 Scores

Measurement Characteristics	All		Platform		Marital Status		Platform by Marital Status		
	<i>N</i> = 64	TMH <i>n</i> = 32	TAU <i>n</i> = 32	Mar <i>n</i> = 43	NM <i>n</i> = 21	TMH _{Mar} <i>n</i> = 21	TMH _{NM} <i>n</i> = 11	TAU _{Mar} <i>n</i> = 22	TAU _{NM} <i>n</i> = 10
<i>Acuity</i>	10.55 (5.66)	8.85 (4.91)	12.25 (5.91)	11.69 (5.65)	8.22 (5.03)	8.13 (4.98)	10.25 (4.67)	15.10 (3.91)	6.00 (4.63)
Initial	12.05 (5.91) *	10.41 (5.79)	13.69 (5.66)	12.63 (5.46)	10.86 (6.73)	9.57 (5.52)	12.00 (6.21)	15.55 (3.53) **	9.60 (7.37)
Middle	10.39 (5.82)	8.74 (5.03)	12.04 (6.16)	11.69 (5.58)	7.73 (5.52) *	8.05 (4.73)	10.06 (5.57)	15.16 (3.88) ***	5.17 (4.40) **
Last	9.28 (6.88) ***	7.34 (6.22)	11.22 (7.06)	10.95 (7.00)	5.86 (5.29) *	7.10 (6.45)	7.82 (6.03)	14.64 (5.41) ***	3.70 (3.47) **
<i>Change</i>	-2.77 (5.25)	-3.06 (5.45)	-2.47 (5.11)	-1.67 (4.72)	-5.00 (5.68)	-2.48 (5.32)	-4.18 (5.97)	-91 (5.26)	-5.90 (5.72)
Therapy Type	Medication	Medication by Platform	Medication by Marital Status	Medication by Platform by Marital Status	Medication by Platform by Marital Status	Medication by Platform by Marital Status	Medication by Platform by Marital Status	Medication by Platform by Marital Status	Medication by Platform by Marital Status
	<i>k</i> = 37	TMH <i>k</i> = 15	TAU <i>k</i> = 22	Mar <i>k</i> = 29	NM <i>k</i> = 8	TMH _{Mar} <i>k</i> = 10	TMH _{NM} <i>k</i> = 5	TAU _{Mar} <i>k</i> = 19	TAU _{NM} <i>k</i> = 3
<i>Medication</i>									
<i>Acuity</i>	12.52 (5.21) *	10.29 (5.45)	14.03 (4.56)	13.08 (5.29)	10.47 (4.62)	9.47 (5.80)	11.93 (4.83)	14.98 (3.97) *	8.03 (3.73)
Initial	13.78 (5.09)	11.60 (5.65)	15.27 (4.18)	13.83 (4.94)	13.63 (6.00)	10.70 (5.64)	13.40 (5.86)	15.47 (3.70)	14.00 (7.55)
Middle	12.38 (5.24)	10.17 (5.28)	13.89 (4.77)	13.05 (5.26)	9.94 (4.71)	9.16 (5.55) *	12.21 (4.52)	15.11 (3.84) *	5.17 (1.61) *
Last	11.35 (6.81) **	8.93 (7.07)	13.00 (6.26)	12.41 (6.61)	7.50 (6.50)	8.80 (7.27)	9.20 (7.46)	14.32 (5.52)	4.67 (4.16)
<i>Change</i>	-2.43 (5.05)	-2.67 (4.61)	-2.27 (5.44)	-1.41 (4.08)	-6.13 (6.69) *	-1.90 (4.07)	-4.20 (5.72)	-1.16 (4.18)	-9.33 (8.14) *
	Psychotherapy	Psychotherapy by Platform	Psychotherapy by Marital Status	Psychotherapy by Platform by Marital Status	Psychotherapy by Platform by Marital Status	Psychotherapy by Platform by Marital Status	Psychotherapy by Platform by Marital Status	Psychotherapy by Platform by Marital Status	Psychotherapy by Platform by Marital Status
	<i>k</i> = 27	TMH <i>k</i> = 17	TAU <i>k</i> = 10	Mar <i>k</i> = 14	NM <i>k</i> = 13	TMH _{Mar} <i>k</i> = 11	TMH _{NM} <i>k</i> = 6	TAU _{Mar} <i>k</i> = 3	TAU _{NM} <i>k</i> = 7
<i>Psychotherapy</i>									
<i>Acuity</i>	7.86 (5.19) *	8.82 (5.43)	8.34 (6.86)	8.82 (5.43)	6.84 (4.92)	6.90 (4.00)	8.84 (4.44)	15.83 (4.21) **	5.13 (4.96)
Initial	9.67 (6.21)	10.14 (5.84)	10.20 (7.07)	10.14 (5.84)	9.15 (6.79)	8.55 (5.47)	10.83 (6.79)	16.00 (2.65) *	7.71 (6.97)
Middle	7.66 (5.54) *	8.85 (5.31)	7.97 (7.14)	8.85 (5.31)	6.37 (5.70)	7.04 (3.82)	8.27 (6.10)	15.50 (5.07) *	4.75 (5.24)
Last	6.44 (6.01) **	7.93 (7.04)	7.30 (7.44)	7.93 (7.04)	4.85 (4.38)	5.55 (5.48)	6.67 (4.97)	16.67 (5.13) *	3.29 (3.40)
<i>Change</i>	-3.22 (5.58)	-2.21 (5.96)	-2.90 (4.56)	-2.21 (5.96)	-4.31 (5.14)	-3.00 (6.40)	-4.17 (6.40)	0.67 (3.21)	-4.43 (4.31)

Note. *N* = 64 subjects (*N* = 391 visit scores, *vTMH* = 230, *vTAU* = 161). *k*: subjects by therapy type. GAD-7: Generalized Anxiety Disorder 7-item scale. TMH: telemental health. TAU:

treatment as usual. NM: Not married. Mar: married. Med: medication. Ther: psychotherapy. Goodness of fit (GOF): z-scores, two-tailed ($\alpha = .05$). Acuity: an average of all GAD-7 scores.

Subject therapy type acuity Gof was calculated using all subject acuity for comparator values. Initial score Gof was determined using the respective acuity for comparator values. Subject therapy type subscores (middle and last) were calculated using the respective therapy type initial GAD-7 scores for comparator values. Therapy type change Gof was calculated using overall change for comparator values. Gof for all other values used the respective values in the subject column for comparator values. Therapy type acuity: mean of all GAD-7 scores for the specified condition.

Treatment course: GAD-7 scores for the specified condition during the eligible treatment episode. Initial: mean of all initial GAD-7 scores. Middle: mean of all GAD-7 scores between initial and last GAD-7 scores. Last: mean of the final GAD-7 scores recorded during the treatment episode. Change: the mean of the differences between first and last GAD-7 scores during the eligible treatment episode.

* $p < .05$, ** $p < .01$, *** $p < .001$

APPENDIX H

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APPENDIX I

Institutional Review Board Determination



DETERMINATION OF EXEMPT STATUS

March 30, 2018

Dear Jeffrey S. Tebbs:

On 3/30/2018, the University of Washington Human Subjects Division (HSD) reviewed the following application:

Type of Review:	Initial Study
Title of Study:	Telemental Health Videoconference Treatment of Anxiety Disorders
Investigator:	Jeffrey S. Tebbs
IRB ID:	STUDY00004336
Funding:	None

Exempt Status

HSD determined that your proposed activity is human subjects research that qualifies for exempt status (Category 4).

- This determination is valid for the duration of your research.
- This means that your research is exempt from the federal human subjects regulations, including the requirement for IRB approval and continuing review.
- Depending on the nature of your study, you may need to obtain other approvals or permissions to conduct your research. For example, you might need to apply for access to data (e.g., to obtain UW student data). Or, you might need to obtain permission from facilities managers to approach possible subjects or conduct research procedures in the facilities (e.g., Seattle School District; the Harborview Emergency Department).

If you consider changes to the activities in the future and know that the changes will require IRB review (or you are not certain), you may request a review or new determination by submitting a Modification to this application. For information about what changes require a Modification, refer to the [GUIDANCE: Exempt Research](#).

Thank you for your commitment to ethical and responsible research. We wish you great success!

Sincerely,
Johanna Salmonson
Reliance Administrator
206.543.4464
salmoj@uw.edu

Institutional Review Board Determination (continued)



DEPARTMENT OF THE ARMY
 REGIONAL HEALTH COMMAND-PACIFIC
 INSTITUTIONAL REVIEW BOARD
 9040 JACKSON AVENUE
 TACOMA WA 98431-1100

MCHJ-CLI (IRBO)

13 August 2018

MEMORANDUM FOR Eileen L. Poupore, DNP, Army - Madigan Army Medical Center (MAMC)

SUBJECT: RHC-P IRB Expedited Approval of Research Project

TITLE: Telemental Health Treatment of Anxiety Disorders

PROTOCOL #218115

1. The subject project has been reviewed for compliance with applicable human subject protection regulations by the Regional Health Command-Pacific IRB. The primary objective of the study is to both compare VC TMH and in-person mental health care outcomes, and examine end-user characteristics that may help tailor future interventions designed to improve mental health care. There are no outstanding human research protections issues to be resolved.

2. In accordance with 32 CFR 219.110 (b)(1), the project may be approved by expedited review because it involves no more than minimal risk and is included in the categories of research listed in the 9 November 1998 Notice in the Federal Register (63 FR 60364-60367) that may be reviewed by the IRB through an expedited review procedure, specifically category 5. The following documents were reviewed by the IRB:

Submission Components			
Form Name	Version	Outcome	
Review Response Submission Forms	Versions 2.0, 1.0	Acknowledged	
EIRB Protocol Template	Version 1.3	Approved	
Study Document			
Title	Version #	Version Date	Outcome
Waiver HIPAA Authorization	Version 1.1	08/13/2018	Approved
Master Key	Version 1.0	05/04/2018	Approved
Data Collection	Version 1.0	05/04/2018	Approved
Impact Statement-Nursing	Version 1.0	02/20/2018	Acknowledged
Letter of Support-Department of Behavioral Health-MAMC	Version 1.0	02/01/2018	Acknowledged
PI Compliance Statement	Version 1.0	03/05/2018	Acknowledged

VITA

The author of this dissertation specialized as a psychiatric nurse in 2002 and served as the head nurse of an inpatient psychiatric unit from 2004 to 2006. He became a Psychiatric-Mental Health Nurse Practitioner in 2008 and worked with a high-risk Army trainee population from 2008 to 2010. He then directed a combat stress control team in Mosul, Iraq. Upon return from deployment, he was appointed as inpatient attending provider with additional consultation liaison service and outpatient cross-coverage duties at Madigan Army Medical Center in Tacoma, Washington. In 2011, prior to retirement from active military duty, he designed, implemented, and directed a hospital-wide behavioral health triage program. In 2012, he returned to work for the Army as a civilian, supervising nurse practitioner, stood up a new behavioral health clinic and piloted a telepsychiatry service to remote Department of Defense sites in various states. In 2013, he entered private practice in Olympia, Washington. While building this practice, he returned to the University of Washington to complete a Doctor of Nursing Practice degree in 2016. The author first published on the topic of TMH in the *Journal of Clinical Nursing* in 2016. He presented his DNP capstone project on TMH referral process adherence at national military medical conferences (AMSUS and MHSRS) in 2017 and in 2018 he published a manuscript detailing this performance improvement effort in *Military Medicine*. Most recently, he collaborated on the telehealth portion of a manuscript reviewing eHealth literacy. This manuscript is presently under review.

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