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Using Mobile Health to Improve Mild Depression Outcomes in Adult Primary Care

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Abstract

Background: Mild depression is a common patient complaint in primary care, potentially impairing role function in multiple dimensions, at high emotional and economic cost to individuals, families, and society. Barriers to care include lack of access to Mental Health Specialists, financial constraints and stigma, all of which can cause escalation of symptoms to the point of disability and are magnified in underserved populations.

Purpose: The primary goal of this quality improvement (QI) project was to improve depression symptoms using the evidence-based mobile app *IntelliCare* to deliver Cognitive Behavioral Treatment (CBT) as part of an eight-week treatment protocol.

Methods: Mildly depressed adult primary care patients (PHQ-9 score 5-9) meeting inclusion criteria were asked to participate in an eight-week collaborative protocol in which they used the IntelliCare app at least weekly. Bi-weekly questionnaires were administered assessing patient symptoms, app usage and patient concerns. A post-intervention PHQ-9 was done at eight-weeks.

Results: The majority of participants (67%) completed the protocol with a 53% improvement in post-intervention PHQ-9 scores which was statistically significant based by Wilcoxon Matched-Pairs analysis ($p<0.01$).

Implications to Practice: Willingness of patients to use the mobile health app IntelliCare with improvement in their depression symptoms support further study of its use in practice.

Conclusion: Evidence-based mobile apps such as IntelliCare as part of a treatment plan for mild depression may help decrease barriers to treatment for depression and improve patient outcomes.

***Keywords*:** depression, primary care, mobile apps, telehealth, adults

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Introduction

The World Health Organization (WHO) ranks unipolar depression as the 11th leading cause of disability and mortality in the world, with primary care clinicians administering treatment 67% of the time through pharmacotherapy, counseling, or a combination of both (Murray et al., 2010). Unipolar depression is the most prevalent mental health problem across the globe and is responsible for "10 million disability-adjusted life years lost" annually in the U.S. at a dollar cost in the billions yearly (Collins et al., 2011). Treatment as usual (TAU) consisting of assessment, counseling, and pharmacotherapy if indicated, followed by a period of "watchful waiting" and reevaluation of patient's symptomatology at a later date. Collaborative care including referral to a mental health specialist (MHS) as well as primary care follow-up has been shown to improve outcomes compared to TAU but is limited by multiple barriers including lack of access to specialists, which is magnified in underserved populations; expense, stigma, and unwillingness on the part of the patient to be referred.

According to the DSM-5 (2013), Unipolar Depression, or Major Depressive Disorder (MDD), is a common and serious medical illness that negatively affects an individual, with symptoms ranging from mild to severe, with increased risk for suicidality. In 2016 suicide was the 10th leading cause of death in the U.S., and the fourth leading cause in adults between the ages of 35 and 54 according to the National Institute of Mental Health (NIMH, 2016). Inadequately treated mild depression can escalate to severe MDD, with risk for suicidality, significant comorbidity, psycho-social and physical impairment, and role dysfunction and disability, at high personal and financial cost to the individual and society. Estimated treatment costs of depression in the U.S. are estimated to be as much as 60 billion per year, and do not

include costs related to days absent from work or the intangible negative effects on role function, educational achievement, and family structure (Insel, 2011).

Barriers to adequate treatment of mild depression include lack of access to clinicians, fear of being stigmatized, geographical, time and financial constraints (Kessler, 2012). All of these are magnified in minority and underserved populations, increasing the risk for greater health care disparities with negative outcomes, and emphasize the need to implement effective, evidence-based, accessible treatment plans utilizing all available resources, including mobile-health technology.

Background

In the U.S., major depression ranks second among all diseases and injuries as a cause of disability, with a high percentage of depressed outpatients being treated by primary care clinicians as compared to psychiatrists (Gaynes, 2017). Unipolar depression is described as a continuum of symptoms ranging from subclinical, mild, and moderate to severe major depression. According to the DSM-5 (2013), criteria for MDD include depressed mood or loss of interest or pleasure in daily activities for two weeks or more; impaired social, occupational or educational functioning; and specific symptoms of depressed mood including significant weight change or change in appetite, insomnia or hypersomnia, psychomotor agitation or retardation, fatigue or loss of energy; inappropriate guilt or worthlessness, and diminished ability to concentrate or indecisiveness, and suicidality. Mild depression is defined as two to four of these symptoms, experienced for a two-week period, along with distress or psychological impairment (Lyness, 2018).

Lifetime prevalence of unipolar depression is estimated to be 12% in the general population, and up to 20% in the chronically ill (Gaynes, 2017). The WHO ranks MDD as the

fourth leading cause of disability worldwide with higher prevalence in economically advantaged nations and predicts that by 2020 it may be the second (Kessler, 2012). In primary care, where there is a high rate of chronic comorbid medical conditions, effective care for depression is critical, and often limited by patient perceived treatment stigma, discontinuation of prescribed anti-depressant medications, deficits in provider skills related to treatment, financial and time constraints on the part of patients, transportation issues, and limited access to mental health specialists (Kessler, 2012). These problems may be magnified in underserved elderly, minority, or low-income populations (Marshal et al., 2011).

Presentation of Mild Depression

The majority of patients experiencing symptoms of mild depression first present to their PCP, with treatment as usual (TAU) consisting of interview and evaluation to rule out underlying pathology, followed by "watchful waiting" for several weeks to ensure that symptomatology is not worsening, and/or pharmacotherapy. An effective adjunct to TAU is Cognitive Behavioral Therapy (CBT), which is the most researched form of treatment for adult depression and has been shown to be more effective than pharmacology alone (Cuijpers et al., 2013). The goal of CBT is to reduce the negative emotional impact of unpleasant thoughts with more realistic and adaptive ones by first identifying them, reappraising them, then challenging the negativity and replacing it with more accurate and adaptive reasoning. The initial thoughts are then re-evaluated and the intensity of the emotions regarding them is rated. This process is repeated for different situations leading to more rational and adaptive thinking, and less negative reality and self-perception, which helps to break the cycle of depression (Beck, 1997).

Collaborative Care Treatment Model

Collaborative care is a treatment model which integrates TAU with CBT administered by a mental health specialist (MHS) and has been demonstrated to be effective in depression treatment (Gaynes, 2017). It can be used in primary care as part of a structured treatment plan that may involve pharmacotherapy, scheduled office visits, and measurement-based care (Gaynes, 2017). Meta-analyses of practice models utilizing collaborative care have been shown to be superior to pharmacotherapy alone, and lower risk of maladaptive behaviors including drug and alcohol abuse, suicidal ideation, and days missed from work (Lyness, 2018). Treatment goals are decreased depressive symptoms, improved general functioning, and prevention of severe MDD. As previously discussed, due to barriers to care, access to traditional collaborative care is often limited. The burden of inadequately treated mild depression in primary care not only results in economic hardship for individuals, families, society, and the healthcare system, but intangible costs which put patients and their families at greater risk for negative outcomes in terms of life goals, family structure, educational achievement, susceptibility to drug abuse, etc., and emphasizes the need for innovative, alternative, evidence-based treatments.

Mobile Health

Advances in technology and the widespread adaptation of "smart-phone" usage in all socio-economic and isolated areas of our society have created a new, potential means for engaging patients with mild depression in collaborative treatment through evidence-based therapy platforms. According to PEW research, as of 2015 64% of all U.S. adults own a smart-phone and use it regularly (Smith, 2015). Rates of smartphone ownership and use are high within low-income populations, which can enable the traditionally underserved to access mental health support via mobile app (Lui, J., & Marcus, D., 2017). One in five smart-phone owners report having a health-related app downloaded to their phone, of which at least seven percent

target mental health (Rainie & Perrin, 2017). Data supporting usage of mobile apps in depression treatment includes a 2015 meta-analysis of effectiveness of psychological treatments for depression in primary care, by Linde, et al., in which remote guided self-help utilizing CBT was shown to yield outcomes similar to face-to-face encounters with mental health providers. In 2016 the American Medical Association (AMA) published a newsletter in support of the use of mobile apps that "have a clinical evidence base to support their use" (AMA, 2016). A recently published study reviewing utilization of mobile apps in behavioral health recommended them as evidence-based approaches to depression treatment to improve access and outcomes, and defined core principles that can be used to guide care including team-based, evidence-based, measurement-based, and population-based (Raney, Bergman, Torous & Hasselberg, 2017).

The principle of using measurement to define depression level as compared to symptom description is recommended by the U.S. Preventive Services Task Force, who released a statement in 2016 supporting depression screening measurement for all adults, using a validated instrument such as the PHQ-9 (USPSTF, 2016). The PHQ-9 (Appendix A) can be used to measure symptoms of depression in primary care patients and provide a baseline for comparison of pre-post intervention quality outcomes. The instrument can be used without permission. Annual depression screening in the 12 and older population is one of the quality metrics recommended by the USPTFS (2015) for primary care providers (PCP's), thereby created an impetus to incorporate such measures in primary care and will be utilized in this QI project.

Purpose Statement

Risk of role dysfunction and disability in inadequately treated mildly depressed adult primary care patients, as indicated by worsening PHQ-9 scores due to decreased access to treatment, can be effectively addressed by patient usage of an evidence-based mobile mental

health app as an adjunct to care. The purpose of this DNP project is to implement a guided treatment protocol for mild depression in primary care utilizing IntelliCare, an evidence-based mobile app, as an adjunct to treatment, with the goal of increasing access to care and improving outcomes.

Organizational "Gap" Analysis of Project Site

The project site was an adult primary care practice on the East Coast where approximately five to ten percent of patients seen daily present with symptomatology of depression. There was no protocol in place for management of depression, and measures such as the PHQ-9 were not routinely used. There was no universal standard for follow-up, and outcomes regarding effectiveness of treatment were not measured. Due to the serious health consequences of inadequately treated mild depression and its prevalence in this patient population, this quality improvement (QI) project consisted of an eight-week guided protocol utilizing the mental health app IntelliCare as an adjunct to treatment of mildly depressed patients that m inclusion criteria and were willing to participate.

Literature Review

To study the current standard of care for mild depression in primary care, gaps in care, and innovations in treatment utilizing mobile applications (apps) a comprehensive search of the literature was conducted using the following databases: Cochrane, CINAHL, PubMed, AHRQ, PsycInfo, Medline and Up to Date. (MeSh) terms "depression, adults, primary care, telehealth and mobile health" were entered in various combinations. Inclusion criteria consisted of full-text articles available in English and focused on the adult population between 2008 and present; exclusion criteria included articles focusing on age groups other than adult; articles not available in English, and articles focusing on severe major depression or severe mental illness and

specialty care. A total of 201 articles were identified using the above search criteria, of which 28 were found to be relevant to the study. Of these, six are systematic reviews/meta-analysis, four are RCT's, two are pilot studies, and the rest are descriptive. Levels of evidence incorporated in this review include three meta-analyses at Level 1A, several RCT's at Level 1B, and a review and several semi-experimental cohort studies at level 3B, based on Johns Hopkins strength of evidence guidelines (Newhouse, Poe, Pugh & White, 2005).

Collaborative Care versus Treatment as Usual (TAU) with Pharmacology Alone

According to a meta-analysis by Linde et al. (2015), MDD is expected to be first on the list of disorders for highest burden of disease in high-income countries by 2030. Most patients with mild symptoms of MDD are initially seen in primary care, where barriers to access and limited resources potentially create a gap in care. The meta-analysis reviewed currently available studies comparing collaborative care versus TAU or placebo. Thirty studies with n = 5,159 patients met inclusion criteria. Categories of comparison to placebo included in-person CBT, in-person problem-solving, in-person interpersonal psychotherapy, remote therapist CBT, remote therapist problem-solving, and guided self-help CBT. Results of this meta-analysis "suggest that the differences between different types of psychological treatments are minor", and remote, therapist-led and guided-self-help can be similarly effective as in-person therapy (Linde et al., 2015). Level of evidence meets 1A criteria. In a meta-analysis by Archer et al. (2012) of 79 randomized trials with more than 24,000 patients, collaborative care involving a treatment plan was much more effective in reducing baseline symptoms of depression by greater than or equal to 50%, than pharmacotherapy alone. These benefits persisted up to 24 months (Archer et al., 2012). Level of evidence meets 1A criteria. In a meta-analysis of 37 randomized trials involving more than 12,000 patients, support for collaborative care including a structured

treatment plan including pharmacotherapy with follow-up by office visit, telephone or email contact, was found to have a significant but clinically small positive effect compared to just pharmacotherapy, which persisted up to five years in a meta-analysis (Gilbody et al., 2006). Level of evidence meets 1A criteria, supporting the role of collaborative care in promoting positive outcomes in depression treatment. In a smaller meta-analysis of 2000 patients, remission occurred in more patients who received collaborative care than those who received just medication management (Sighinolfi et al., 2014). Level of evidence is 3B due to the smaller sample size. A Cochrane review of self-help-based CBT through a variety of media including m-health is currently being conducted by Rummel-Kluge, Dietrich, and Koburger (2015), focusing on primary outcomes of treatment efficacy, as well as improvement in quality of life and overall symptoms, adherence to CBT/behavioral based self-help, adverse effects, and economic benefits. Results of this analysis are expected to align with the above findings.

In a recent RCT study published in JAMA (Rollman et al., 2017) three groups of primary care patients diagnosed with mood or anxiety disorder (n = 704) were randomized to three study arms: one treatment as usual by PCP, one treatment utilizing an online eight-session Computerized Cognitive Behavioral Therapy (CCBT) protocol, and one CCBT plus an internet-based support group. Results indicated that patients using CCBT reported greater improvements in mood at the six-month mark. Level of evidence meets 1A criteria, in support of collaborative care administered via a non-traditional approach.

Telehealth Based Collaborative Care versus TAU

Studies specifically addressing the role of tele or mobile health in the treatment of depression include a 2014 descriptive study by Sheldon et al., Sheldon's group discussed gaps in the care of depressed primary care patients emphasizing that while most people in the U.S. are

treated by primary care providers for depression, often treatment is just antidepressant medication with low adherence rates. According to their review, less than 10% of primary care patients with depression receive evidenced-based psychotherapy, with limited access especially pronounced in low-income communities where issues such as transportation, child-care, fees for care may play a larger role as barriers to care. They developed a telephonic based behavioral activation treatment (TASC) to reduce depression, based on teaching individuals to monitor their mood and daily activities, and increase activities which have the potential for providing positive experiences. The TASC program was implemented in eight primary care clinics in an urban public health setting. Up to five phone calls were made to participants over time, with general improvements on PHQ-9 scores. Due to the lack of statistical analysis, this study is graded as 4B, but underscores the ability of phone-based interventions to help improve access to care (Sheldon, 2014). In a 2016 RCT specifically focusing on benefits of telehealth in depression treatment conducted by Salisbury, et al., in England, 609 patients recruited from 43 general practices with PHQ-9 scores of 10 or more were assigned to two treatment groups, 307 in intervention group and 302 in the TAU group. TAU consisted of initial face to face visit, with or without pharmacology. The treatment plus group had an initial visit, and possibly pharmacology prescribed, but also utilized a web portal with links to several web-based self-help programs, with “advisees” placing phone calls to participants over a four-month period. The primary outcome of the study was defined as a reduction in PHQ-9 score by at least five points by the fourth month. Results demonstrated that 27% of participants in the treatment plus group reduced their PHQ-9 scores by at least five points, compared to 19% in the treatment as usual group. Effects were sustained at the eight and 12-month mark, with gradual diminishment of between group differences. Another RCT comparing TAU to an online depression care management

system through patient EMR, was conducted in Washington State in 2010 (Katon, et al., 2010). A total of 208 patients, all of whom who had been seen in primary care and started antidepressant medication, were randomized to the TAU group or to the intervention group, where three online contacts with a trained psychiatric nurse were conducted over five months. For patients in the TAU group no additional interventions were provided, but no treatment was withheld, including follow up visits, mental health specialist referral, medication changes, and patient initiated online messaging, etc. In the treatment group, patients received a welcome email by the nurse with links to an online depression assessment and to questions regarding medication. Patient satisfaction surveys were conducted at the five-month mark. The primary outcome measure was depression score as measured by Symptom Checklist Scale (SCL). Approximately 55% of patients in the treatment group compared to 41% of patients in the TAU group experienced 50% or more improvement of SCL scores, again supporting usage of a tele-health-based treatment algorithm. Both RCT trials are graded at the 1B level of evidence and provide support for the use of tele-health and mobile health as an adjunct to treatment as usual.

In terms of the global stage, one current trial in Denmark is the RADMIS-reducing the rate and readmissions among patients with unipolar and bipolar disorder using smartphone-based monitoring and treatment study (Faurholt-Jensen, et al., 2017). Rural communities in India have been identified as being particularly underserved and the use of mobile apps is being addressed in the SMART trial-the Systematic Medical Appraisal Referral and Treatment Mental Health Program using mobile-based mixed intervention methods (Maulik, Devarapalli, Kallakuri, Praveen Jha, & Patel, 2015) Recognizing the need for accessible strategies at the onset of depressive symptoms, Romania is currently conducting an RCT trial using smartphones for large-scale dissemination of CBT, with a control group of patients whose PHQ-9 scores

demonstrate no depression and a treatment group of those scoring in the mild depression range. The primary end points are to reduce vulnerability to depression and improve symptoms (Giosan, Mogoase, Cobeanu, Szentagotai Tator, Muresan, & Boian, 2016).

Evidence-based Mental Health Apps

As of 2015, 165,000 health-related apps have been released for Android and Apple platforms, with an estimated seven percent targeting mental health (Van Ameringen, Turna, Khalesi, Pullia & Patterson, 2017). Due to the extensive number of apps, this literature review focused on "evidence-based" apps which were studied in cohort or RCT trials, available free of charge, and in English.

In a 2013 systemic review by Donker et al., eight papers describing five apps for depression treatment showed significant reduction in symptoms related to app usage, supporting an apps potential to be effective and improve access to treatment. Ease of use, helpfulness and satisfaction ratings by app users indicated acceptability. Technical issues related to connectivity, and problems with downloading the apps occurred but were not insurmountable. The review supported the use of mobile health (mHealth) utilizing CBT as an option for treatment of mild to moderate depression, either as a stand-alone treatment or in conjunction with a guided treatment protocol such as the one being implemented in this QI project (Donker et al., 2013). The authors of this review emphasize the fact that although many apps are getting to market, there are very few apps that meet the criteria for evidence-based, and this is an area in which the public needs to be educated (Donker et al., 2013). In a meta-analysis conducted by Firth (2017), 18 RCTs of app interventions for depression versus no apps found that there was a significant reduction in depression among app users, further strengthening support for using evidence-based apps as an adjunct for depression treatment, at an evidence level of 1A. Firth's analysis was reviewed by

Muoio in “Mobile Health News” in support of mHealth utilization to treat depression, with the caveat that future studies need to be conducted (Muoio, 2017).

Two promising evidence-based app include a mobile phone app based on “Behavioral Activation Treatment for Depression” (BATD), called “Moodivate”, which is currently being studied in an ongoing clinical trial of depression in primary care (Dahne et al., 2017). As of the time of writing of this review, results are not yet available. Prime-D, a mobile app utilizing “social networking, goal setting, and a mental-health coach” to deliver weekly texts (Arean, et al., 2017) demonstrated similar improvements in PHQ-9 scores at the end of the trial but had only 36 participants and was not randomized, consistent with 3B level of evidence.

SuperBetter, a smartphone and web-based app for the treatment of depression, recently underwent an RCT study in collaboration with researchers at the University of Pennsylvania. In the RCT study of n=283, participants were recruited through public announcements on the “Penn Authentic Happiness Web Site”, where they were directed to an internet site to take a depression screening tool. Participants meeting score criteria were randomly assigned to one of three groups: a version of the app using CBT with “Positive Psychotherapy” (CBT/PPT); a version using just the SuperBetter app (SB), and a waiting list. Preliminary results showed that SB participants achieved greater reductions in depression scores than those in the FG arm, but there was no significant difference in symptom improvement for CBT/PPT versus SB (Roepke et al., 2015). Level of evidence for this RCT is 1A.

IntelliCare is a mobile app suite developed by researchers from Northwestern University led by psychologist David Mohr, consisting of 13 self-help-based CBT apps which utilize positive-psychology and physical-activity based interventions and can be down-loaded on android and apple supported smartphone, tablet or computer (Mohr, et al., 2017), (see Appendix

B). The apps are free to the public and available on both android and apple platforms, though limited to three apps on Apple devices. The app was piloted by the Northwestern research group in a 2016 one-arm study of patient outcomes in mild depression, where patients were recruited over an eight-week period and were taught to use the IntelliCare app with weekly text check-in with coaches. At the end of the trial 37% of 99 participants had no symptoms of depression, 40% showed PHQ-9 score improvement, and 22% met criteria for referral, i.e., a PHQ-9 score greater than or equal to 10 (Mohr, et al., 2017). Due to lack of randomization and a control group, evidence level is 3B, providing evidence for efficacy based on a semi-experimental design. Subsequent to this pilot, the NIH has sponsored three additional clinical trials using IntelliCare.

Summary of Literature Review

In summary, the literature review supports the fact that limited access to psychiatric and behavioral therapist-based care for depression is a serious treatment barrier and renders most of mild depression treatment to primary care. Collaborative protocols are lacking, and care as usual often consists of pharmacotherapy and sporadic provider visits, which the literature shows is inferior in producing positive outcomes as compared to a comprehensive, guided treatment plan. Using tools such as the PHQ-9 to document level of depression is not yet the standard of care but is supported by the literature as a validated measure to document outcomes (USPTFS, 2015).

The review also supports the use of evidence based mobile apps in the treatment of depression in primary care, with the goal of improving patient access and outcomes. Limitations of the review include the fact that in the RCT's supporting use of tele-health, web-based, or mobile app interventions, it is not possible to determine how much of the positive effect seen is

due to the intervention or to other factors not controlled for, such as treatments rendered that are not recorded, life style changes, medication changes, and possibly respondent bias.

The "immaturity" of evidence in this rapidly developing field (Peiris, Miranda, & Mohr, 2017) is being addressed in several ways including ongoing RCT trials and by using well-established collaborative care app protocols when possible, that involve close follow-up in the clinical setting.

Evidence Based Practice: Verification of Chosen Option

After review of the literature finding support of the utilization of an evidence-based CBT mobile app as an adjunct to treatment of mild depression, a guided treatment protocol utilizing IntelliCare was developed by this DNP student and is the focus of this paper. The IntelliCare App Suite developed by researchers from Northwestern University led by David Mohr (2017), is free, available in English, and can be accessed on both Android and Apple operating systems. IntelliCare is currently being studied in two NIH trials and preliminary data from an eight-week study completed in October of 2018 has been favorable in terms of participant completion (NIH, 2018). The fact that this suite is being studied by the NIH factored in the decision to utilize this app in this QI project, where the goal was to offer patients access to effective evidence-based treatment which they can use during their enrollment and thereafter, to improve their depression symptoms and outcomes. Although funding by the NIH does not increase evidence for a study, it is the result of a process where the application earns points through several categories including the investigator, innovation, approach, environment, and timeline (NIH, 2018). Usability data regarding the IntelliCare suite was very positive, with acceptable app completion times in 22 patients supporting the feasibility of app usage (Stiles-Shields et al., 2017). As of 2016, Lattie, et al., (2016) determined that the rate of use of the IntelliCare suite of apps was higher than other

comparable mHealth apps, which the author's point out is a necessary requirement before "effectiveness" can be analyzed. Ease of usability of the app supported it as the choice for this QI project, as well as the fact that it was available on two smart-phone platforms, increasing patient access.

Theoretical Framework/Evidence Based Practice Model

The theoretical framework behind this quality improvement project is based on the Health Promotion Model by Nola Pender (Petiprin, 2016), where health is defined as a positive dynamic state rather than simply the absence of disease. As exemplified in this project, health promotion is directed at increasing a patient's level of well-being, which in this project is improvement in symptoms of mild depression.

Pender's model describes the multidimensional nature of people as they interact within their environment to pursue health, and focuses on individual characteristics and experiences, behavior-specific cognitions and affects, and behavioral outcomes (Heydari & Khorashadizadeh, 2014). Health promoting behavior is the desired behavioral outcome, which makes it the end-point in the Health Promotion Model (Appendix B). The model emphasizes 13 theoretical components, several of which specifically apply to the design of this QI project, including patients being more likely to engage in health-promoting behavior when it is expected to occur, and they are assisted and supported to engage in it (Petiprin, 2016).

In this project patients agreed to perform health-promoting behaviors by participating in a protocol where they utilized a self-help app at least once weekly and communicated with this DNP student ideally every other week and as needed. By enlisting in this project, they acknowledged their desire to improve their depression symptoms. Consistent with Pender's theory in which health promoting behavior is most likely to occur when it is expected, clear

guidelines regarding patient expectations in the protocol were outlined for them, and they consented to participate. Patients agreeing to be part of this project were engaging in health-promoting behaviors to improve their depression, which according to Pender, is the desired behavioral outcome.

Methods

This was a Quality Improvement (QI) Practice Intervention Project based on implementation of a collaborative treatment protocol for mildly depressed primary care adult patients utilizing the IntelliCare mobile app as an adjunct to TAU. This QI protocol involved an eight-week treatment plan that combined initial physical and mental health office assessment, self-help app usage, bi-weekly provider-patient communication to document patient self-report of symptom improvement or worsening, app utilization, and patient assessment of ease of use of the app. Quantitative measures included pre and post intervention PHQ-9 scores and when available, bi-weekly measures of symptom status, app use, and ease of app use determined by questionnaire. Qualitative data included patient's comments regarding the app and are addressed in the discussion section.

Project Site and Population

The project site was a four-provider primary care practice where this APRN DNP student is employed in a suburban Northeastern location. The office is in a modern building on a bus-line, with free parking, elevator access, and private exam rooms as offices, supporting patient confidentiality.

The project sample was drawn from a community of 63,200 people with a median age of 41.8. The ratio of males to females was .9 to 1. English was the primary language for 77% of

the population while 7% were Spanish-speaking. Approximately 81% of the population was Caucasian, 9% African-American, and 7% Asian. Zip codes of participants were not recorded.

Study Design

The study design was a one-group pretest post-test design using a convenience sampling method with a recruitment goal of 25 patients. Patients who presented to this DNP students primary care practice between August and December of 2018 with symptoms of depression, or were at risk for depression, were asked to complete the PHQ-9 depression screening tool. They underwent appropriate physical examination including detailed review of systems and history, as well as diagnostic testing when indicated. Inclusion criteria consisted of being age 18-64, having access to an Android or Apple smart-phone and the ability to use it; not having any serious mental health comorbidity or history of suicidality, and being able to communicate in English. Patients on anti-depressant medications were not excluded from the protocol if they met other inclusion criteria. Patients who scored in the mild depression range (PHQ-9 scores of five through nine) and who satisfied other inclusion criteria were asked to participate in the eight-week QI project where they agreed to access one app from the IntelliCare Suite weekly and engage in bi-weekly EMR or phone contact with this DNP student. They were scheduled for an eight-week follow-up appointment where a post-intervention PHQ-9 was administered. If they did not return for the appointment the PHQ-9 was mailed to them with a stamped return envelope. Demographic data including age and gender was recorded. Throughout the course of the protocol participants were reassured that if they needed an office visit or other contact during this period they were encouraged to do so, and that it was crucial that they report any worsening of symptoms. Patients were given a document summarizing the protocol that they could refer to.

In the week prior to implementation of the QI project office staff was in-serviced, and any questions addressed. The three physician practice owners each received copies of the protocol had the app demonstrated to them. During the project implementation they were updated regularly on the project status.

Measurement Instruments

The PHQ-9 questionnaire (Appendix A) was utilized for measurement of pre and post intervention depression scores. It has multiple references supporting its usage as a valid, reliable measure of depression (USPSTF, 2016), and does not require permission to be used. The diagnostic validity and reliability were established in several primary care and obstetrical studies and was shown to have both sensitivity and specificity scores of 88% for Major Depressive Disorder (USPSTF, 2016).

Another measurement tool in this study consisted of a bi-weekly questionnaire developed by this DNP student (Appendix C) in which patients were asked to rate their depression symptoms as the same, improving, or worsening; whether they had accessed the app; and their rate of ease using the app. The purpose of the questionnaire was to ensure that depression symptoms were not significantly worsening during the protocol, which would initiate referral to an MHS and protocol cessation. A second purpose was to track issues in app usability which might interfere with app access.

Goals, Objectives and Outcomes

Goals	Objectives	Outcomes
The primary goal of this DNP project was to improve	A protocol was developed which addresses the gap in	PHQ-9 scores for the 17 patients completing the

depression outcomes measured by PHQ-9 scores in adult primary care patients through a guided treatment protocol utilizing an evidence-based mobile app as an adjunct to care.	practice between large numbers of adults who screen positively for mild depression based on PHQ-9 scores, but do not have a specific treatment plan in place to improve outcomes. The treatment protocol was implemented utilizing bi-weekly communication with patients with at least weekly patient usage of the evidence-based mobile app IntelliCare.	protocol were improved by an average of 53% by the end of the eight-weeks. This was a significant decrease in depression scores as determined by Wilcoxon matched-pairs test of pre and post intervention scores ($p<0.01$).
Secondary goals of this project: For patients to access the IntelliCare app on a regular basis during the protocol.	Patients accessed an IntelliCare app at least once weekly determined by self-report on bi-weekly questionnaires. Problems accessing the apps were addressed by this DNP student as they arose and resolved when possible.	Despite at least three attempts to reach patients by phone or portal at week 2, 4 and 6 to administer bi-weekly questionnaire, contact was not made for greater than 50% of respondents for at least one response period, leaving data "holes" for those weeks as depicted by "999" in the data fields for responses. When meeting with patients at week eight at least 60% stated that they had used the app on at least a weekly basis. 2/17 (12%) of completers stated

		they had some issue with the app which was addressed and resolved.
The majority of participants would complete the protocol.	At least 51% of participants would complete the post-intervention PHQ-9.	68% of protocol participants completed the pre and post intervention PHQ-9.

Project Framework and Implementation

This QI project was implemented in August of 2018. The PDCA model was the framework for the project (Deming, 1997) and is outlined below.

Plan: An identified gap in practice for treatment and follow-up of mildly depressed patients in this DNP student's practice was identified and became the focus of this QI practice intervention project. Literature review was undertaken with development of a guided treatment protocol utilizing the evidence-based mobile app IntelliCare, as an adjunct to treatment as usual.

Do: Appropriate patients were asked to complete the PHQ-9 to help determine their level of depression. Patients who scored between five through nine on the PHQ-9 and met inclusion criteria were asked if they were interested in participating in this project. Patients were provided with a summary of the study protocol which included the bi-weekly questionnaire they were asked to respond to. The need for timely reporting of worsening depression symptomatology was discussed with patients and detailed in the paperwork they received.

Descriptive, demographic data including age and gender was collected, along with patient bi-weekly questionnaire results regarding status of depression symptoms, if apps were accessed weekly, and patient evaluation of app ease of use. Tracking of bi-weekly questionnaire responses was on paper, recorded on the back of their initial PHQ-9 questionnaire.

At the time of participant sign on to the project an eight-week follow-up appointment was scheduled, and dates for bi-weekly phone or EMR patient-portal follow-up were established by calendar and were written on the top of each participant's questionnaire. Notes regarding these conversations were recorded on the PHQ-9 questionnaire to allow tracking of bi-weekly patient contact. Questionnaires were organized with newest participant on the bottom, and oldest participants on the top, then removed at completion and placed in a folder in the locked desk draw. Establishment of an ongoing therapeutic relationship with the patient was an important means to assess their level of symptomatology and is a goal of the provider-patient relationship. Patients were reassured that at any time they could stop participation in the project and were encouraged to initiate contact if they needed to be seen in the office or were experiencing any difficulties. They were encouraged to communicate via EMR as desired, but instructed that if a quick response was needed, they should place a telephone call to the office, which would be answered the day they were received barring absence of this provider; EMR response would be within 24 hours of patient-initiated contact.

In cases where patients were on medication prior to the protocol, they were asked whether they were taking their medication. If it was determined that patients needed an adjustment in medication they were withdrawn from the official protocol, which happened in one case.

Check: Primary outcome data was statistical analysis of pre and post PHQ-9 scores after eight weeks of treatment to determine whether the protocol completers experienced a significant improvement in depression symptoms. Secondary outcome data included the number of patients who "dropped-out" or did not complete the protocol with the goal of having the majority complete. Another secondary outcome was the goal of having the majority of protocol participants completing bi-weekly questionnaires.

Act: Based on data analysis of the primary outcome demonstrating a significant improvement in depression symptoms, the incorporation of this guided treatment protocol into TAU was validated. The secondary outcome of having the majority of participants complete the protocol was achieved at 68%. The secondary outcome goal of bi-weekly communication and questionnaire completion for most participants was not met and will need modification in future QI projects.

Cost-Benefit Analysis/Budget

Due to this project occurring during working hours there was no additional financial cost to accessing the office or utilizing staff while seeing patients. Time spent on phone and EMR communication was estimated at one hour daily. For cost of packet construction, ink and paper costs, and incidentals, see Appendix D.

In terms of benefits to practice owners in undertaking this project, there were gains toward satisfying CMS metrics requiring depression screening by PHQ-9 as well as EMR communication via patient portal. There was also increased patient flow due to the eight-week scheduled follow up visit as well as any other needed visit. Cost of app usage did not increase cost to patients above their usual technology fees, providing an equitable platform for patients to engage in a guided treatment protocol without additional expense.

Ethical Considerations/Protection of Human Subjects

This project was declared not to be Human Subjects Research by the appropriate Institutional Review Board (Appendix G). In accordance with HIPAA regulations, all patient data was confidential and data analysis was done anonymously by assigning case numbers to patients; data was kept in a locked desk drawer. EMR access was password protected at two levels and was HIPAA compliant.

Since the app was accessed through the patient's cell phone or mobile device of their choice, patients were asked to acknowledge that despite security measures any electronic or mobile device could be breached. For those who needed instruction on downloading and accessing the app written directions were provided in the protocol description and when necessary they were instructed on downloading and usage during the initial office meeting. A disclaimer stating that this DNP student has no vested interest or anything to gain from utilizing this app was included in the packet.

Results

A total of 25 patients meeting criteria were recruited into the protocol beginning August 1 through December 31 of 2018. Demographic data on gender and age of protocol participants are shown in Table 1. Eighty percent (n=20) of participants were females, 20% (n=5) were males. Ages represented were from 21 to 64 with only one patient in the 61-64 category.

Table 2 depicts average pre and post PHQ-9 scores by gender. Average pre-protocol PHQ-9 for female completers was 7.5, for males it was 7. Average post-protocol PHQ-9 for females was 3.76 and 2 for males, representing an approximately 51% improvement for females and a 69% improvement for males. The small sample size prohibits any meaningful analysis of the discrepancy in score improvement by gender but may be of future interest.

Table 3 depicts average pre and post PHQ-9 scores by age. Of note, all age groups were represented in the initial 25 participant enrollment. The single patient in the 61-64 age group had the highest pre-protocol PHQ-9 score and achieved the highest percentage of post protocol improvement at 78%. Again, the sample size limits any meaningful statistical analysis to determine significant effects due to age group but may be of future interest.

Sixty-eight percent (n=17) of protocol participants completed the pre and post PHQ-9. Of these, the mean pre-protocol PHQ-9 was 7.2 (SD=1.78) and mean post-protocol PHQ-9 was 3.4 (SD=1.69), a 3.82 point or 53% average score improvement for completers, n=17 (see Table 4).

IBM SPSS® 25 was used to run the non-parametric Wilcoxon matched-pairs test to determine whether there was a significant improvement in post-PHQ-9 scores after completing the protocol. Results indicated a significant improvement in post-protocol PHQ-9 scores and are shown in table 4 with a mean improvement of 3.82 points for completers which was statistically significant at $p<0.01$. (See Table 5).

If a patient did not complete the post protocol PHQ-9, their demographics, initial PHQ-9 scores, and bi-weekly responses were excluded from analysis. One (1) patient formally withdrew, one (1) patient experienced a catastrophic event affecting a family member, contacted this provider, was prescribed medication, referred for therapy and was not included as a completer. One (1) patient did return the post-intervention questionnaire by mail but was excluded from the analysis because there was no other contact for the entire protocol. The remaining five (5) non-completers did not return for follow-up or complete the mailed post-intervention PHQ-9, excluding them from analysis.

The secondary goal of having the majority of patients completing the protocol was achieved with a completion rate of 68%. In terms of the secondary goal of bi-weekly contact and questionnaire completion, for week two only 33% of patients completed the response questionnaire, for week four 36% completed, and for week six 32% completed, despite three attempts. These results will be addressed under discussion.

Discussion

MDD is currently the fourth leading cause of disability worldwide, and by 2020 is predicted to be the second, at great financial and emotional cost to patients and society (Kessler, 2012). Most patients first present to their primary care provider for evaluation and treatment of depression where their care can be limited by lack of knowledge or experience of the provider, financial constraints, fear of stigma, and insufficient access to mental health specialists, all accentuated in underserved populations, leading to risk of severe MDD. Innovative, evidence-based treatments are needed to address this gap in care and was the focus of this QI project.

Nola Pender's Health Promotion Model describes health as a dynamic state between person and environment and not just the absence of disease. This QI project exemplifies Pender's theory based on patients agreeing to interact with the environment, which in this project was the IntelliCare app and protocol, to help decrease their depression symptoms and improve their well-being. This protocol enhanced treatment as usual by utilizing a validated measure of depression to evaluate outcomes, encouraged access to and utilization of an evidence-based self-help mobile app which has been shown to improve depression symptomatology, and implemented a follow-up communication strategy that is often lacking in traditional care for mild depression.

Patients who used the IntelliCare app and completed this protocol experienced an average 53% improvement in their depression symptoms, supporting the use of the app as an adjunct to treatment of mild depression in an appropriate patient population. Having a majority of patients completing this protocol supports the feasibility of using the mobile app IntelliCare as an adjunct to TAU that patients can access at will, free of charge, with positive outcomes and is supported by results in NIH trials to date (Mohr, et al., 2017) (NIH, 2018). On October 29, 2018 the NIH released preliminary results on Clinical Trial NCT02176226, with results supporting continued use of IntelliCare based on patient usage. IntelliCare staff can be contacted online through their website https://**intellicare**.cbits.northwestern.edu. IntelliCare is currently being studied at other universities for possible modification and improvement to the app (Greene, 2018).

To address the issue of difficulty having patients respond on a bi-weekly basis, future protocols could include just one four week "check-in" as opposed to every two weeks, with EMR contact versus telephone, decreasing the potential barrier of phone lines being busy, messages not being given to the protocol provider, and to facilitate patient convenience, i.e., EMR contact can take place any time from the patients perspective. A qualitative approach with an EMR record of the patient's responses/comments versus a questionnaire may also increase patient engagement and satisfaction while facilitating tracking of progress of the patient. It will also aid the QI leader in compiling qualitative data for review.

Facilitators and Barriers

Setting facilitators included this APRN DNP student having the support of practice owners, staff to schedule appointments, relay patient concerns to this DNP student, and answer telephone calls during routine business hours. There was a secure EMR with patient portal access, and an appointment schedule which allowed patients with depression to be seen for a 30-

minute visit by this DNP student APRN provider. Document copying was also available and utilized for protocol patient handouts. One of the practice owners agreed to be the onsite preceptor and signed a letter stating support for the implementation of the QI project to show support for the project. The physician providers in the office were responsible for patient coverage for this DNP student in case of work absence or after-hours emergencies; neither of these situations occurred.

Barriers in this setting included six patients missing their eight-week follow-up appointment and not being rescheduled due to miscommunication with staff, necessitating a modification in the protocol which was addressed with this DNP student's advisor as well as the practice owners. Mailing of post-protocol questionnaires to patients who missed their eight-week follow-up appointment was done with responses from three. A second barrier was identified at the time of the eight-week follow-up when several patients stated they had called regarding the bi-weekly questionnaire, but the message was not relayed. Modifications to circumvent these barriers in the future are addressed under Discussion.

Limitations

Major limitations of the QI project included small sample size, the absence of a control group and the gaps in bi-weekly response data. Further QI projects should involve larger number of participants, a control group if possible, notation of anti-depressant medications the patient is taking, and a record of patients who meet inclusion criteria but refuse participation, with their reasons for refusal, which could help determine potential modifications to the protocol. Changing the protocol check-in points from bi-weekly to one at the four-week mark which is a conversation via phone or ideally EMR may facilitate better communication.

Conclusion

In summary, the goal of this QI project was to implement a guided treatment protocol for patients to improve depression symptoms utilizing the evidence-based mobile app IntelliCare as a self-help, CBT-based adjunct to TAU. Based on 68% completion rate with an average of 53% symptom improvement, the use of the IntelliCare app as an adjunct to treatment is supported. Integration of the PHQ-9 screening into practice as well as following up of patients for an eight-week time frame were part of this protocol and will be maintained in this DNP student's primary care practice. This data will be shared by PowerPoint presentation with practice owners with the goal of them implementing this protocol in their work with mildly depressed patients. A poster presentation of this project will be presented at the 2019 ENRS conference with the goal of increasing visibility regarding the use of evidence-based mobile apps such as IntelliCare, to stimulate further work in this area.

Primary care providers see the majority of mildly depressed patients but have few tools for treatment and are often overwhelmed by time constraints due to complexity of EMR systems as well as increased patient workload. Parallel to this are patients being financially constrained when making medical appointments by high deductibles and copays, as well as fear of stigma and lack of availability to see mental health specialists. Mobile health apps have the potential to play an important role in the future of mental health care-not in place of but as an adjunct to treatment. They should be evidence-based, free, and available on a variety of smartphones and in different languages and have contact information for support to patients. Widespread adoption is limited by the lack of experimental evidence and need to be further studied in ongoing RCT trials as previously discussed. The potential endpoints of improved treatment and follow-up with consequent decreased disability, emotional and financial cost to individuals, families, and society, are critical to the success of the healthcare system.

Quality Improvement projects implemented by DNPs utilizing innovative, evidence-based tools are essential to achieving the triple aim of "improving the health of the population, enhancing patient experiences and outcomes, and reducing per capita cost of care (Taylor, et al., 2014). Further study to determine best treatment protocols in depression where mobile health can play an acceptable and beneficial role in improving access and outcomes for patients is an area that presents a challenge to primary care DNP providers, whose focus on translating research into practice can improve care. The goal of improving depression symptoms and patient outcomes is to decrease related illness and disability and improve quality of life, with economic and emotional benefit for patients, families, society, and the healthcare system.

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Appendix A

PHQ-9: Nine-symptom Checklist

Name _____ Date _____

Over the *last 2 weeks*, how often have you been bothered by any of the following problems?	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself—or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed? Or the opposite—being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3

(For office coding: Total Score ____ = ____ + ____ + ____)

2. If you checked off any problem on this questionnaire so far, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?	Not difficult Somewhat Difficult Very Difficult Extremely difficult

Total Score and
Depression Severity

- 0-4 No Depression
- 5-9 Mild Depression
- 10-14 Moderate Depression
- 15-19 Moderately Severe Depression
- Over 20 Severe Depression

Appendix B

Description of IntelliCare Apps

IntelliCare Hub: Uses an algorithm that manages personalized messages and notifications for each user from the other apps within the IntelliCare framework.

Aspire: Guides user to identify the values that inspire one's life and specific actions someone does to live these values. Aspire helps keep track of these actions throughout the day and supports the user in living a more purpose-driven and satisfying life.

Day to Day: Delivers a daily stream of tips, tricks, and other information throughout the day designed to boost the user's mood. Day to day prompts the user to work on a particular theme each day, which changes every week. And to learn more about how to effectively cultivate gratitude, activate pleasure, increase connectedness, solve problems, and challenge one's thinking.

Daily Feats: Encourages the user to incorporate worthwhile and productive activities into the day. Users add accomplishments to the Feats calendar, where they track their positive activity streaks and ratchet up by completing more tasks. Daily Feats helps motivate users to spend their days in more meaningful, rewarding ways with the goal of increasing overall satisfaction in life.

Worry Knot: Teaches the user to manage worry using lessons, distractions, and other worry management tools. Worry Knot provides a guided tool to address specific problems that a user can't stop thinking about and provides written text about ways to cope with tangled thinking. Worry Knot also presents statistics about progress as the user practices coping with worry, gives daily 'tips and tricks' for managing worry and provides customizable suggestions for ways to distract oneself.

Social Force: Prompts the user to identify supportive people in their lives and provides encouragement for the user to get back in touch with these positive people.

My Mantra: Prompts the user to create mantras (or repeatable phrases that highlight personal strengths and values that can motivate the user to do good and feel good). My Mantra constructs virtual photo albums to serve as encouragement and reminders of these mantras.

Thought Challenger: Guides the user through an interactive cognitive restructuring tool to examine thoughts that might exaggerate negative experiences, lead someone to be overcritical and bring down one's mood. Thought Challenger teaches the user to get into the habit of changing perspective and moving toward a more balanced outlook on life.

iCope: Allows the user to send oneself inspirational messages and reassuring statements, written in their own words, to help the user get through tough spots or challenging situations.

Purple Chill: Provides users with a library of audio recordings to relax and unwind. Purple Chill teaches a variety of relaxation and mindfulness practices to de-stress and worry less.

Move Me: Helps the user select exercises to improve mood. Move Me provides access to curated exercise videos and to written lessons about staying motivated to exercise. This app allows the user to schedule motivational exercise time for oneself throughout the week.

Slumber Time: Prompts the user to complete sleep diaries to track sleep. Slumber Time provides a bedtime checklist intended to clear one's mind before going to sleep. It also provides audio recordings to facilitate rest and relaxation and features an alarm clock function.

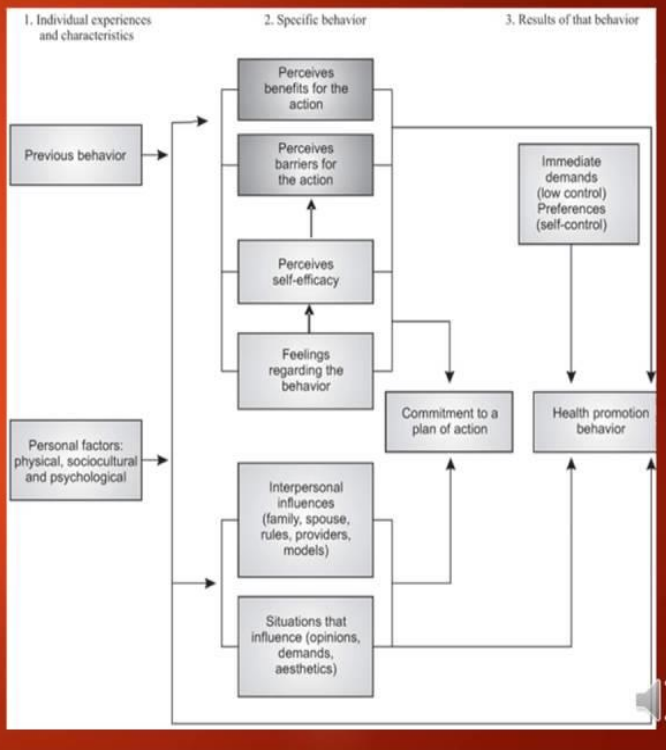
Boost Me: Encourages users to select and schedule positive activities ("boosts") whenever the user notices a drop in his or her mood. Boost Me tracks specific activities the user tags as positively impacting mood. This app includes animated mood tracking for pre/post positive activities, calendar integration, and suggested activities that are auto-populated based on past mood improvement (Mohr, et al., 2017).

Appendix C

Theoretical Framework

Health Promotion Model Breakdown

- Three focus areas
  - Individual experiences
  - Behavior-specific knowledge and affect
  - Behavioral outcomes
- Five Key Sections
  - Person
  - Environment
  - Nursing
  - Health
  - Illness



Appendix D

Protocol Summary

Thank you for your interest in participating in this project! The goal is to improve your symptoms of depression through treatment as usual along with the use of a mobile app called "IntelliCare" which has been shown in previous studies to help with depression if used on a regular basis. The project is for eight-weeks.

There are two parts to this project-one will be bi-weekly communication with me via the "My Care" patient Electronic Medical Record (EMR) portal which you will be given information on how to sign on to when you leave here today, or via telephone, based on your preference. I will initiate communication with you within 24 hours of this office visit through the portal or by telephone and will do so bi-weekly for eight-weeks. I will ask you a series of three questions (see below) on a bi-weekly basis. The portal can be used to communicate any non-urgent questions to me regarding your care. An eight-week follow-up appointment will be scheduled when you check out today. Please call the office at 860-313-0448 for any issues that need a fast response.

The second part of this project asks that you download the "IntelliCare" app on to your Android or Apple phone, tablet, or computer-whichever hardware you will be using to run the app. Android devices facilitate downloading of the entire app suite, while apple devices, as of the writing of this guide allow three apps to be accessed "Daily Feats", "Worry Knot", and "Thought Challenger". Apps are found in the app store on your device and are free and published in English. I ask that you use an app at least once weekly with the goal of improving depression symptoms. If at any time you feel your depression is worsening, I ask that you contact me at the office. Below you will find the weekly questions I will ask you to answer. Thank you for your interest in this project.

Bi-Weekly Questionnaire

1. How would you rate your level of depression symptoms compared to the beginning of the protocol?
   1=same, 2=Improved, 3=Worsening

2. How often have you used one of the IntelliCare apps in the last two weeks?
   1=not at all, 2=at least once per week

3. How would you rate the ease of use of the IntelliCare app?
   1=easy, no problems, 2=slightly challenging, occasional issues, 3=very difficult to use

   Is there anything you would like to address? Please notify me by telephone 860-313-0448 if you feel your symptoms are worsening.

Appendix E

Cost Analysis

There is no direct financial benefit involved in the undertaking of this translation of evidence into practice project for this DNP student, participants, and practice employers. No one involved in this protocol including participants were paid to undertake this project or recommend the IntelliCare app.

Copy Paper/Ink: Estimating 50 copies of a 2-page document describing the protocol at a maximum estimated cost of 5 cents per copy=$4.00.
Estimating 50 copies of a 3-page Informed Consent document at 15 cents per copy=$7.50
Benefits to the practice employers included this protocol satisfying CMS recommendations for PHQ-9 usage as well as communication with patients via the My Care EMR portal. Both these functions help satisfy CMS Quality Measurements.

Instructions to sign on to the HIPAA protected EMR portal "My Care" are printed for every patient at the conclusion of every office visit so do not constitute any additional charge.

Time: Patient visits took place during working hours. This APRN spent approximately five hours per week in additional uncompensated time communicating with patients which did not result in additional cost to employers.

Dollar Cost of DNP Project				
Paper/Printing	**Cost Per Page**	**# of Pages**	**# of Copies**	**$**
Introduction	.05	2	50	5.00
Consent	.05	2	50	5.00
Total	N/A	N/A	N/A	10.00

Appendix F

Timeline

TASKS	July 2018- August 2018	September 2018- December 2018	January 2019- March 2019	April 2019	May 2019
Obtain paper approval by faculty advisor and IRB	X				
Recruitment of QI participants and implementation of protocol		X			
Data analysis and paper revision			X		
QI results shared with stakeholders				X	
Approval of final paper by faculty advisor				X	X
Submission of final paper					X

Appendix G

IRB Letter

University of Massachusetts Amherst
Human Research Protection Office
Mass Venture Center
100 Venture Way, Suite 116
Hadley, MA 01035

Office of Research Compliance
voice: (413) 545-3428
fax: (413) 577-1728

Memorandum – Not Human Subjects Research Determination

Date: June 27, 2018

To: Michele Marek, Nursing

Project Title: Using Mobile Health to Improve Mild Depression Treatment Outcomes in Adult Primary Care

IRB Determination Number: 18-130

The Human Research Protection Office (HRPO) has evaluated the above named project and has made the following determination based on the information provided to our office:

☐ The proposed project does not involve research that obtains information about living individuals [45 CFR 46.102(f)].

☐ The proposed project does not involve intervention or interaction with individuals OR does not use identifiable private information [45 CFR 46.102(f)(1),(2)].

☒ The proposed project does not meet the definition of human subject research under federal regulations [45 CFR 46.102(d)].

Submission of an Application to UMass Amherst IRB is not required.

Note: This determination applies only to the activities described in the submission. If there are changes to the activities described in this submission, please submit a new determination form to the HRPO prior to initiating any changes.

A project determined as "Not Human Subjects Research", must still be conducted in accordance with the ethical principles outlined in the Belmont Report: respect for persons, beneficence, and justice. Researchers must also comply with all applicable federal, state and local regulations as well as UMass Amherst Policies and procedures which may include obtaining approval of your activities from other institutions or entities.

Please do not hesitate to call us at 413-545-3428 or email humansubjects@ora.umass.edu if you have any questions.

Iris L. Jenkins

Iris L. Jenkins, Assistant Director
Human Research Protection Office

Table 1

Sample Demographics

Table 1

Number of Participants by Age Group and Gender

Age Group	Males	Females
21-30	4	2
31-40	1	5
41-50	0	6
51-60	0	6
61-64	0	1
Total=25	5 (20%)	20 (80%)

Table 2

Pre and post PHQ-9 Scores by Gender

Table 2

Mean Pre and Post-Intervention PHQ-9 by Gender

Pre-protocol PHQ-9 Score *Mean (SD)*		*Post-protocol PHQ-9 Score* *Mean (SD)*	
Female (n=13)	*Male (n=4)*	*Female* (n=13)	*Male (n=4)*
7.5 (1.64)	7.0 (2.00)	3.76 (1.69)	2 (.82)

Table 3

Pre and Post Intervention PHQ-9 Scores by Age Group

Table 3

Mean Pre- and Post-Intervention PHQ-9 by Age Group

	Pre-Intervention PHQ-9 (n=17)		Post-Intervention PHQ-9 (n=17)	
	Mean	*SD*	Mean	*SD*
Age 21-30	6.83	1.83	2.6	1.52
Age 31-40	7.33	1.63	3.66	1.53
Age 41-50	8.16	1.6	5	1.63
Age 51-60	7.16	1.83	2.75	1.5
Age 61-64	9.0	0.0	2.0	0.0
Total	7.7	1.15	3.2	1.03

Table 4

Pre-and post PHQ-9 Completer Group Scores

Table 4 Pre- and post PHQ-9 Scores

*IntelliCare Completer Group (*n=17)	
Pre-protocol PHQ-9 Score *Mean (SD)* 7.2 (1.78)	*Post-protocol PHQ-9 Score* *Mean (SD)* 3.4 (1.69)

Table 5

Wilcoxon Matched-Pairs Sample Test

Table 5

Wilcoxon Matched-Pairs Sample Test Protocol Completers n=17

Null hypothesis	*Test*	*Sig.*	*Decision*
The median of differences between pre- and post-PHQ-9 scores =0.	Wilcoxon Matched-Pairs Sample Test	p<.01 alpha= .05	Reject the null hypothesis