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**MHEALTH FOR THE TREATMENT OF DEPRESSION IN PRIMARY CARE: A
FEASIBILITY STUDY**

by
Krista L. Herbert

A Dissertation

Submitted to the
Department of Psychology
College of Science and Mathematics
In partial fulfillment of the requirement
For the degree of
Doctor of Philosophy
at
Rowan University
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Dedications

I would like to dedicate this manuscript to my parents, Cheri and James, and my sister, Jessica.

Acknowledgments

I would like to express my gratitude to Dr. Jim A. Haugh for his continued mentorship, support, and guidance. I am very grateful to have you as my mentor and sincerely thank you for the skills and knowledge you have imparted to me. I would also like to thank Drs. Danielle Arigo, Jeffrey Greeson, and Joanna Petrides for being active members of my dissertation committee. I would also like to express gratitude to Dr. Megan Vermeulen for her collaboration on this project. Finally, I would like to thank Juliana D'Onofrio, Sean Martin, Danielle Schweitzer, and the rest of the research team for assisting me on this project.

Abstract

Krista L. Herbert
MHEALTH FOR THE TREATMENT OF DEPRESSION IN PRIMARY CARE: A
FEASIBILITY STUDY

2020-2021

Jim A. Haugh, Ph.D.
Doctor of Philosophy

The primary aim of this study was to evaluate the feasibility and acceptability of using mobile applications (apps) designed to ameliorate depressive symptoms in primary care. The secondary aim was to examine whether participants utilizing a mobile app would experience reductions in depressive symptoms and improvements in quality of life. Recruitment was conducted in two primary care practices. Participants who agreed to be part of the trial completed measures of depressive symptoms and quality of life at baseline, post-treatment, and a one-month follow-up. Measures of acceptability and feasibility were also gathered throughout the study duration. Results provided partial support for the feasibility of conducting such a trial on a larger scale. However, specific difficulties in recruitment were noted that warrant correction in additional trials. On the other hand, individuals who did use the apps were retained across the study duration, reported a reduction of depressive symptoms at post-intervention, and found the intervention acceptable. Additionally, improvements in certain areas of quality of life, such as energy level, fatigue, and emotional well-being at post-intervention were also reported. Together, the results provide preliminary evidence in support of the acceptability and effectiveness of using mobile apps in a primary care setting.

Table of Contents

Abstract	v
List of Figures	ix
List of Tables	x
Chapter 1: Introduction	1
Chapter 2: Method	8
Participants.....	8
Group Assignment	9
Setting and Procedure	9
Eligibility Criteria	10
Recruitment.....	11
Mobile Apps.....	13
Measures	14
Treatment Preference	14
Barriers to Mental Health Treatment	14
Feasibility.....	15
Acceptability	15
Health Service Utilization.....	16
The Patient Health Questionnaire-9 (PHQ-9).....	16
The Patient Health Questionnaire-8 (PHQ-8).....	16
36-Item Short Form Health Survey (SF-36)	17
The Five Facet Mindfulness Questionnaire (FFMQ).....	17
The Social Problem-Solving Inventory-Revised: Short-Form (SPSI-R: SF)	18

Table of Contents (Continued)

Automatic Thoughts Questionnaire-Negative (ATQ-N)	19
Data Analyses	19
Chapter 3: Results	20
Feasibility	20
Establishment of the Research Team	20
Screening and Recruitment	20
Retention Rates & Treatment Adherence	22
Assessment Process	23
Unexpected Barriers to Screening and Recruitment	24
Changes Made to Accelerate Recruitment	26
Acceptability	27
Treatment Preference	30
Treatment Progress & Outcomes	31
Participant One	31
Participant Two	33
Participant Three	36
Chapter 4: Discussion	40
Feasibility	40
Access to Patients	40
Eligibility Criteria	42
Retention	44
Acceptability	46

Table of Contents (Continued)

Treatment Progress & Outcomes47

Limitations & Future Directions47

Conclusion50

References51

Appendix A: Acceptability Measure57

Appendix B: Health Service Utilization Measure60

Appendix C: Provider Handout62

Appendix D: Flyer for Waiting and Exam Rooms63

Appendix E: Facebook Advertisement64

List of Figures

Figure	Page
Figure 1. Consolidated Standards of Reporting Trials (CONSORT) Diagram	21
Figure 2. Participant One: PHQ-8 Total Scores.....	31
Figure 3. Participant One: SF-36 Total Scores, Role Functioning and Fatigue	32
Figure 4. Participant One: SF-36 Total Scores, Social and Overall Health.....	33
Figure 5. Participant Two: PHQ-8 Total Scores	34
Figure 6. Participant Two: SF-36 Total Scores, Role Functioning and Fatigue.....	35
Figure 7. Participant Two: SF-36 Total Scores, Social and Overall Health	36
Figure 8. Participant Three: PHQ-8 Total Scores	37
Figure 9. Participant Three: SF-36 Total Scores, Role Functioning and Fatigue.....	38
Figure 10. Participant Three: SF-36 Total Scores, Social and Overall Health	39

List of Tables

Table	Page
Table 1. Participant Characteristics	8
Table 2. Participants' Mobile App Use.....	22
Table 3. Survey Completion Times	23
Table 4. Program Evaluations.....	27

Chapter 1

Introduction

Primary care has become the first point of contact for a majority of individuals experiencing depressive symptoms (Kessler & Stafford, 2008). It is estimated that 5 to 13% of patients seen by primary care providers are diagnosed with major depressive disorder, while the 12-month prevalence of depressive symptoms in primary care is 12.5% (Mitchell et al., 2009; Pignone et al., 2002). According to Moussavi et al. (2007), individuals with a history of depression endorse lower scores on measures of overall health when compared to those diagnosed with cardiovascular disease, asthma, arthritis, or diabetes. Further, symptoms of depression not only impact an individual's functionality in terms of missed work and reduced productivity (Wang et al., 2004), but those diagnosed with depression are more likely to report poorer overall physical health and experience higher rates of comorbid chronic diseases (Katon, 2003; Kessler & Stafford, 2008). As a result, individuals diagnosed with depression utilize a significantly greater amount of healthcare services and emergency room visits when compared to nondepressed individuals (Kessler & Stafford, 2008). Of the \$201 billion spent on mental health disorders in 2013, \$98.9 billion were spent on treating major depressive disorder (MDD) alone (Greenberg et al., 2015).

The standard of care for treating depression within primary care typically involves prescribing antidepressant medication, referral for outpatient psychotherapy, or some combination of these two treatments (Trangle et al., 2016). However, many patients do not adhere to treatment recommendations, discontinue treatment prematurely, or do not respond to antidepressants or psychotherapy (Kessler & Stafford, 2008; Sansone &

Sansone, 2012; Trangle et al., 2016). Additionally, these treatments may be too intensive for individuals with less severe depressive symptomatology. Given the problems associated with treating depression in primary care, alternative modes of treatment delivery have been proposed to increase the efficiency, accessibility, and effectiveness of mental health services.

One alternative to traditional, clinic-based care is the use of less intensive, more personalized mHealth interventions, which include mobile applications (apps). Mobile apps have distinct advantages over traditional mental health interventions, including lower costs, increased treatment accessibility, and greater retention (Donker et al., 2013). Additionally, these apps are generally available at little to no cost and can circumvent the stigmas associated with receiving professional help for psychological symptoms. Further, mobile apps provide individuals with the opportunity to track and monitor their symptoms and progress in real-time, which is a more accurate representation of their experience of symptoms and impact on daily life (Donker et al., 2013; Proudfoot et al., 2010). Thus, if individuals can monitor and track their symptoms and progress, they may be more inclined to adhere to the recommended treatment (Proudfoot et al., 2010). These advantages have led to the rapid development of mobile apps in recent years, with one recent review reporting the existence of over 1,000 apps available for the management of depression (Shen et al., 2015).

Numerous studies have examined the impact of using mobile apps on depression. One way in which researchers have explored the effectiveness of apps is by investigating whether individuals who utilize an app experience a statistically significant reduction of depressive symptoms. Preliminary evidence suggests that using mobile apps can reduce

depressive symptoms. For example, in their meta-analysis of 18 randomized controlled trials with 22 mobile apps, Firth et al. (2017) found that individuals using mobile apps to manage depressive symptoms experienced a significant reduction of symptoms when compared to control conditions ($g=0.38$, $p<0.001$). The authors reported moderate effect sizes compared to inactive control groups ($g=0.56$) and small effect sizes compared to an active control condition ($g=0.22$). In a large scale randomized controlled trial, Moberg et al. (2019) found that participants utilizing the mobile app Sanvello (i.e., Pacifica) experienced greater decreases in depression ($d=0.54$, $p<.001$), anxiety ($d=0.40$, $p<.01$), and the Depression Anxiety and Stress Scales-21 (DASS-21) scores ($d=0.46$, $p<.001$) at 4-weeks post-intervention when compared to the waitlist control condition.

Another way of defining outcome is through examining remission rates or clinically significant reductions of depressive symptoms. While definitions of remission rates vary across studies, evidence suggests that some individuals experience remission of depressive symptoms when utilizing mobile apps. Arean et al. (2016) evaluated remission rates, as defined by a reduction of pre-treatment Patient Health Questionnaire-9 (PHQ-9) scores of at least 50%, in three self-guided mobile apps: a problem-solving application, a cognitive training application, and a health information application, which served as the active control group. Results indicated that 45 out of the 100 participants (45%) randomized to the cognitive training application and 36 out of 79 participants (46%) randomized to the problem-solving therapy app experienced a remission of symptoms. In comparison, 34 out of 100 participants (34%) of the control condition participants experienced remission. Pratap et al. (2018) evaluated recruitment, engagement, and remission rates of individuals experiencing depressive symptoms, utilizing the same

conditions as Arean and colleagues. In this study, remission was defined as a decrease in PHQ-9 scores of at least 5 points or more from baseline. They found 117 out of 345 participants (34%) experienced a remission of symptoms. However, results also indicated that 51% of participants were "nonresponders" (i.e., experiencing a change in PHQ-9 scores of <5 points), and 11% experienced an increase in depressive symptomology.

In addition to examining whether apps can reduce depressive symptoms or cause a remission of symptoms, studies have also explored whether the severity of symptoms one experiences influences the effectiveness of mobile apps. Results from these studies are mixed. For example, a recent meta-analysis revealed moderate effect sizes ($g=0.51$) for individuals with self-reported mild to moderate depressive symptoms, suggesting that mobile apps may be most effective for this subsample of depressed patients (Firth et al., 2017). In contrast, Pratap et al. (2018) found that changes in depressive symptomology were significantly associated with baseline severity of symptoms, in that participants who endorsed severe depressive symptoms experienced the greatest reduction of depressive symptoms during the first four weeks of treatment ($\beta=4.19, p<.001$). The findings from Pratap et al. (2018) not only stand in contrast to results from Firth et al. (2017) but also to the existing self-help literature, which recommends the use of self-help interventions for mild to moderate depressive symptoms (Clarke et al., 2009; Cuijpers et al., 2010). Therefore, they may need further replication.

A more recent question being explored in the literature is related to the long-term effects of mobile apps for depression. Results from these studies are also mixed. For instance, Arean et al. (2016) found no significant changes in PHQ-9 scores at the 12-week follow-up. Similarly, Pratap et al. (2018) found no significant reductions of PHQ-9

scores across conditions at the 12-week follow-up. On the other hand, Moberg et al. (2019) found that two months post-intervention, the rates of clinically significant changes for participants in the Pacifica condition was 35% for the PHQ-8 (compared to 42% at four weeks-post baseline). Given the issues with retention and engagement in both Areal et al. (2016) and Pratap et al.'s (2018) studies, the long-term effects of mobile apps may be related to one's engagement with the mobile app.

While the results from these studies indicate that mobile apps have the potential to effectively treat depressive symptoms, there are several gaps within the current literature. First, most mobile apps currently available to the general public have been inadequately evaluated for their effectiveness in treating depressive symptoms (Donker et al., 2013; Firth et al., 2017). For example, Martinez-Perez et al. (2013) found that out of the 1,536 depression apps available to the general public, only 32 published articles evaluated the effectiveness of depression apps.

Second, many of the published studies have been plagued with retention and engagement issues; however, it is unclear what factors contribute to these issues and the user end experience of utilizing a mobile app. For example, Areal et al. (2016) reported that 58% of the 626 participants did not download either of the two intervention apps. Those who did download and use the app, only used the mobile app an average of eleven times over the course of four weeks. Pratap et al. (2018) successfully enrolled 1040 participants; however, only approximately 34% (348 out of 1040) were active in the study, as defined by completing at least one PHQ-9 measure. Furthermore, by week 4 of the study, approximately 50% of participants dropped out. Given these issues with

engagement and retention, it is important to understand factors that might motivate app engagement and prolong app usage.

Third, the studies to date have neglected to examine patient preferences towards specific mobile apps. Mobile apps offer more flexibility than routine clinical care, as patients can select mobile apps based on their individual preferences. Additionally, there is evidence to suggest that primary care patients have specific preferences regarding the type of psychotherapy they would prefer to receive (e.g., cognitive therapy, behavioral activation, problem-solving therapy, interpersonal psychotherapy, and mindfulness) if they were to seek treatment for depression (Haugh et al., 2019). Specifically, Haugh et al. (2019) conducted a cross-section survey to assess the acceptability of the stepped care model of depression treatment and treatment preferences in a group of primary care patients. Results indicated that participants most frequently preferred cognitive therapy (28%, $n=26$), followed by problem-solving therapy (25%, $n=24$), mindfulness (18%, $n=17$), behavioral activation (17%, $n=16$), and interpersonal (12%, $n=11$). Further, numerous studies have indicated that incorporating patient treatment preferences throughout treatment improves clinical outcome (Firth et al., 2015; Lin et al., 2005; Swift & Callahan, 2009), increases adherence (Kwan et al., 2010), and reduces rates of attrition (Swift & Greenberg, 2015). Thus, examining patient preference for mobile apps might help us understand factors that could enhance treatment outcomes.

Finally, these apps have yet to be examined within the context of primary care. Due to the barriers of accessing mental health care, the potential costs of untreated or inadequately treated depression, and existing gaps in the literature regarding the modest quantity and poor quality of most empirical evidence to date, it is necessary to explore

mobile apps for treating depression in primary care settings. Through such research, we might improve the accessibility, efficiency, and effectiveness of mental health services within primary care.

Therefore, this study's primary aim is to evaluate the feasibility and acceptability of implementing three mobile apps designed to ameliorate depressive symptoms within primary care. Specifically, this study aims to evaluate the feasibility of recruitment, randomization, retention, assessment procedures, and participant engagement with the mobile apps. Participants will be randomized, with a 1:1:1:1 allocation, to receive a) MoodTools, a cognitive behavioral therapy app, b) Moving Forward, a problem-solving therapy app, c) Mindfulness Coach, a mindfulness-based app, or d) the waitlist control condition. Regarding acceptability, previous research suggests that both patients and physicians in primary care find these mobile delivery methods acceptable (Haugh et al., 2019). Furthermore, most patients in that sample (44%, $n=57$) reported if they were to seek treatment for depressive symptoms, they would prefer to begin treatment with a self-help intervention, specifically delivered via a mobile app.

The secondary aim is to examine whether participants utilizing a mobile application will experience a reduction of depressive symptomology and improvements in quality of life when compared to a waitlist control condition. Based on previous literature, we hypothesize that patients utilizing mobile apps will show a clinically significant reduction in depressive symptoms and improved quality of life when compared to the waitlist control condition.

Chapter 2

Method

Participants

Participant characteristics ($N=3$) are displayed in Table 1.

Table 1

Participant Characteristics

Variable	Participant 1	Participant 2	Participant 3
Age	21	33	27
Gender Identity	Man	Woman	Woman
Marital Status	Prefer not to answer	Never married	Married
Race	White	White	White
Ethnicity	Prefer not to answer	Non-Hispanic/Latinx	Non-Hispanic/Latinx
Education	Associate Degree	Associate Degree	Associate Degree
Employment Status	Full-time	Part-time	Full-time
Income	\$25,000-\$49,000	Less than \$14,999	\$25,000-\$49,000
Insurance	Medicare only	Medicaid	Private or commercial insurance
Medication	--	Zoloft	Lexapro & Wellbutrin
Length	--	3 years	2 years

Variable	Participant 1	Participant 2	Participant 3
Previous Psychotherapy	No	Yes	Yes
How long ago did you receive psychotherapy for depression?	--	3 or more years ago	3 to 6 months ago
Satisfaction with Treatment	--	Somewhat satisfied	Somewhat satisfied
Do you believe that the treatment you received was helpful?	--	Somewhat agree	Somewhat agree
During the past 12 months, was there any time when you needed mental health treatment but did not get it?	--	No	Yes
Reasons for not seeking treatment	--	--	The hours were not convenient

Group Assignment

Participants one and two were randomized to the Mindfulness Coach app, and participant three was randomized to the MoodTools App. Due to low enrollment rates, there were no participants randomized to the waitlist control condition as initially planned.

Setting and Procedure

Participants were recruited between August 25, 2019 and March 12, 2020 from two Family Medicine clinics affiliated with the School of Osteopathic Medicine at Rowan University. Due to the COVID-19 pandemic, recruitment for this project was

prematurely terminated on March 15, 2020. At that time, Rowan University required all students to cease all in-person data collection that would put them in direct contact with the public. Additionally, the Family Medicine clinics affiliated with the School of Osteopathic Medicine only allowed essential employees in the facility and did not allow in-person recruitment for research protocols. When the first author left for a doctoral internship in June of 2020, these policies remained.

Eligibility Criteria

Initial eligibility criteria required participants to (1) be at least 18 years of age or older, (2) own an iPhone with Wi-Fi or 3G/4G capabilities, and (3) obtain a score between five and fourteen on the nine-item Patient Health Questionnaire (PHQ-9). For those who were managing their depression through psychotropic medication, their medication regimen must have been stable for six weeks. This information was confirmed through the patient and their primary healthcare provider.

Participants were deemed ineligible if they (1) scored fifteen or higher on the PHQ-9 at prescreening, (2) were actively suicidal or exhibiting suicidal ideation (as determined by an endorsement of one or higher on item 9 on the PHQ-9 at prescreening), (3) were receiving psychotherapy (by self-report), (4) were pregnant (by self-report), or (5) had a self-reported history of bipolar disorder, substance use disorder, dementia, neuro-developmental disorders, or schizophrenia spectrum disorders. Before approaching a patient, a member of the research team asked their primary care provider if the patient had a history of the psychiatric diagnoses mentioned above.

Recruitment

Participants were prescreened using the PHQ-9. Yearly administration of this instrument was already a routine practice at these locations. The certified medical assistants notified a member of the research team of patients who scored between five and fourteen on the PHQ-9. A member of the research team approached those patients following their visit with their provider to explain the study, assessed interest and eligibility, and completed informed consent. After informed consent, participants completed the baseline survey. The first section of the baseline survey comprised questions inquiring about sociodemographic information, mental health treatment history, barriers to engaging in mental health treatment, treatment preferences, and health service utilization. Additionally, participants completed the following measures: The Patient Health Questionnaire-8 (PHQ-8), Self-Report Quality of Life (SF-36), The Five Facet Mindfulness Questionnaire (FFMQ), The Social Problem-Solving Inventory-Revised: Short Form (SPSI-R: SF), and the Automatic Thoughts Questionnaire-Negative (ATQ-N). The survey was administered through Qualtrics, an online survey platform, via an iPad.

After completing the baseline assessment, all participants were then randomized with a 1:1:1:1 allocation to receive a) MoodTools, a cognitive behavioral therapy app, b) Moving Forward, a problem-solving therapy app, c) Mindfulness Coach, a mindfulness-based app, or d) the waitlist control condition. Participants randomized to the waitlist control condition would be informed that they would have access to the mobile apps after completing the final study survey. They would also be given the opportunity to be re-entered into the study using their most preferred mobile application.

For participants randomized to a mobile app condition, a member of the research team helped all participants download the mobile application and provided brief training (~10 minutes) on the mobile application's specific features and how to use the mobile application effectively. Participants were also provided with a link to an instructional YouTube video created by the study coordinator on the app's specific features and how to use it effectively. Participants were encouraged to use the mobile app daily but were asked to use it at least once per week.

Participants were contacted via email weekly by the research study coordinator to help with any difficulties or problems encountered when using the mobile application. Within that email, participants were provided with a link to a brief Qualtrics survey containing the PHQ-8 and two questions inquiring about how often they use the mobile app (i.e., "How many days per week, on average, did you use the app" and "On average, how many total minutes do you spend using the app per day").

All measures were completed via Qualtrics. Outcomes were assessed at three time points: baseline, post-treatment (i.e., six weeks later), and follow-up (i.e., ten weeks after baseline). The post-treatment and follow-up surveys comprised the same questions and measures as the baseline, except for questions inquiring about sociodemographic information, mental health treatment history, barriers to engaging in mental health treatment, and treatment preferences. Additionally, for participants who were randomly assigned to an app condition, the post-treatment survey included questions about the acceptability of and satisfaction with the mobile app used throughout the study.

Participants received compensation for each survey packet they returned. Specifically, participants were given a \$10 gift card for completing the baseline survey, a

\$15 gift card for completing the post-treatment survey, and a \$20 gift card for completing the follow-up survey (total possible compensation for completion of all surveys was \$45).

The University's Institutional Review Board approved this study.

Mobile Apps

The mobile apps used in this study were chosen based on their consistency with evidence-based treatments for depression as outlined on the American Psychological Association's Society for Clinical Psychology's website (Society for Clinical Psychology, 2020) and those endorsed by the American Academy of Family Medicine (Rebebrew, 2018). Clinical practice guidelines for treating depression recommend the use of empirically supported treatments, including behavioral therapy, cognitive therapy, cognitive-behavioral, mindfulness-based cognitive therapy, interpersonal psychotherapy, psychodynamic psychotherapies, and problem-solving therapy (American Psychological Association, 2019; Society for Clinical Psychology, 2020). Based on the apps available within the Apple app store, three treatments were selected: cognitive-behavioral, social problem-solving, and mindfulness. We then selected three apps based on their consistency with the underlying theory, ease of use, design quality, and cost (i.e., free).

The cognitive-behavioral-based app, MoodTools (version 1.6), was created by Inquiry Health LLC. MoodTools provides users with information on the components of cognitive-behavioral therapy. The application focuses on teaching individuals how to monitor and challenge maladaptive beliefs and increase engagement in previously enjoyable activities. The social problem-solving app, Moving Forward (version 1.3), was created by the Department of Veterans Affairs and the Department of Defense. This application was designed to help individuals identify their problem-solving style,

understand factors that inhibit problem-solving abilities, teach patients how to effectively solve problems, and provide the ability to track progress over time. The mindfulness-based app, Mindfulness Coach (version 2.3), was created by the Department of Veterans Affairs. This application focuses on teaching individuals how to engage in mindfulness practice. The application provides users with information on mindfulness, 21 audio-guided mindfulness exercises, and allows users to track their progress over time.

Measures

Participants were asked to indicate their gender identity, age, marital status, racial identity, ethnicity, level of education, employment status, and income. Participants were also asked to provide information regarding their current health insurance status, prior engagement in psychotherapy, and prior and current psychopharmacological treatment. The following variables were also measured.

Treatment Preference

Participants were asked to indicate their strength of preference for the mobile application on a 5-point Likert scale ranging from 1 (*Not strong*) to 5 (*Very strong*). Prior to this, they were provided with a brief overview of problem-solving therapy, cognitive-behavioral therapy, and mindfulness and asked to indicate which of those treatments they would prefer and the strength of that preference.

Barriers to Mental Health Treatment

One question from the National Comorbidity Survey Replication (Mojtabi et al., 2011) regarding reasons for not seeking mental health treatment was included in this survey. More specifically, participants were asked, "During the past 12 months, was there any time when you needed mental health treatment or counseling for yourself but did not

get it?" If participants answered "yes" to this question, they were then able to select from a list of 14 statements that included reasons involving structural barriers (e.g., transportation, financial/insurance concerns), low perceived need for treatment, the desire to handle the problem on their own, the presence of stigma, and concerns that therapy or counseling would not be helpful.

Feasibility

In accordance with recommendations from Leon et al. (2011), feasibility was assessed through the following variables: number of participants screened per month; number enrolled per month; the proportion of those eligible participants who enrolled in the study; participant adherence to the protocol, as measured through self-reported daily use of the app; the proportion of planned assessments completed by participants; and duration of assessments.

Acceptability

Acceptability was assessed via a self-report measure created by the author. These questions were modified from Arigo et al. (2015). Participants were surveyed about their satisfaction with the application, perceived effectiveness, the likelihood of participating in the study again, whether they would recommend the application to a friend or family member with depression, and level of confidence regarding future use of the app and use of specific skills. Items were rated on a 5-point Likert scale. Participants were also encouraged to provide written feedback about the mobile app features they liked the most and least, specific ways in which the mobile app helped them manage depressive symptoms, recommendations for improvements, and whether they still needed assistance

managing specific depressive symptoms. This measure contains a total of 12 items. See Appendix A for the full measure.

Health Service Utilization

Health service utilization was evaluated using a self-report measure created by the author. Participants were asked to indicate how often they used specific health care services (i.e., medical/specialty services, primary care, emergency department, and psychiatry services) in the past month and the purpose of those visits. This measure consisted of 10 items. See Appendix B for the full measure.

The Patient Health Questionnaire-9 (PHQ-9)

The PHQ-9 is a 9-item self-report questionnaire that assesses each of the DSM-5 criteria for Major Depressive Disorder (MDD; Kroenke et al., 2001). Items are rated on a 4-point Likert scale, ranging from 0 (not at all) to 3 (nearly every day). Total scores on the PHQ-9 range from 0 to 27, and a total score of 10 or greater is used as a clinical cut-off for the indication for a probable DSM-5 diagnosis of MDD. The PHQ-9 has high sensitivity (88%) and specificity (88%); (Kroenke et al., 2001) and excellent validity and reliability (Kroenke et al., 2001).

The Patient Health Questionnaire-8 (PHQ-8)

The PHQ-8 is an 8-item self-report questionnaire that assesses eight of the nine DSM-5 criteria for Major Depressive Disorder (MDD; Kroenke et al., 2009). The ninth item, which assesses thoughts of death and self-harm, is omitted. Items are rated on a 4-point Likert scale, ranging from 0 (not at all) to 3 (nearly every day). Total scores on the PHQ-8 range from 0 to 24, and a total score of 10 or greater is used as a clinical cut-off for the indication for a probable DSM-5 diagnosis of MDD (Kroenke et al., 2009).

Treatment recommendations for individuals who endorse scores between five and fourteen include watchful waiting, education, self-management, psychotherapy, or medication (DeJesus et al., 2007). Individuals who endorsed scores of fifteen or higher warrant treatment for depression using antidepressant medication, psychotherapy, or a combination of the two (DeJesus et al., 2007). Therefore, these individuals proceeded with the level of care recommended by their primary care provider.

36-Item Short Form Health Survey (SF-36)

The SF-36 is a 36-item self-report questionnaire that assesses health status and quality of life (McHorney et al., 1993). The SF-36 consists of eight subscales that are intended to measure health-related quality of life: the physical functioning subscale consists of 10 items, the role limitations due to physical health subscale consists of 4 items, the role limitations due to emotional problems subscale consists of 3 items, the energy/fatigue subscale consists of 4 items, the emotional well-being subscale consists of 5 items, the social functioning subscale consists of 2 items, the pain subscale consists of 2 items, and the general health subscale consists of 5 items. Items are rated on a Likert-scale, with some items rated on a 5 or 6-point scale and others on a 2 or 3-point scale. The eight subscales demonstrate excellent reliability, with alpha coefficients of .93, .84, .83, .86, .90, .85, .78, and .78, respectively (McHorney et al., 1993).

As part of a larger project, participants also completed the following measures.

The Five Facet Mindfulness Questionnaire (FFMQ)

The FFMQ is a 39-item self-report questionnaire developed to assess mindfulness skills (Baer et al., 2006). Baer et al. (2006) used exploratory factor analysis to examine the facet structure of five independently developed self-reported mindfulness

questionnaires: The Mindful Attention Awareness Scale, The Freiburg Mindfulness Inventory, The Kentucky Inventory of Mindfulness Skills, The Cognitive and Affective Mindfulness Scale, and The Mindfulness Questionnaire. Results from the exploratory factor analysis yielded five independent, yet related, facets of mindfulness: the *Observe* subscale consists of 8 items, the *Describe* subscale consists of 8 items, the *Acting with Awareness* subscale consists of 8 items, the *Nonjudging of inner experience* subscale consists of 8 items, and the *Nonreactivity to inner experience* subscale consists of 7 items. Items are rated on a 5-point Likert scale, ranging from (1) *never or very rarely true* to (5) *very often or always true*. The five separate subscales, Observe, Describe, Acting with Awareness, Nonjudging of inner experience, and Nonreactivity to inner experience demonstrate high internal consistency (Cronbach's alpha = .83, .91, .87, .87, and .75, respectively; Baer et al., 2006).

The Social Problem-Solving Inventory-Revised: Short Form (SPSI-R: SF)

The SPSI-R: SF is a 25-item self-report questionnaire that assesses two kinds of problem-solving orientations and three problem-solving styles (D'Zurilla et al., 2002). Items are rated on a 5-point Likert, ranging from (0) *not at all true of me* to (4) *extremely true of me*. The SPSI-R-SF measures all five dimensions of the social problem-solving model, including Positive Problem Orientation (PPO; 5 items), Negative Problem Orientation (NPO; 5 items), Rational Problem-solving Style (RPS; 5 items), Impulsive-Careless Style (ICS; 5 items), and Avoidance Style (AS; 5 items). The SPSI-R-SF demonstrates high internal consistency (Cronbach's alpha = .93) and test-retest reliability ($r=.84$) for the total score. The five separate subscales (PPO, NPO, RPS, ICS, and AS) demonstrate moderate to high internal consistency (Cronbach's alpha = .79, .80, .88, .78,

and .89 respectively) and adequate test re-test reliability ($r=.72, .79, .74, .72, \text{ and } .73$, respectively, D’Zurilla et al., 2002) in young adult and adult samples.

Automatic Thoughts Questionnaire –Negative (ATQ-N)

The ATQ-N is a 30-item self-report questionnaire that assesses the frequency of negative automatic cognitions associated with depressive symptoms (Hollon & Kendall, 1980). Items are rated on a 5–point Likert scale, ranging from (1) *not at all* to (5) *all the time*. Total scores range from 30 to 150. The ATQ-N demonstrates high internal consistency (Cronbach’s alpha = .96; Hollon & Kendall, 1980).

Data Analyses

Data analyses were conducted using IBM SPSS 27 and Microsoft Excel 2020 for graphical representations of data. Descriptive analyses are used to present the frequency and duration of app use, completion time of study surveys, and acceptability of the mobile apps. Individual participant changes in depressive symptoms and self-reported quality of life are depicted graphically.

Chapter 3

Results

Feasibility

Establishment of the Research Team

The research team comprised a full-time faculty member within the Psychology Department at Rowan University, a Licensed Clinical Psychologist and Physician from the Department of Family Medicine, two advanced level doctoral students, one undergraduate research assistant, and one post-baccalaureate research assistant.

Recruitment Team. Recruitment was completed by one doctoral-level student, one undergraduate research assistant, and one post-baccalaureate research assistant. Recruitment team members were available for recruitment for a total of 16 hours per week. The licensed clinical psychologist and physician from the Department of Family medicine prescreened potential patients at the beginning of each week for the research assistants to approach.

Primary Care Office Staff. The primary care staff comprised family medicine residents, physicians, nurse practitioners, and certified medical assistants.

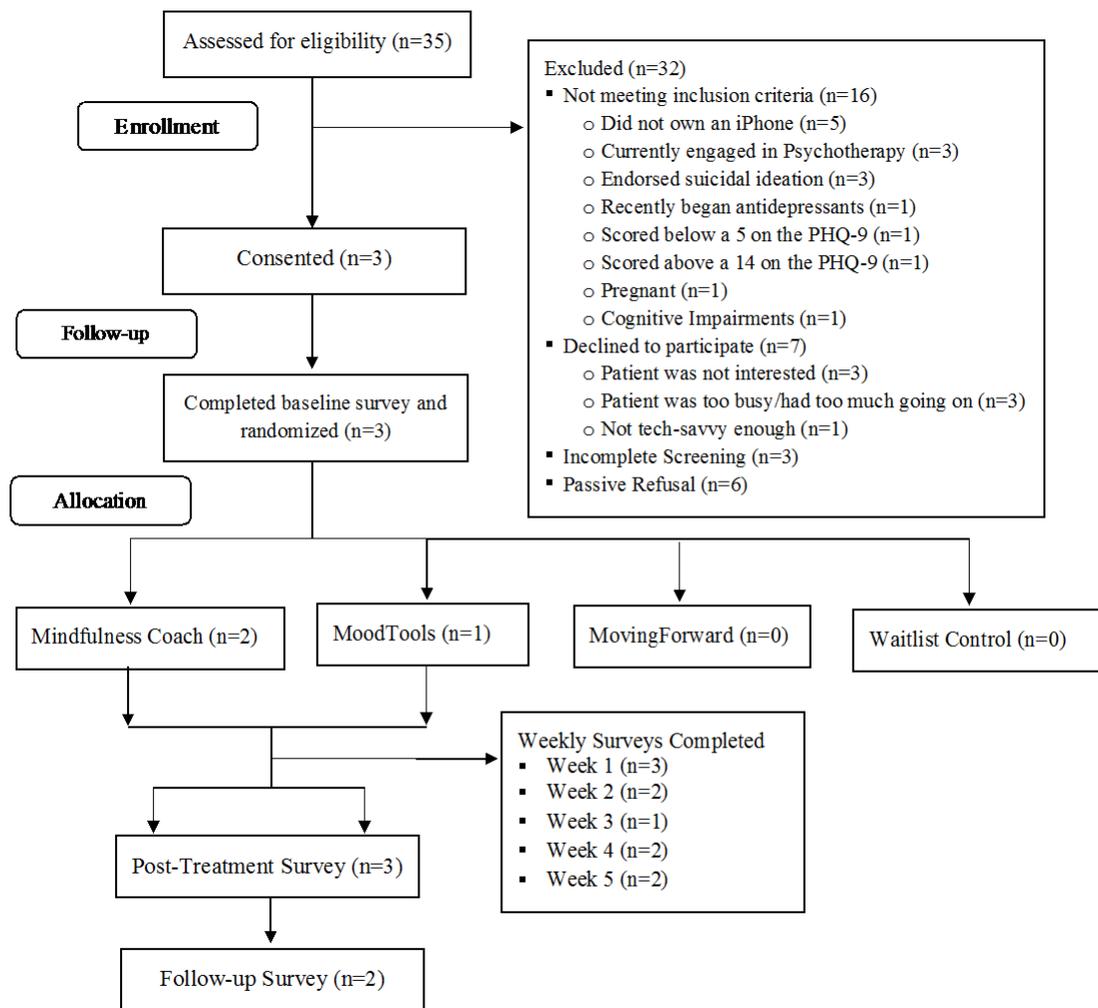
Screening and Recruitment

Screening and recruitment data are displayed in Figure 1. Approximately 5.33 patients were screened per month, resulting in 35 potential participants. Over a six-month period, 35 primary care patients were screened, and three were enrolled, resulting in an 8.6% screening to enrolled ratio. Of those not enrolled, sixteen did not meet the inclusion criteria, seven declined to participate, three did not finish screening, and six patients could not be contacted after expressing interest in the study. As displayed in Figure 1,

two participants were randomized to the Mindfulness Coach condition and one participant was randomized to the MoodTools condition. No participants were randomized to the MovingForward or Waitlist Control conditions because of initial low enrollment. However, and most importantly, pandemic circumstances precluded additional data collection.

Figure 1

Consolidated Standards of Reporting Trials (CONSORT) Diagram



Note. Due to low enrollment rates, there were no participants randomized to the waitlist control condition.

Retention Rates & Treatment Adherence

As displayed in Figure 1, all three participants completed the 6-week intervention and the post-treatment survey, yielding a 100% retention rate. Participants were encouraged to use the mobile app daily but were asked to use it at least once per week. Participants' app use (i.e., days per week and minutes per day) is presented in Table 2.

Table 2

Participants' Mobile App Use

Participant One ^a		
Survey	App Use (Average days per week)	Minutes per use
Week 1	Rarely (1 Day)	7
Week 2	Some of the time (2-3 days)	5
Week 3	Did not complete survey	--
Week 4	Did not complete survey	--
Week 5	Some of the time (2-3 days)	5
Week 6	Some of the time (2-3 days)	7
Participant Two ^b		
Survey	App Use (Average days per week)	Minutes per use
Week 1	A moderate amount of the time (4-5 days)	5
Week 2	Did not complete survey	--
Week 3	Did not complete survey	--
Week 4	A moderate amount of the time (4-5 days)	5
Week 5	Did not complete survey	--
Week 6	Some of the time (2-3 days)	2
Participant Three ^c		
Survey	App Use (Average days per week)	Minutes per Use
Week 1	Some of the time (2-3 days)	10
Week 2	Some of the time (2-3 days)	10
Week 3	Some of the time (2-3 days)	5
Week 4	Rarely (1 day)	5
Week 5	Some of the time (2-3 days)	5
Week 6	Not at all	0

^a Participant one tracked their app use for four out of the six weeks of the intervention.

^b Participant two tracked their app use for three out of the six weeks of the intervention.

^c Participant three tracked their app use during all six weeks of the intervention.

As displayed in Table 2, none of the participants engaged with the app daily; however, two of the three participants used the app two to three days per week, for approximately 5 minutes during each use. Participants who completed the follow-up survey indicated they continued to use the app after study completion. One participant used the app two to three days per week for approximately five minutes each time. Another participant reported using the app at least one day per week for approximately five minutes each time.

Assessment Process

Participants were asked to complete the baseline assessment, five weekly surveys, the post-intervention survey, and the follow-up survey. As presented in Figure 1, participation in the weekly surveys varied, and the week one survey was the only survey completed by all three participants. Two out of three participants completed the weeks two, four, and five surveys, while only one participant completed the week three survey. There was a 100% completion rate for the post-intervention survey, while only two out of three participants (67%) completed the follow-up survey. The average completion times for each survey are presented in Table 3.

Table 3

Survey Completion Times

Survey	<i>M (in minutes)</i>	<i>SD</i>
Baseline	37.19	20.78
Week 1	1.91	0.89
Week 2	1.45	0.31
Week 3	1.03	--
Week 4	1.31	0.22
Week 5	1.13	0.08
Week 6	19.41	3.51
Week 10	12.18	0.56

Unexpected Barriers to Screening and Recruitment

As previously mentioned, 5.33 patients were screened per month, which was lower than anticipated. There were several unexpected barriers to screening and enrolling patients throughout the recruitment process. The first barrier was accessing potentially eligible patients. Members of the research team were not granted access to this institution's electronic medical record (EMR) system. Therefore, we were not able to prescreen and identify potentially eligible patients before going to the clinic. To overcome this barrier, both of our collaborators, who are providers within the Department of Family Medicine, prescreened potential participants at the beginning of the week for the research assistants to approach.

A second barrier was achieving a steady referral rate from residents and providers. A handout was created and provided to residents and providers (see Appendix C for a copy of the handout). The handout explained the purpose of the study and the eligibility criteria. Additionally, each week the research assistants would make their presence known to the providers and residents and remind them about the research study. However, members of the research team only received five direct referrals from providers and residents. This could be further explained by the fact that the resident schedules would change every four weeks, and/or a new set of residents would come to the clinics. The research team members would then have to introduce the study to the new residents or review the study protocol and eligibility criteria with the previous residents.

The third barrier to recruitment was the number of potential participants to approach varied at each location. For instance, at one of the locations, research team members recruited for 32 hours over 7 months and approached 11 patients. At the other

location, research team members recruited for 90 hours over 7 months and approached 17 patients.

The fourth barrier to recruitment was patients' ability to stay after their appointments to discuss the research study. To not disrupt clinic flow, research assistants were asked to approach patients after visiting with their provider. However, many patients often waited for extended periods of time for their provider, and some would immediately leave before the research assistants had a chance to approach them. There were also times when the research assistants would attempt to approach the patients right after their appointment, and they would state that they could not stay and asked to be contacted at a later time.

A fifth barrier to recruitment was being unable to contact patients who requested follow-up calls to learn more about the study. For the six patients who requested follow-up calls, research team members could not reach those patients despite contacting each patient four times after the initial meeting. More specifically, six patients were sent one follow-up email following their appointment. Additionally, a member of the research team called each patient three times on three separate occasions and left voicemails when possible. These patients did not return any phone calls or emails.

The sixth barrier to recruitment was the availability of research staff to assist with the recruitment process. The doctoral-level student was available for recruitment sixteen hours per week. The undergraduate and post-baccalaureate research assistants were each available for recruitment four hours per week and predominantly recruited alongside the doctoral-level student. Additionally, during December and January, when the doctoral

level student was interviewing for predoctoral internship positions, recruitment occurred twice.

A final barrier to recruitment was our eligibility criteria. Of the 35 patients approached, 45.7% ($n=16$) were ineligible, suggesting that our initial criteria were too restrictive. As seen in Figure 1, the most common reasons participants were not eligible to participate in this study were because they did not own an iPhone ($n=5$), were currently engaged in psychotherapy ($n=3$), and they endorsed item 9 (i.e., thoughts that you would be better off dead, or thoughts of hurting yourself in some way) on the PHQ-9 ($n=3$).

Changes Made to Accelerate Recruitment

To accelerate recruitment, two modifications were made to the initial research protocol. The first modification was made two months after recruitment began and incorporated the use of flyers advertising the study. Flyers were displayed in examination and waiting rooms (see Appendix D for a copy of the flyer). Additionally, primary care providers could refer patients to the study coordinator. The second modification was made seven months into recruitment and including advertising the study on the Department of Family Medicine's Facebook page (see Appendix E for the Facebook advertisement). Interested patients were directed to a link to the prescreening survey, which consisted of the PHQ-8 and was administered through Qualtrics. Those who were eligible to participate were contacted via phone or email within 24-hours to schedule an in-person meeting with the study coordinator to complete the recruitment and consent process.

An additional change that was made during the second modification was related to the eligibility criteria. The initial criterion appeared too restrictive, given that 50% of

the patients approached were deemed ineligible. Thus, it was decided to expand the eligibility criteria. Since two of the three mobile apps were available across all platforms (i.e., MoodTools and Mindfulness Coach) and no participants were randomized to the application that was only available on the iOS platform, it was decided to remove the MovingForward app from randomization. We also expanded the PHQ-9 inclusion criteria to include participants who scored between a five and twenty-four on the PHQ-9. However, due to the COVID-19 pandemic, recruitment for this study prematurely ended on March 12, 2020, and we were unable to assess to what extent the proposed changes would accelerate the recruitment process.

Acceptability

Participants answered six Likert scale questions about their willingness to participate in the study again, satisfaction with the application, perceived effectiveness, the likelihood of participating in the study again, whether they would recommend the application to a friend or family member with depression, and level of confidence regarding future use of the application and use of specific skills. Results from the acceptability survey are presented in Table 4.

Table 4

Program Evaluations

Survey Item	Participant One	Participant Two	Participant Three
How likely would you be to participate in this study again?	Somewhat likely	Extremely unlikely	Somewhat likely

Survey Item	Participant One	Participant Two	Participant Three
How satisfied are you with the mobile application you worked with?	Somewhat satisfied	Somewhat satisfied	Very satisfied
Would you recommend this mobile application to a friend or family member with depression?	Yes, I would recommend it with some hesitation	Yes, I would strongly recommend it	Yes, I would strongly recommend it
How well do you think you would have managed your depressive symptoms during these 6 weeks without the mobile application?	Slightly better	Slightly better	Slightly better
How effective was the mobile application at helping you with your depression?	Neither effective nor ineffective	Somewhat effective	Somewhat effective
How often did you use the skills suggested by the mobile application?	Once a week	2-3 times per week	Once a week
How confident did you feel using the skills that were presented in the mobile app to manage depressive symptoms?	Neither confident or not confident	Somewhat confident	Somewhat confident
Please indicate how confident you are that, over the next three months, you will continue to use the mobile application?	Neither likely nor unlikely	Somewhat likely	Somewhat likely

Participant feedback varied regarding views on satisfaction with the app, as participants one and two reported that they were "somewhat satisfied." Participant three endorsed being "very satisfied" with the mobile app. Despite some variability in satisfaction with the app, all participants reported that they would recommend the app to a friend or family member with depressive symptoms; however, all participants reported that they believe they would have managed their depressive symptoms "slightly better" without the mobile app. Additionally, participants two and three reported the apps were "somewhat effective" in helping them manage their depressive symptoms. Participant one reported the app was "neither effective nor ineffective".

Acceptability was also assessed through the use of open-ended questions. Participants were asked to indicate factors they liked most and least about participating in the study and the specific features of the app they liked most and least. They were also asked about how the mobile app helped them manage depressive symptoms and what, if anything, they believed they still need help with related to managing their depressive symptoms.

Qualitative feedback showed that participants two and three reported they liked the mobile apps the most, and participant one liked having their depressive symptoms normalized. The factor participants one and two liked least about the study was "having to complete the surveys." Additionally, participants two and three reported that "time" would be the only factor influencing their decision to participate in this study again.

Regarding the mobile apps' specific features, participant one stated that they liked "how easy it is to use the app and how convenient it was having it on my phone." Participant two reported they liked the mindfulness of breath exercise the best, while

participant three stated, "I like how you talk yourself through a bad thought. This made me start to do it automatically without needing the app." Regarding features of the app's participants liked the least, participants two and three did not have any feedback, while participant one reported that they "wished there were less options to choose from."

In terms of the specific ways the mobile app helped them manage their symptoms, participant one stated, "it helped me realize that my symptoms are normal and other people have them, I'm not the only one." Participant two reported that the app was relaxing and calming, while participant three stated, "when I had a negative thought, I thought about the app and how I may be overreacting and such." Regarding continued depressive symptom management, participant one reported "I feel like I'm getting a better grasp on it," participant two reported they need help "lowering stress," and participant three stated "getting motivated to get up and move and not just sit around all day."

Treatment Preference

Preference for the type of mobile app was assessed by first providing participants with a brief overview of problem-solving therapy, cognitive-behavioral therapy, and mindfulness. They were then asked to indicate which of those treatments they would prefer and the strength of that preference on a 5-point Likert scale ranging from 1 (*Not strong*) to 5 (*Very strong*). Preference data is available for two out of the three participants, as one participant skipped this item. Participants two and three answered the preference questions identically. Both participants indicated a moderately strong (i.e., rating of a 3 out of 5 on the Likert Scale) preference for Cognitive Behavioral Therapy.

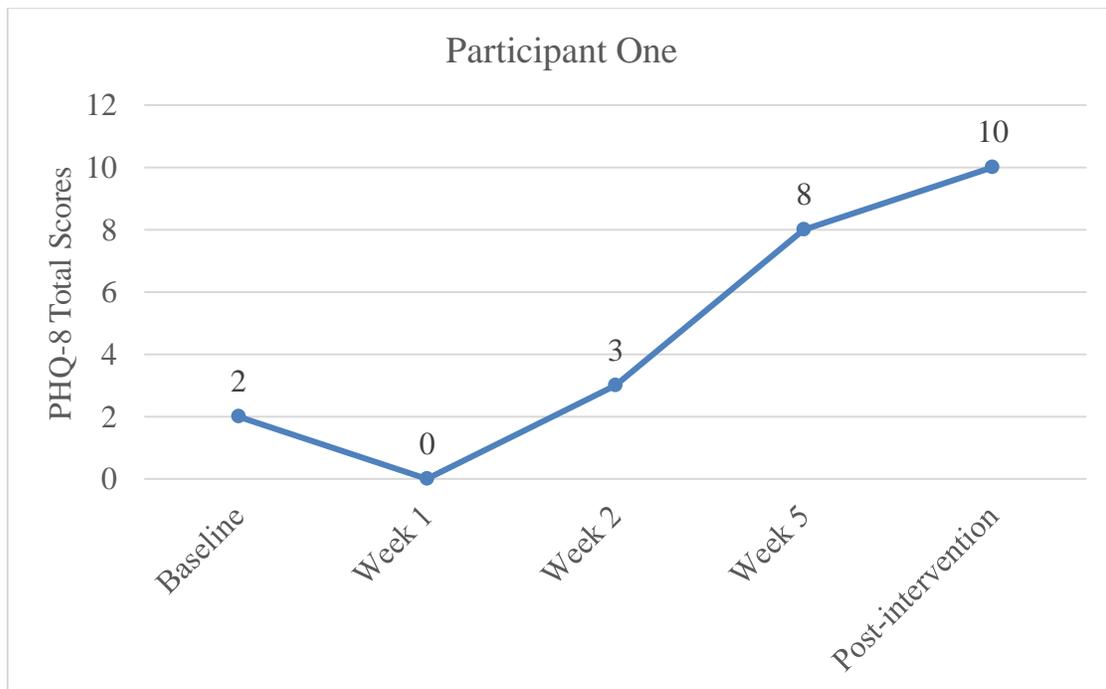
Treatment Progress & Outcomes

Participant One

Depression. When participant one completed the PHQ-9 in the office, with the CMA administering it, they endorsed a score of six, while their baseline PHQ-8 score was a two. During the six-week period, participant one experienced an eight-point increase in depressive symptoms. See Figure 2 for participant one's PHQ-8 scores throughout the study.

Figure 2

Participant One: PHQ-8 Total Scores



Quality of Life. Participant one's SF-36-SF scores are displayed in Figures 3 and 4. During the six-week intervention period, participant one experienced a decline in

physical functioning, as evidenced by a 15-point decrease in their scores on this subscale (please see Figure 3). However, participant one reported an improvement in energy level and fatigue (see Figure 3) and overall health (see Figure 4) during the intervention period.

Figure 3

Participant One: SF-36 Total Scores, Role Functioning and Fatigue

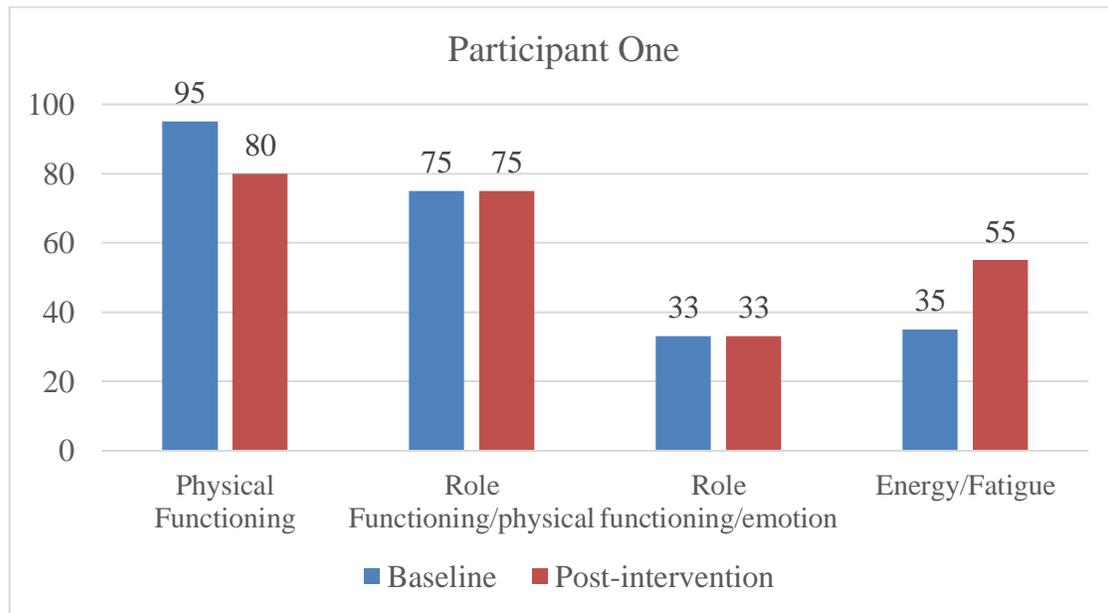
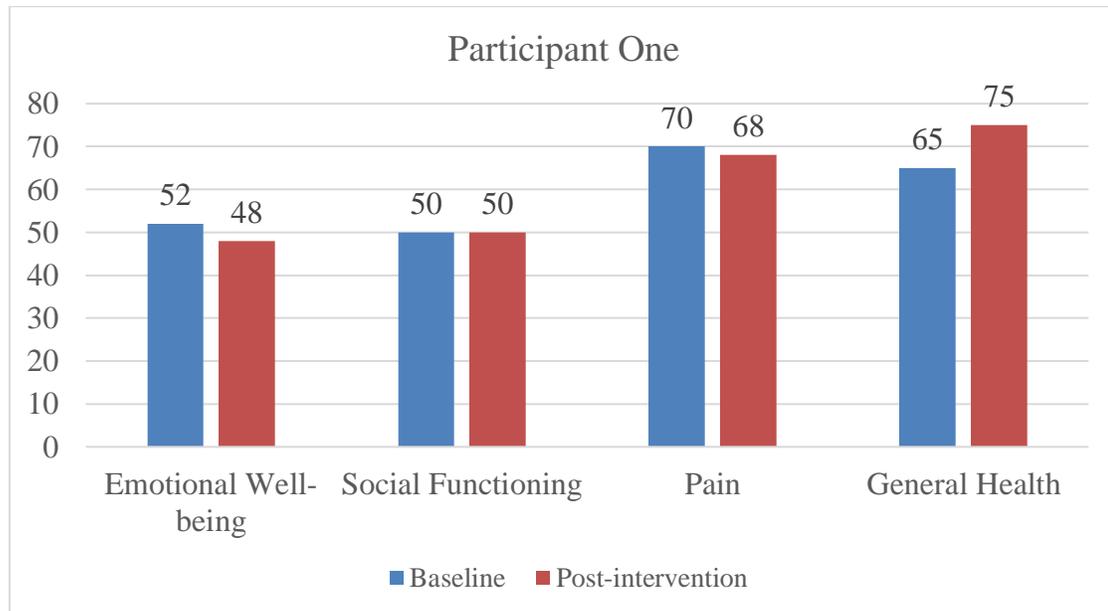


Figure 4

Participant One: SF-36 Total Scores, Social and Overall Health



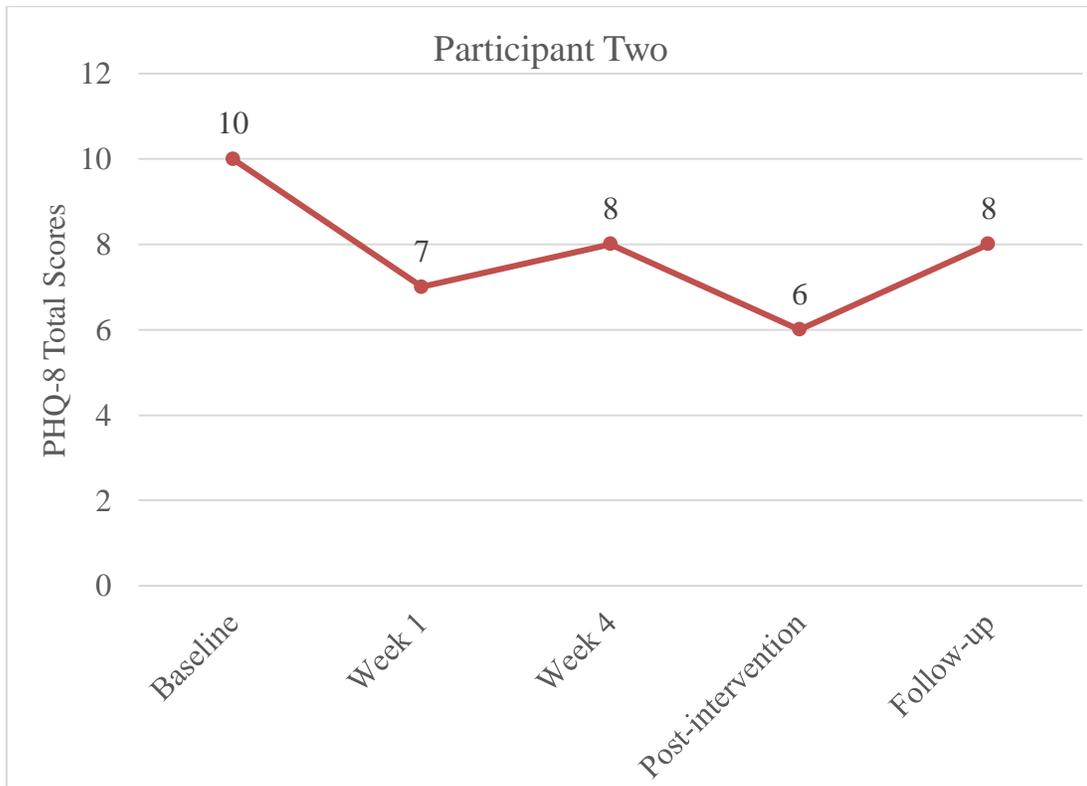
Health Care Utilization. Participant one did not attend any medical appointments throughout the study period.

Participant Two

Depression. Participant two's prescreen PHQ-9 score, and baseline PHQ-8 scores were a 10. During the six-week period, participant two experienced a four-point decrease in depressive symptoms. On the follow-up survey, participant two reported a two-point increase in depressive symptoms, resulting in a PHQ-8 score of 8; however, their final PHQ-8 score remained two points lower than the score reported at baseline. Participant two's PHQ-8 scores throughout the study are presented in Figure 5.

Figure 5

Participant Two: PHQ-8 Total Scores



Quality of Life. Participant two's SF-36-SF scores are displayed in Figures 6 and 7. During the six-week intervention, participant two experienced a decline in physical functioning (a 30-point difference in scores; see Figure 6), role limitations due to emotional problems (a 100-point difference in scores; see Figure 6), energy and fatigue (30-point difference in scores; see Figure 6), and general health (5-point difference; see Figure 7). However, they did experience an improvement in role limitations due to physical functioning (25-point increase; see Figure 6), emotional well-being (8-point increase; see Figure 7), social functioning (13-point increase; see Figure 7), and pain (23-

point increase; see Figure 7) over the course of the intervention. At the follow-up survey, participant two reported a decline in scores on the following subscales: physical functioning (10-point decrease see Figure 6), emotional well-being (8-point decrease, see Figure 7), pain (20-point decrease, see Figure 7), and general health (12-point decrease, see Figure 7). They endorsed an improvement in role limitations due to emotional problems (100-point increase, see Figure 6) and energy and fatigue (10-point increase, see Figure 6).

Figure 6

Participant Two: SF-36 Total Scores, Role Functioning and Fatigue

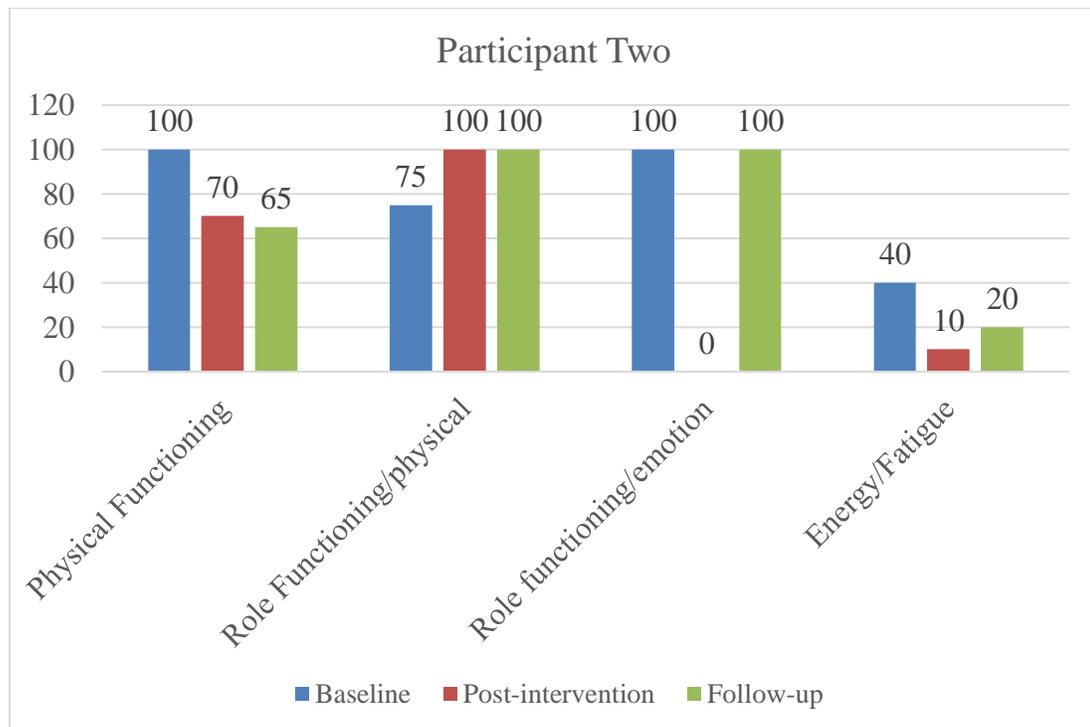
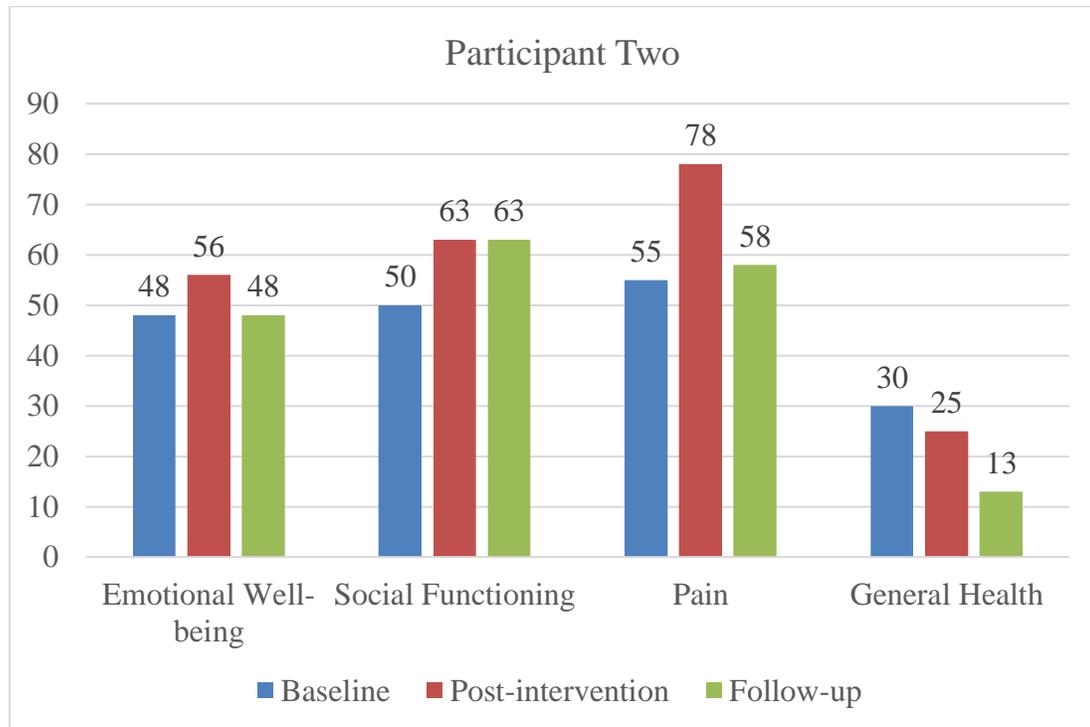


Figure 7

Participant Two: SF-36 Total Scores, Social and Overall Health



Health Care Utilization. Participant two attended five medical appointments during the 10-week period, which includes both specialty and family medicine care. The reasons for all appointments included either getting a "check-up" or refilling prescriptions.

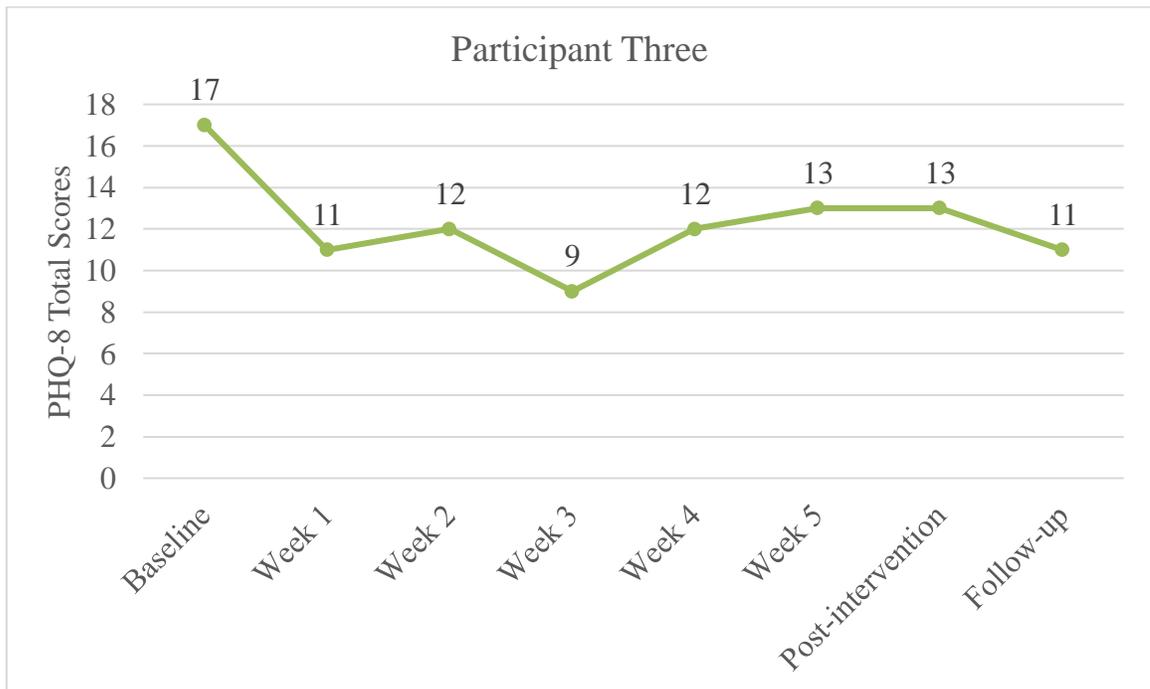
Participant Three

Depression. At the prescreen, participant three endorsed a score of 10 on the PHQ-9; however, they endorsed a score of 17 when completing the PHQ-8 at baseline. During the six-week period, participant three experienced a four-point decrease in depressive symptoms, resulting in a PHQ-8 score of 13. On the follow-up survey,

participant three reported a two-point decrease in depressive symptoms, resulting in a final PHQ-8 score of 11. Participant three's PHQ-8 scores throughout the study are presented in Figure 8.

Figure 8

Participant Three: PHQ-8 Total Scores



Quality of Life. Participant three's SF-36-SF scores are displayed in Figures 9 and 10. During the 6-week intervention, participant three experienced an improvement in role limitations due to emotional problems (33-point increase, see Figure 9), energy and fatigue (15-point increase, see Figure 9), emotional well-being (40-point increase, see Figure 10), and social functioning (13-point increase, see Figure 10). They experienced a decline in scores on the role limitations due to physical functioning subscale (25-point

decrease, see Figure 9) and no changes in scores on the physical functioning (see Figure 9) and pain subscales (see Figure 10). At the follow-up survey, improvements in role limitations due to emotional problems (see Figure 9) remained. They also experienced an improvement in energy and fatigue (5-point increase, see Figure 9) and role limitations due to physical functioning (25-point increase, see Figure 9). However, they did experience a decline in scores on the following subscales: emotional well-being (20-point decrease, see Figure 10) and social functioning (13-point decrease, see Figure 10). Their scores on the general health subscale did not change from the post-intervention survey to the follow-up survey (see Figure 10).

Figure 9

Participant Three: SF-36 Total Scores, Role Functioning and Fatigue

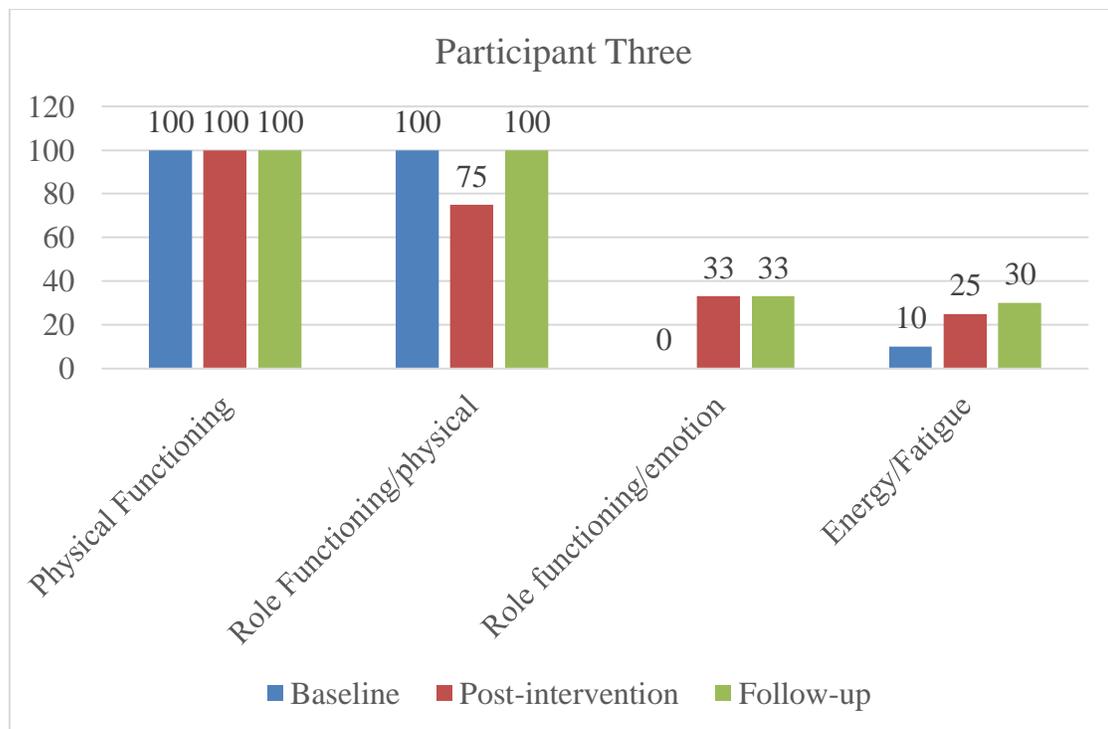
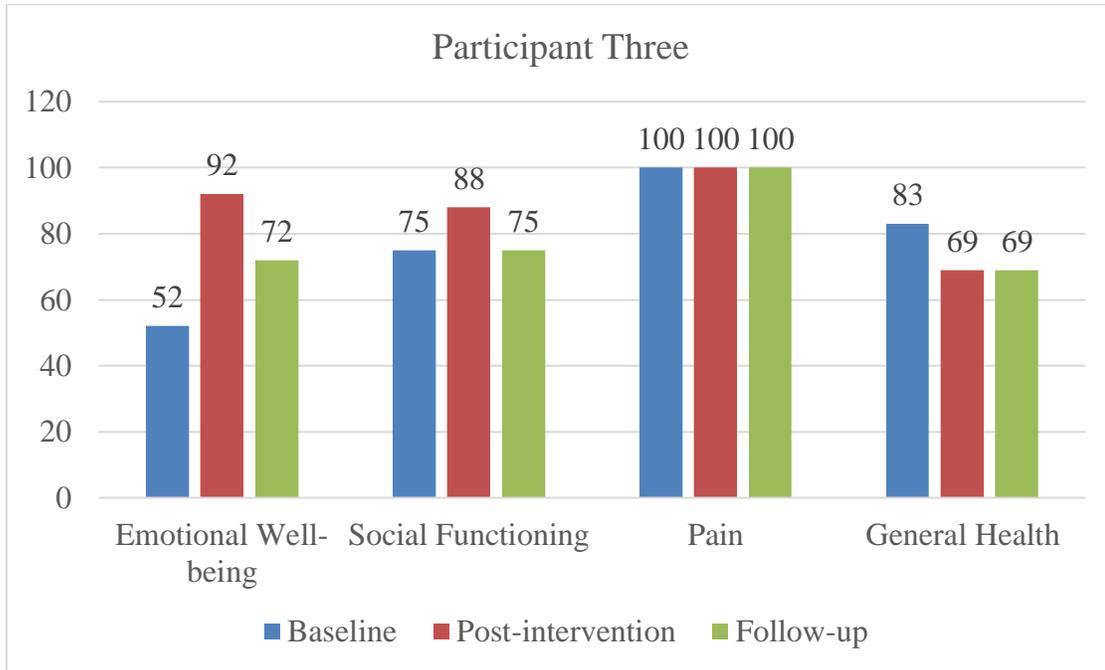


Figure 10

Participant Three: SF-36 Total Scores, Social and Overall Health



Health Care Utilization. Participant three attended two medical appointments during the 10-week period, which also included specialty and family medicine care. The reasons for all appointments included either getting a "check-up" or refilling prescriptions.

Chapter 4

Discussion

The primary aim of this study was to evaluate the feasibility and acceptability of three mobile apps designed to ameliorate depressive symptoms within primary care. The secondary aim was to examine whether mobile app use would reduce depressive symptomology and improve quality of life. The insights gained from this study were examined in order to inform future, larger scale studies in this area. The following is a review the major themes of study regarding feasibility and acceptability, discussion of the study limitations, and implications for future directions of research.

Feasibility

Feasibility outcomes included recruitment, randomization, retention, assessment procedures, and participant engagement with the mobile apps. Recruitment proved to be most challenging. There were two main factors that interfered with the successful recruitment of participants. One was the limited number of patients we were able to approach and the second was the initial eligibility criteria.

Access to Patients

It is possible that the recruitment challenges faced could be best explained by issues related to the number of patients we were able to approach. Over the course of seven months and 122 total hours of recruitment, only 35 patients were approached or contacted about the study. Due to the low volume of patients approached during the first few months of recruitment, several attempts were made to improve recruitment efforts, including advertising the study via flyers posted in the waiting room and exams room, advertising the study on the Department of Family Medicine's Facebook page, and

receiving referrals from physicians. In addition, a handout, which explained the purpose of the study and eligibility criteria, was given to providers. Each week the research assistants would also make their presence known to the providers and residents and remind them about the research study. The data demonstrates these efforts did not drastically improve the number of patients we had access to, as we only received five referrals from providers and six referrals from the Facebook post and waiting/exam room flyers.

The final modification made to improve recruitment included removal of the iOS specific app and expansion of PHQ-9 inclusion criteria to include scores ranging from five to twenty-four. While the COVID-19 pandemic impacted our ability to assess whether this modification would have accelerated recruitment, difficulty recruiting within primary care is a commonly cited problem within the literature (Bell-Syer & Moffett, 2000; Chew-Graham et al., 2007; Johnston et al., 2010; Kaur et al., 2012; Malhotra et al., 2017). For example, barriers to recruitment have included lack of staff and training, provider time constraints and heavy workload, provider difficulties remembering eligibility criteria, concerns about the demands of the research on the patient, worry about the efficacy of the treatment, interruption of patient flow, lack of familiarity of research objects, forgetfulness, and clinical relevance of the research (Bell-Syer & Moffett, 2000; Kaur et al., 2012). The literature also suggests several strategies to improve recruitment rates, including use of physician recruiters, having an in clinic “champion” for the research project, minimizing the burden of participation on the practice, have clear and simple eligibility criteria, and building personal connections with the providers and staff within the clinics (Johnston et al., 2010). Although much of this research is from the

United Kingdom, these recruitment insights are applicable to this study based in the northeastern United States.

Eligibility Criteria

The results indicated the initial eligibility criteria were too restrictive. About 47% of participants approached did not meet initial eligibility criteria. This was a surprising outcome given our eligibility criteria were similar to other studies with better enrollment rates (Arean et al. 2016; Dahne et al., 2019; Moberg et al., 2019; Pratap et al. 2018; Roepke et al., 2015). The three most frequent reasons participants were not eligible to participant were because they did not own an iPhone ($n=5$), endorsed a score of one or higher on item 9 on the PHQ-9 (i.e., how often have you been bothered by thoughts that you would be better off dead, or of hurting yourself; $n=3$), or were currently engaged in psychotherapy ($n=3$).

The decision to exclude Android and other smart phone owners was due to one of the mobile apps (MovingForward) only being available on iOS platforms. Previous studies overcame this barrier by providing participants with an iPhone or other iOS products (e.g., Dahn et al., 2019). This approach was not possible for our research study due to insufficient funding. However, providing mobile devices to suit desired app platforms may be an alternative for future larger scale studies with increased budgets for such allocations. Given the fact that approximately 47% of all smartphone users in the United States own an Android smartphone (Statista, 2021), it may be more feasible and fiscally responsible for future researchers to identify and evaluate mobile apps that are common across all platforms.

In addition, participants who endorsed a score of one or higher on item 9 on the PHQ-9 were excluded because the research team was not able to screen and track risk over time. The exclusion of participants indicating risk of self-harm or suicide is consistent with previous studies (Arean et al., 2016; Dahne et al., 2019). However, it is worth noting the face validity of this item does not extend to the evaluation or assessment of suicidal ideation, but rather morbid thoughts or thoughts of self-harm. Therefore, it is worth questioning whether this criterion for exclusion should be used in future studies without further assessment for suicidality or other risk factors, such as prior suicide attempts, misuse and abuse of alcohol or substances, and access to lethal means (Suicide Prevention Resource Center, 2021).

Several studies have examined the relationship between endorsement of item 9 and suicidal ideation, plan, and attempts. Na and colleagues (2018) examined the positive predictive value, sensitivity, and specificity of item 9 on the PHQ-9 when compared to assessment of suicidality using the Columbia Suicide Severity Rating Scale (C-SSRS). Results indicated that approximately 41% out of 841 patients were identified as being suicidal through the PHQ-9 compared to 13.4% of patient who completed the C-SSRS. The authors concluded that item 9 on the PHQ-9 has low positive predictive validity and specificity, which suggests that this item is an inadequate assessment tool for suicidality. Corson et al. (2004) evaluated the proportion of primary care patients who would screen positive for depression and suicidality using the PHQ-2, the PHQ-9, and a structured clinical interview. Out of 962 primary care patients, 7% reported thoughts of death or suicide, 2% reported thoughts of self-harm, and 1% reported having a specific plan for suicide. Additionally, the authors found that approximately one third of the patients who

endorsed item 9 reported active suicidal ideation. Razykov et al. (2012) found that 110 (10.8%) out of 1,022 coronary artery disease patients endorsed a score of 1 or higher on item 9. Of those 110 patients, 22 (19.8%) reported suicidal ideation and 9 (8.1%) reported thinking about a specific plan to commit suicide in the last year. Walker et al. (2011) evaluated the nature of thoughts of death and suicide in a sample of oncology patients who endorsed item 9 on the PHQ-9. Results indicated that two thirds of the sample (n=330) who endorsed item 9 denied any thoughts that they would be better off dead or endorsed morbid thought but denied suicidal ideation on follow up. Results of these studies suggest endorsement of item 9 may not warrant immediate exclusion from participation in the study. Rather, item 9 should be utilized in conjunction with additional risk assessment tools to accurately assess for eligibility.

Retention

Despite the issues encountered during recruitment, retention was high across the study duration. All three participants completed the post-intervention survey, and two of the three participants completed the follow-up survey. Additionally, participants were engaged with the app throughout the study duration, with all three participants reporting they used the app on average one to three times per week across the 6-week intervention period. Two out of the three participants reported continued use at the follow-up survey. It is possible that our retention and engagement rates were high due to our initial recruitment efforts of participants. In the current project, participants were recruited in-person, and a member of the research team spent approximately ten minutes showing participants how to use the app and answering questions about the app. Additionally, participants were provided with a link to a YouTube video reviewing the features of the

app. Furthermore, participants were sent weekly surveys inquiring about their app use and current depressive symptoms, potentially serving as reminders to engage with the app. Participants also were informed of their ability to contact the study coordinator via email at any time with questions about app or their participation in the study. These efforts are consistent with previous literature that has found lower retention rates in trials where participants were required to have either a telephone or in-person interview or meeting with the research staff (Linardon & Fuller-Tyszkiewicz, 2019). Additionally, trials that offer monetary incentives, reminded participants to engage with the mobile app, offer feedback from research team members, and incorporate some level of mood monitoring produce significantly lower attrition rates when compared to studies that do not employ those strategies (Linardon & Fuller-Tyszkiewicz (2019; Torous et al., 2020).

Clearly, we cannot make generalizable conclusions or comparisons regarding retention due to the sample size of three participants. Retention rates may continue to be a challenge for mobile app research as recent studies report high attrition rates and lower levels of engagement with mental health apps (Arean et al., 2016; Pratap et al., 2018). For example, Baumel et al. (2019) analyzed data from 93 mental health apps and found that 90% of users abandoned apps within ten days of installation. Linardon & Fuller-Tyszkiewicz (2019) conducted a meta-analytic review of randomized controlled trials of mHealth interventions and found that the mean percentage of complete protocol adherence amongst depression specific apps were 34% and the percentage of participants who did not download the app or engage with the app was approximately 41%. Their findings also suggest that on average one quarter of participants drop out of trials within the first eight weeks and up to one third drop out of trials that require participant for

longer than eight weeks. As noted above, our results suggest concerted efforts during initial recruitment shows promise in addressing retention issues. It would be wise for larger scale studies to develop multiple ways to engage participants such as user-instructions (i.e. handouts, YouTube videos) as well as in-person and “remote” check-in for additional support. This front-end approach may help participants feel comfortable with app, identify and address barriers (e.g. technical issues with app), and increase engagement.

Acceptability

Acceptability regarding the use of mobile apps was also examined and results indicate contradictory results. Specifically, participants indicated they were somewhat to very satisfied with the mobile app. Two participants rated that the app was somewhat effective at helping them with their depressive symptoms, while one participant indicated that it was neither effective nor ineffective. However, all three participants reported they would have been able to manage their depressive symptoms slightly better without the mobile app. The fact that participants endorsed benefit from the app yet believed they would manage symptoms slightly better is an important finding. One possible explanation is related to the content validity of this question (*How well do you think you would have managed your depressive symptoms during these 6 weeks without the mobile application?*) and that it is not assessing the construct that it was intended to measure of perceived effectiveness of the app. Another possible explanation is the first few times participants engaged with the app, they found it to be particularly useful as each app incorporated a psychoeducational and self-monitoring component. Perhaps, as

participants continued to engage with the app, they found it less helpful leading to the belief they would have managed their symptoms of depression better without the app.

Treatment Progress & Outcomes

The secondary aim was to examine whether participants utilizing a mobile application would experience a reduction of depressive symptomology and improvements in quality of life. The results indicate that two out of the three participants experienced a reduction of depressive symptoms at the post-intervention survey, and the improvement remained stable for those two participants at the follow-up survey. Additionally, all three participants reported improvements in certain areas of quality of life, such as energy level, fatigue, and emotional well-being at the post-intervention survey. These results are consistent with previously literature that show mobile app use can reduce depressive symptoms (Arean et al., 2016; Firth et al., 2017; Ly et al., 2013; Pratap et al., 2018). Due to the small sample size and our inability to use inferential statistics, we are unable to firmly state whether these changes were due to their engagement with the mobile apps or external factors. The lack of efficacy data is a major problem within mental health app research, as the number mental health apps significantly outweighs the available research supporting the efficacy of apps as a whole (Neary & Schueller, 2018). Increase research and clinical trials along with transparent efficacy data are needed so that healthcare providers can recommend evidence-support mental health apps that suite the unique mental health needs of the patients they care for.

Limitations & Future Directions

The challenges encountered during enrollment of this study provided key insights and valuable lessons that could be applied to future research. As previously mentioned, it

is vital to establish and maintain a collaborative relationship with the entire primary care staff prior to attempting to recruit research participants. In hindsight, one of the biggest limitations of this project was the research team not building stronger personal connections with the providers prior to implementing the protocol. It may have been advantageous to regularly attend the Department of Family Medicine faculty meetings to not only introduce the study protocol, purpose, and eligibility criteria, but to also build relationships with the providers to address questions, discuss their concerns, and assess their interest in collaborating on this project. This would also serve as an opportunity to have regular contact with the providers throughout the recruitment process to provide recruitment updates, challenges, and reminders, which would be consistent with the recommendations of Ash et al. (2000) and Shelton et al. (2002). Future research should focus on aspects of feasibility such as patient-flow, provider-time demands, and comfortability with mobile apps. Future research on implementation of app-based interventions may wish to explore facilitators and barriers within clinical environments including timeliness (e.g., implementing within a busy clinical environment) and provider knowledge about applications.

Additionally, research aimed at better understanding acceptability through the use of standardized measures is warranted. A limitation of our design is that a threshold for acceptability was not predetermined prior to study enrollment. This makes it challenging to provide meaningful conclusions regarding acceptability. The heterogeneity of defining and assessing acceptability of mental health apps appears to be a common problem within the mobile app literature and studies often rely on custom, subjective scales to measure satisfaction and acceptability rather than preexisting standardized assessment tools (Ng et

al., 2019). In future studies, it will be important to not only provide an operational definition of acceptability and satisfaction at the beginning of the study, but to also utilize preexisting standardized assessments to evaluate user engagement indicators of mental health apps. This will allow comparison of results across studies to better understand potential challenges around usability and engagement with mental health apps.

While this study had high retention rates, we cannot make generalizable conclusions or comparisons due to the sample size. It is clear that retention and engagement will continue to be a central challenge for mobile app research. As a result, it is critical for future studies to further assess factors that may influence adherence, such as real-world engagement with apps, digital health literacy, and patient preferences.

Increased contact with study team members in order to help participants navigate the app or provide a reminder to use it may prove effective to increase adherence. This is consistent with the research on guided versus unguided self-help interventions, which suggests that guided self-help interventions are more effective than unguided interventions (Andersson & Cuijpers, 2009; Richards & Richardson, 2012). Additionally, future studies may want to explore patient expectations, needs, and attitudes towards mHealth apps. A qualitative study of the mindfulness app Headspace found that barriers to utilizing the app included difficulty finding time, negative expectations about mindfulness, negative experiences using the app, the opinions of other people, and uncomfortable emotions (Laurie & Blandford, 2016). Future research efforts in mobile apps might consider user end perspectives (e.g., attitudes about mobile apps), research methodology (e.g., reminders and in-person meetings with study team members), and

real-world factors (e.g., time limitations and barriers). Implementing this type of multidimensional approach may aid in reducing issues of retention in mobile health apps.

Lastly, COVID-19 has resulted in a tremendous increase in the use of digital mental health tools within healthcare. The level of engagement and incorporation of digital mental health tools will likely continue beyond the COVID-19 pandemic. It is vital for future research to ensure that these tools are safe and effective for users. Inkster and colleagues (2020) highlight the importance of increasing access to digital healthcare, including converting conventional mental health services and resources to mobile apps and digital formats, making higher-quality mobile apps available for free, and creating a data repository in order for researchers to understand mobile app effectiveness across socio-cultural demographics. The contributing factors explored in this research regarding feasibility and acceptability require additional exploration for population sub-groups to address mental health concerns in primary care.

Conclusion

This study provides key insights and important lessons from attempting to implement a randomized controlled trial within a primary care setting. Given the results of this study and previous literature, the future of mobile app research is contingent upon understanding factors that influence user engagement with apps. Addressing the aforementioned limitations will shed light on the ways in which user engagement, patient expectancy effects, and clinical environments influence intervention outcomes.

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Appendix A

Acceptability Measure

The following questions will ask you about your use and satisfaction with the mobile application used during this study.

1. How likely would you be to participate in this study again?

- Extremely unlikely (1)
- Somewhat unlikely (2)
- Neither likely nor unlikely (3)
- Somewhat likely (4)
- Extremely likely (5)

2. What did you like most about participating in this study?

3. What did you like least about participating in this study?

4. What factors might impact your decision to participate again?

5. How satisfied are you with the mobile application you worked with?

- Not at all satisfied (1)
- Somewhat unsatisfied (2)
- Neither satisfied nor unsatisfied (3)
- Somewhat satisfied (4)
- Very satisfied (5)

6. What specific features of the mobile application did you like the most?

7. What specific features of the mobile application did you like the least?

8. Would you recommend this mobile application to a friend or family member with depression?

- No, I would not recommend it
- I am not sure
- Yes, I would recommend it, with some hesitation
- Yes, I would strongly recommend it

9. How well do you think you would have managed your depressive symptoms during these 6 weeks without the mobile application?

- Much better (1)
- Slightly better (2)
- About the same (3)
- Slightly worse (4)
- Much worse (5)

10. How effective was the mobile application at helping you with your depression?

- Not at all effective (1)
- Somewhat not effective (2)
- Neither effective nor ineffective (3)
- Somewhat effective (4)
- Very effective (5)

11. How often did you use the skills suggested by the mobile application?

- Never
- Once a week
- 2-3 times a week
- 4-6 times a week
- Daily

12. How confident did you feel using the skills that were presented in the mobile app to manage depressive symptoms?

- Very confident (1)
- Somewhat confident (2)
- Neither confident or not confident (3)
- Somewhat not confident (4)
- Not at all confident (5)

13. Please indicate how confident you are that, over the next three months, you will continue to use the mobile application?

- Extremely likely (1)
- Moderately likely (2)
- Slightly likely (3)
- Neither likely nor unlikely (4)
- Slightly unlikely (5)
- Moderately unlikely (6)
- Extremely unlikely (7)

14. Could you provide any specific comments about the ways in which the mobile application helped you manage your depressive symptoms?

15. If you were able to add anything to the app to make it more helpful, what might you add? (State "nothing" if there is nothing you would add).

16. What, if anything, do you feel you still need help with related to managing depressive symptoms?

17. Is there anything else you can tell us about the features, layout, or other design aspects of the app that you have found to be either helpful or problematic? (State "nothing" if there is nothing else you want to tell us).

Appendix B

Health Service Utilization Measure

The questions below are going to ask you about your use of health care services **in the past month.**

1. **In the past month,** how many times did you go to a doctor, nurse, or other health professional to get care for yourself?

- None
- One time
- Two times
- Three times
- Four times
- Five or more times

2. What was the purpose of the visit?

3. **In the past month,** how many times have you visited your primary care provider at Rowan Family Medicine for a health concern?

- None
- One time
- Two times
- Three times
- Four times
- Five or more times

4. What was the purpose of the visit?

5. In the **past month,** have you seen a psychiatrist to discuss and/or receive medications for mental health concerns?

- Yes
- No

7. **In the past month**, how many times did you use psychiatric services?

- None
- One time
- Two times
- Three times
- Four times
- Five or more times

8. What was the purpose of the visit?

9. In the **past month**, did you visit the emergency room?

- Yes
- No

10. In the **past month**, how many times did you visit the emergency room?

- None
- One time
- Two times
- Three times
- Four times
- Five or more times

11. What was the purpose of the visit?

Appendix C

Provider Handout

Mobile Apps in Primary Care

Brief Project Description

The goal of this study is to test the feasibility, acceptability, and preliminary effectiveness of mobile applications for **depression**. Patients will be randomized to one of four conditions: a) a cognitive behavioral therapy app, b) a problem-solving therapy app, c) a mindfulness-based app, or d) the waitlist control condition.

We are looking for patients who:

- 1) are 18 years of age or older
- 2) have a known history of depression AND/OR score between 5 and 14 on the PHQ-9**
 - 2a) **Patients must score a 0 on question 9 of the PHQ-9.**

Appendix D

Flyer For Waiting and Exam Rooms



If you are at least 18 years old and own an iPhone, this study may be for you.

Study for Adult Patients of Rowan Family Medicine with Depression

We are looking for adults (18 years and older) who experience depression and are **a patient of one of the Rowan Family Medicine offices** to examine whether we can use mobile applications to effectively treat depressive symptoms.

Participants will receive compensation!

Version #: V1
Version Date: 10/18/19

Location

You only need to meet with a member of the research team **once!** This will happen after your appointment with your doctor. All other study activity will take place online.

Are you eligible?

- Are you 18 years old or older?
- Do you own an iPhone?
- Are you experiencing symptoms of depression?

If you're unsure if you meet the requirements, email or call the study coordinator:

- Krista Herbert, MA
- Phone: 609-290-1153
- Email: Herbertk9@rowan.edu



APPROVED
IRB# IR02019000363
APPROVAL DATE: 10-22-2019
EXPIRATION DATE: 5-15-2020

Appendix E

Facebook Advertisement

Mobile Applications in Primary Care

Are you a patient of Rowan Family Medicine? Are you experiencing symptoms of depression? If you are 18 years old and over and own an iPhone, this study may be for you!

We are conducting a study to assess whether we can use mobile applications to treat depression in primary care. Additionally, we want to see if the use of mobile applications helps reduce symptoms of depression and improve quality of life. Participation in the study is completely voluntary.

To find out if you are eligible, please click here:

https://rowan.co1.qualtrics.com/jfe/form/SV_ehw1Lpq0wUbaPzL

This study has been approved by Rowan Universities IRB #Pro2019000363.

For additional information or questions, please contact:

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