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## Implementation of a Follow-Up Procedure for Patients Treated with Transcranial Magnetic Stimulation at a Primary Care Clinic

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UNIVERSITY OF SAN DIEGO

Hahn School of Nursing and Health Science

Beyster Institute of Nursing

Implementation of a Follow-Up Procedure for Patients Treated with Transcranial Magnetic

Stimulation at a Primary Care Clinic

by

Brooke R. Marino, BSN, RN

A Doctor of Nursing Practice Portfolio presented to the

FACULTY OF THE HAHN SCHOOL OF NURSING AND HEALTH SCIENCE

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DOCTOR OF NURSING PRACTICE

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My Hanh (Theresa) Nguyen, PhD, PMHNP-BC, Faculty Advisor

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### Abstract

**Background:** Depression is one of the most common mental disorders in the United States. In 2020 alone, an estimated 21 million adults experienced at least one depressive episode, representing 8.4% of all U.S. adults. Transcranial magnetic stimulation (TMS) therapy is a cutting-edge option for treatment-resistant depression, and up to 70% of patients treated with TMS will achieve at least a 50% reduction in depression symptoms. For some, these results are long-lasting; for others, depression symptoms may return. For those who experience return of their depression symptoms, more TMS may be necessary. Currently, there is no standardized follow up procedure after patients finish a course of TMS to assess the need for more treatment sessions.

**Purpose of Project:** The purpose of this project is to implement a follow-up procedure for patients who are treated with TMS therapy.

**PICO(T):** How does implementing a standardized follow up procedure utilizing the PHQ-9 depression screening tool help to identify patients who need to return for retreatment or maintenance treatment 3 months after a course of TMS therapy?

**Methods:** The DNP student collaborated with the patient care team to implement a new follow-up procedure to identify patients who met criteria for maintenance treatment 3 months after their initial course of TMS. The procedure included administering the PHQ-9 depression screening tool, along with a telephone follow-up. Patients were considered for retreatment if the criteria for nonresponse was met (< 25% reduction in PHQ-9 score) or maintenance treatment if their 3-month PHQ-9 score and telephone interview indicated symptom relapse.

**Results:** Twelve patients were identified for follow-up. Three months after completing a course of TMS (40 sessions over the course of 5 days), 100% of patients filled out the PHQ-9 and 75%

agreed to a follow-up phone call. Two patients were identified for further treatment.

**Implications for Clinical Practice:** Patient follow-up after a course of TMS can lead to early identification of depression symptoms, therefore leading to better patient outcomes.

## **Implementation of a Follow-Up Procedure for Patients Treated with Transcranial Magnetic Stimulation at a Primary Care Clinic**

Major depressive disorder (MDD) is one of the most common mental disorders in the United States and is the leading cause of disability in Americans aged 15 to 44 (U.S. Department of Health and Human Services, 2022). In 2020, approximately 14.8 million adults in the United States aged 18 or older had at least one major depressive episode with severe impairment in the past year, representing 6.0% of all U.S. adults (HHS, 2022). Depression is associated with many costs, both financial and nonfinancial. In 2020, the economic burden of MDD was estimated to be \$326.2 billion (Greenberg et al., 2021). Potentially greater than the economic burden of depression is the intangible burden: the toll it takes on an individual's ability to function.

A major depressive episode is classified by the symptoms of depressed mood and anhedonia lasting at least 2 weeks. These symptoms are often accompanied by low motivation, changes in sleep and appetite, decreased concentration and focus, and/or suicidal ideation. Symptoms of MDD can present at any time across the lifespan. In 2020, approximately 66% of U.S. adults with major depressive episode received treatment for their depression through psychotherapy, medications, or other modalities (HHS, 2022).

Currently, first-line treatments for major depressive disorder include antidepressant monotherapy, psychotherapy, or the combination of both. Approximately half of adults who experience a depressive episode will receive treatment with medication (Zhdanova et al., 2021). Several large-scale clinical trials have evaluated treatment outcomes using the traditional approaches for treatment of MDD (Voineskos et al., 2020). The widely recognized Sequenced Treatment Alternatives to Relieve Depression (STAR\*D) trial, the largest prospective clinical trial of treatments for major depressive disorder, found cumulative remission rates after four

trials of antidepressant medications to be 67% (Rush et al., 2006).

Although antidepressant medications can be very effective in treating MDD for many, approximately one in three patients who are treated with antidepressants will fail to achieve remission. Once two trials of antidepressant medications of adequate dose and duration have been unsuccessful, the illness can be classified as treatment-resistant depression (TRD) (Zhdanova et al., 2021). Once the illness is considered treatment-resistant, there are several options that can be considered. One option is augmentation, where an additional medication that is not classified as an antidepressant is added to a first-line pharmacotherapeutic option. Some adjunctive options include lithium, triiodothyronine (T3), and second-generation antipsychotic medications (Voineskos et al., 2020). Another option is the pursuit of psychotherapy in addition to antidepressant medications. Some psychotherapeutic approaches include cognitive behavioral therapy, interpersonal therapy, dialectical behavioral therapy, and short-term dynamic psychotherapy. A third option for TRD is brain stimulation, which is the focus of this DNP project. Specifically, this manuscript will discuss a type of brain stimulation called transcranial magnetic stimulation (TMS) therapy.

### **About TMS**

TMS, originally designed to be a neurodiagnostic tool, was first introduced in 1985 by Anthony Barker at the University of Sheffield in England. Multiple studies from researchers around the world since the introduction of TMS in 1985 have repeatedly demonstrated that TMS has antidepressant effects greater than sham treatment, and that these effects are clinically meaningful. A large industry-sponsored trial, published in 2007, resulted in the U.S. Food and Drug Administration (FDA) approval in October 2008 for the treatment of adult patients with MDD (Cohen et al., 2021). Since 2008, TMS has been FDA-approved to treat obsessive



compulsive disorder, anxious depression, migraine headaches, and smoking cessation; current research is showing promising results for the use of TMS in the treatment of bipolar disorder, post-traumatic stress disorder, tinnitus, autism spectrum disorder, and Alzheimer's disease, along with many other disorders.

A typical TMS treatment course consists of daily TMS sessions 5 days per week for 6-8 weeks. Some clinics provide accelerated TMS, which describes a regimen in which patients receive more than one treatment per day (up to 10 daily treatments) over a shorter period of time (usually 1 to 2 weeks). TMS is very efficacious, with treatment response rates (defined as a  $\geq$  50% reduction in depression symptoms) up to 70% and remission rates up to 50%.

Clinics providing TMS differ in the screening tools used to assess depressive symptoms. Some commonly used screening tools include the Patient Health Questionnaire (PHQ-9), Inventory of Depressive Symptomatology-Self Report (IDS-SR), Hamilton Rating Scale for Depression (HAM-D), and Beck's Depression Inventory (BDI). In most clinics, patients are screened prior to the initiation of treatment. Depending on clinic protocol, patients are also screened daily or weekly throughout the duration of treatment to assess progress. When it comes to follow-up after the completion of treatment, there are not well-defined procedures. Some clinics will call patients to check in; others will wait until patients contact the clinic. The Clinical TMS Society recommends that patients have regular follow-ups with the treating clinician after treatment and suggests that some patients may benefit from maintenance TMS if symptoms reemerge. However, the specific protocols chosen for maintenance treatment vary between clinics and providers and are based on patients' individual symptom presentation.

### **Literature Review**

A literature review was conducted to inform this project. Electronic databases utilized for

this project included PubMed, PsycINFO, Cochrane, and CINAHL. Keywords used for this search included: *transcranial magnetic stimulation, TMS durability, TMS retreatment, TMS outcomes, major depressive disorder, TMS treatment response, treatment-resistant depression, and TMS follow-up.*

Dunner et al. (2014) evaluated the durability of benefit of TMS over a 1-year follow-up period. In this study, adult patients with the primary diagnosis of MDD received TMS in 42 clinical practices. Two hundred fifty-seven patients completed the primary series of TMS and consented to a 1-year follow-up; two hundred five patients ended up completing 12 full months of follow-up. Assessments were obtained at 3, 6, 9, and 12 months using the Clinical Global Impressions-Severity of Illness Scale (CGI-S), PHQ-9, and IDS-SR. For the CGI-S, response was defined as a rating of 3 or less and remission was defined as an endpoint rating of 2. For the PHQ-9, response was defined as a score less than 10 and remission was defined as a score less than 5. For the IDS-SR, response was defined as a  $\geq 50\%$  reduction from baseline rating and remission was defined as a score  $< 15$  (Dunner et al., 2014). After 1 year, 62.5% of the patients who initially responded or remitted continued to meet response criteria. Of those who did not maintain a sustained response, symptom reemergence tended to occur during the first 6 months after treatment. Notably, 32% of patients in this study who met protocol-specified criteria for symptom recurrence had TMS reintroduced. All maintenance TMS was done at least 2 months after the initial course of treatment (Dunner et al., 2014). This study shows that treatment response is long-lasting for most patients, but not all of them. I used this study to help me choose a timeline for follow-up screening and as guidance for maintenance treatment for patients who were nonresponders or experienced symptom reemergence following an initial course of TMS.

Senova et al. (2018) performed a systematic review of studies that reported

antidepressant outcome measures collected 3 or more months after the end of a course of TMS for depression. In this review, they used a meta-analytic approach to assess TMS patient response rates 3 months, 6 months, and 12 months after treatment. Nineteen studies were included in this review, with a total of 732 patients. Results showed that among patients who initially responded to TMS, 66.5% sustained antidepressant response 3 months posttreatment, 52.9% 3 months posttreatment, and 46.3% 12 months posttreatment (Senova et al., 2018). This review shows that there can be variation in the durability of treatment effects in different individuals, and I used this study as support for the need for follow-up care after TMS treatment.

Arici et al. (2020) conducted a follow-up study on response and relapse rates following an acute trial of TMS in patients with major depression. In this study, 31 drug-resistant depressed patients were followed for 6 months. Psychometric scales to assess treatment response over time included the HAM-D, Hamilton Anxiety Scale (HAM-A), and CGI-S. These scales were administered at 1, 3, and 6 months posttreatment. 64.5% of patients were acute responders, and the remaining 35.5% of patients were evaluated for the occurrence of delayed response. Of the remaining patients who were not acute responders, 64% of them showed response during the follow-up period and were classified as late responders. During the 6-month follow-up period, 10% of the acute responders in this study experienced symptom relapse (Arici et al., 2020).

In a study by Donse et al. (2018), the effects of TMS combined with psychotherapy were analyzed. One hundred ninety-six patients with MDD were treated with at least 10 sessions of rTMS and psychotherapy. Results showed that combining rTMS and psychotherapy resulted in an initial 66% response and 56% remission rate. Seventy-three patients completed the BDI and Depression Anxiety Stress Scales (DASS) at a 6-month follow-up. Out of initial responders, 65.2% retained response at follow-up. Six months after treatment completion, 60% of acute

remitters still met remission criteria. Conclusions from this study showed that TMS plus psychotherapy resulted in relatively high response and remission rates when compared to findings in previous randomized controlled studies (Donse et al., 2018). This study was unique and relevant to my project because the patients treated with TMS at Kind Health Group were receiving daily psychotherapy for the duration of their treatment.

Currently, there is no existing standard of care for maintaining clinical benefit following a successful initial course of TMS. Existing literature provides strong support for the safety and efficacy of maintenance treatment or retreatment following an initial treatment series but suggests that there is significant variation in protocols for maintenance treatment. Protocols used for maintenance TMS are mainly supported by prospective open trials and case series (Wilson et al., 2022). In 2019, Fukuda et al. aimed to characterize the course and outcomes of retreatment for treatment-resistant depression in a naturalistic setting. In this study, data from patients with MDD who received TMS at Butler TMS clinic from 2009 to 2018 was analyzed. Cases of patients who received an initial course of TMS with clinical benefit and then returned to receive 10 or more sessions in a repeat course of TMS were included for analysis. Outcome measures included the PHQ-9 and the Inventory of Depressive Symptoms Self-Report (IDSSR). These scales were administered at baseline (prior to treatment starting) and posttreatment. Results showed that retreatment successfully relieved symptoms in most of the patient cases, with about half of the patients who were retreated returning to their prior level of improvement. Retreatment response rates via PHQ-9 and IDSSSR were 73.8% and 59.5%, respectively. Approximately 57% of patients remitted when applying criteria from either the PHQ-9 or IDSSR. The degree of improvement during the initial course of TMS was significantly associated with retreatment improvement, and initial remission was correlated with retreatment remission (Fukuda et al.,

2019). The results of this study suggest that TMS retreatment after symptom recurrence or relapse is a viable option to consider for those who have a clinically meaningful response to an initial course of TMS and informed my project by providing insight into what treatments should be offered to patients who were nonresponders or experienced symptom relapse.

### **PICO(T) Question**

How does implementing a standardized follow-up procedure utilizing the PHQ-9 depression screening tool help to identify patients who need to return for retreatment or maintenance treatment 3 months after an initial course of TMS therapy?

### **Methods**

#### **Project Approval**

The chief medical officer (CMO) of Ampa, the TMS company partnered with Kind Health Group, wrote a letter of support approving this DNP project. The letter of support, along with a letter from the student's clinical faculty member, was then presented to the University of San Diego's Institutional Review Board, and approval to begin the project was received.

#### **TMS Treatment Course**

Patients were treated using TMS at Kind Health Group, a concierge primary care clinic. Patients received eight treatments each day over the course of 5 days, for a total of 40 treatments. During the treatment week, patients worked with a team that included a physician, a TMS technician, a health coach, and the DNP student. The patients received daily psychotherapy along with TMS treatment.

#### **Evidence-Based Intervention**

The DNP student piloted a standardized follow-up procedure which included assessing depression severity using the PHQ-9 depression screening tool and a phone call 3 months after

the completion of TMS treatment. The PHQ-9 is a valid and reliable screening tool used to assess the severity of depression. The nine questions involved in this screen are based on the DSM-IV criteria for depression. Each criterion is scored from “0” (not at all) to “3” (nearly every day; Kroenke et al., 2001). To measure severity, the final score can range from 0 to 27. A score of 0-4 indicates no depression-minimal depression, 5-9 indicates mild depression, 10-14 indicates moderate depression, 15-19 indicates moderately severe depression, and 20-27 indicates severe depression (Kroenke et al., 2001).

The PHQ-9 was used to assess each patient’s depression symptoms over time. Patients were sent the PHQ-9 screening tool prior to starting treatment, 1, 2, and 3 months after the completion of treatment. The forms were sent through Kareo, a HIPAA-compliant electronic health record. Three months after treatment completion, the DNP student analyzed each of the PHQ-9 forms sent to the patients. Then, the DNP student conducted follow-up phone calls with the patients to further assess their depression symptoms. During the phone call, the DNP student asked the following set of questions, which are based on the current American Psychiatric Association practice guidelines for the treatment of patients with MDD:

1. Since completing treatment, have you met with health coaches?
2. What changes have you noticed since completing treatment, if any?
3. Are you still taking any medications?
4. Are you noticing the return of any of your symptoms?
5. At this time, do you feel like you could benefit from more TMS sessions?

Patients were classified as nonresponders if their 3-month score on the PHQ-9 was < 25% decrease in score from baseline (pretreatment) score. Patients were considered to have relapsed if their depressive symptoms returned after having gone away in the acute period after treatment.

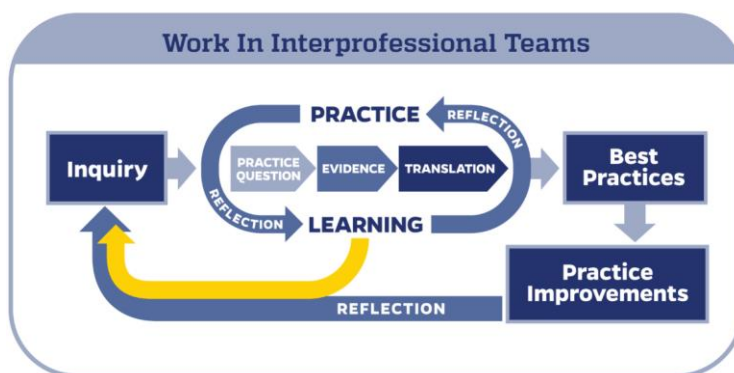
For those who met criteria for nonresponse or relapse, a plan to reintroduce TMS for maintenance treatment was made based on the individual's symptom presentation.

### Evidence-Based Practice Model

The Johns Hopkins evidence-based practice model was used as the framework for implementation of this EBP project. This model uses a three-step process known as PET (Practice Question, Evidence, and Translation) to guide the EBP process. In the first step, the EBP question is identified. In the second step, the individual or team appraises the evidence. In the third step, the evidence is translated to practice. This model was chosen due to its emphasis on individual use, along with its straightforward approach to guide practice changes.

**Figure 1**

*Evidence-Based Practice Model*



### Data Analysis and Evaluation Plan

#### Presentation of Outcomes

Twelve patients were identified for this project. Each patient completed the PHQ-9 screening tool prior to treatment and 3 months posttreatment. Additionally, 75% of patients agreed to have a follow-up phone call with the DNP student.

After comparing each individual patient's initial PHQ-9 scores with their 1-month and 3-month scores and conducting follow-up phone interviews, two patients were identified for

further treatment. The first patient had an initial PHQ-9 score of 7. One month after completion of TMS, the PHQ-9 score was 4. Three months post-treatment, the patient's PHQ-9 score increased to 10, indicating a relapse of depression symptoms and "moderate" depression. Upon assessment using the above follow-up questions, the patient reported significant limitations in functioning due to the return of their depression symptoms which included decreased concentration, loss of motivation, and difficulty sleeping.

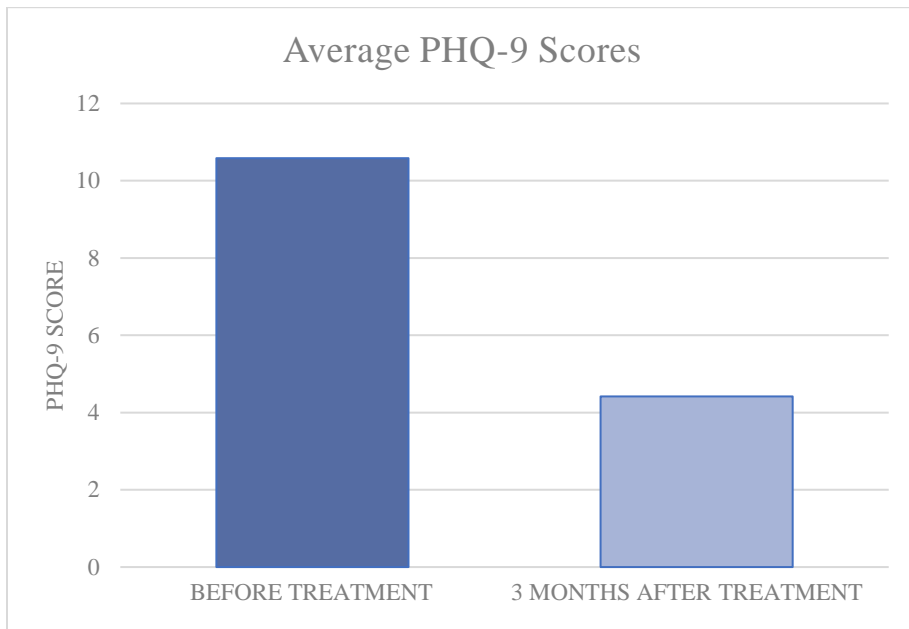
The second patient had a PHQ-9 score of 7 prior to the start of treatment. Three months after completion of treatment, the PHQ-9 score was 8. Based on these scores, the patient was classified a "nonresponder" to TMS and was identified for further treatment. When the DNP student conducted a follow-up phone call with this patient, subjective reports confirmed that the patient did not notice any improvements in their functioning since completing TMS. Of note, this patient had co-occurring diagnoses of generalized anxiety disorder and post-traumatic stress disorder. The patient did not notice improvements in any related symptoms following treatment with TMS. If this patient returns for treatment, they will likely be treated with a different TMS protocol (orbitofrontal instead of the standard dorsolateral prefrontal cortex treatment).

After collecting PHQ-9 scores and following up with the patients over the phone, the DNP student discussed the above findings with the physician and other care team members involved. The patients were contacted, and a plan was put into place to initiate further treatment.



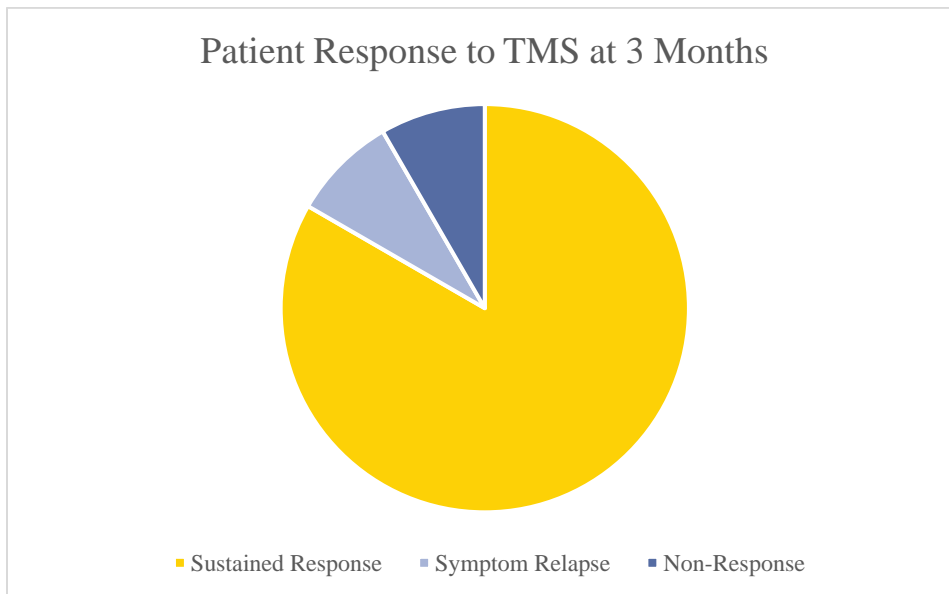
**Figure 2**

*Average PHQ-9 Scores Prior to Treatment versus 3 Months Posttreatment*



**Figure 3**

*Patient Response to TMS at 3 Months*



**Sustainability Plan**

Kind Health Group has decided to adopt this follow-up procedure for all patients treated with TMS. PHQ-9 screening tools will be sent to patients by the physician 1, 2, 3, and 6 months following treatment completion. Additionally, staff will conduct monthly follow-up phone calls or in-office visits with patients to discuss patient progress and most current symptoms.

**Cost-Benefit Analysis**

Since the PHQ-9 screening tool was sent to each patient virtually and the person conducting the follow-up interviews with the patients was the DNP student, the cost of implementing this follow-up procedure was zero. If continued by a PMHNP in the future, the main associated cost would be the PMHNP's salary. Each follow-up interview took approximately 20 minutes, so if a PMHNP had a \$90/hour salary, the cost per patient would be \$30. In this specific clinic, insurance was not billed, but if this intervention were to be introduced into a clinic that accepts Medicaid, the insurance could be billed for a 99213 E/M code for follow-up, which would be approximately a \$100 reimbursement per patient.

The benefits of implementing this project far outweigh the costs. The economic burden of depression in the United States is steadily increasing over time as the number of people with depression increases. From 2010 to 2018, the incremental economic burden of adults with Major Depressive Disorder increased by 37.9%. In 2020, the economic burden of MDD in the United States totaled \$326.2 billion (Greenberg et al., 2021). In 2018, 35% of costs were attributable to direct costs, 61% to workplace costs, and 4% to suicide costs (Greenberg et al., 2021). On average, the direct excess costs for an individual with depression range from \$1000 to \$2500, indirect costs—mostly made up of workplace costs—range from \$2000 to \$3700, and mortality costs range from \$200 to \$400 (Thilina & Yadurshini, 2020).

## Discussion

### Challenges

One challenge to completion of this project was the timeline for follow-up. When this project was created, the original plan was to follow up with patients for 6 months. However, this timeline had to be condensed in order to evaluate outcomes because patients were only treated with TMS at Kind Health Group once every 2-6 weeks. Additionally, only four patients could be treated in any given treatment week due to the limitation of only having a single TMS device, which reduced the number of patients that the DNP student was able to follow up with. Moving forward, patients treated with TMS at Kind Health Group will be followed up with for a longer duration of time.

A second challenge to this project was patient engagement for follow-up, both filling out PHQ-9 scales and over the phone. Eventually, all 12 patients filled out PHQ-9 scales, but it took multiple reminders for some of them. After multiple text messages and e-mails sent to request a phone call with patients, 3 patients did not respond at all, limiting the DNP student's ability to gather subjective data from those patients. For the patients who did agree to a follow-up phone call, it was difficult to schedule time to talk with some of them based on their complex and busy schedules. One solution to this problem could be to follow up with the patients immediately before or after their 3-month visit with the health coach so that they do not have to schedule an additional appointment on a different day.

Third, there is a major limitation in this DNP project. This project's evaluation is based on patients' symptoms of depression, but many of the patients had co-occurring diagnoses such as GAD and PTSD. When conducting phone calls with the patients, some reported that

symptoms related to their other disorders had improved, but that their milder depression symptoms had not changed.

### **Implications For Clinical Practice**

Implementing depression screening in clinics providing TMS can improve identification of depression symptoms following a course of treatment. Early symptom identification and subsequent early treatment leads to better patient outcomes. Therefore, TMS clinics should aim to improve patient follow-up in the months following TMS treatment. Psychiatric nurse practitioners are adequately trained and well-equipped to follow up with patients following TMS therapy.

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