Reducing Polypharmacy with Mobile Apps Among Mental Health Patients

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Abstract

Polypharmacy among psychiatric patients is a concerning trend. From 2007-2010, 58.2% of women and 41.8% of men reported taking five or more prescription drugs within the last 30 days (CDC, 2014). Negative outcomes include prescription drug abuse, side effects, interactions, treatment failure, patient dissatisfaction, and lack of treatment control. The associated practice challenges have led to the following PICOT question. In persons with mental health issues receiving care at an outpatient mental health clinic, does engaging in mindfulness practice versus no mindfulness practice change polypharmacy use over a 3-month period? The project purpose was to evaluate the effectiveness of Insight Timer mobile mindfulness app at helping patients self-manage distressing symptoms and reduce polypharmacy. Over three weeks, mental health clinic nurse practitioners (NPs) voluntarily recruited patients (n=12) over age 18 using as needed prescriptions (PRNs), and agreed to use Insight Timer mobile mindfulness app for adjunct symptom management. Consenting participants downloaded the mobile app, and completed a brief questionnaire measuring PRN use at the start of app use, and PRN use at their next visit. A Wilcoxon signed-rank test indicated a 10-week mindfulness app trial did not significantly lower total PRN doses compared with pre-app dosing ($Z = -.534$, $p = .593$). Paired t-tests revealed no significant change in pre ($M = 65.17$, $SD = 28.64$) versus post ($M = 67.75$, $SD = 20.22$) OQ45 life functionality results ($t(11) = -.420$, $p = .683$) ($d = .121$) as a result of app use. Clinically relevant results illustrated 83.33% of participants taking greater than nine PRN doses over the study period used the app six times or more in place of medication. High PRN users employed the app frequently in place of medication regardless of total PRN doses taken. Practice implications and sustainability recommendations include incorporating mobile app use in

treatment plans for high PRN users and educating NP's on the tangible benefits of mindfulness apps in reducing polypharmacy and easing symptom distress on an ongoing basis.

Keywords: mindfulness, mhealth, mobile apps, mobile smart phone, online, RCT, behavior change, polypharmacy.

Reducing Polypharmacy with Mobile Apps Among Mental Health Patients

Chapter 1

Mental healthcare expenditures have changed in nature and grown significantly since the 1980's. Americans spent $186 billion on mental health treatments in 2014 (CDC, 2014). From 1986 to 2014, spending on mental health medications increased 19%. During the same time, outpatient treatment expenditures increased 11% (CDC, 2014). As more patients have been funneled toward outpatient mental health clinics, the share of inpatient and residential spending has decreased (CDC, 2014). Trends toward outpatient treatment with a greater focus on medication management versus impatient hospitalization show no signs of abating. While cost cutting measures have been effective at reducing inpatient stays and associated expenditures, medication-based management of complex mental health issues has led to increased prescribing resulting in polypharmacy (Shuman-Olivier, Noordsy, & Brunette, 2013). From 2007-2010, 58.2% of women and 41.8% of men reported taking five or more prescription drugs within the last 30 days (CDC, 2014). Valid concerns have surfaced regarding polypharmacy including prescription drug abuse, drug interactions, adverse drug events, side effects, and reduction in individual functioning (Bry, Chou, Miguel, & Comer, 2017).

Expanding prescription medication use presents new clinical challenges. Intensive inpatient hospitalization is no longer widely available or cost effective. Psychiatric experts struggle with how to provide comprehensive mental health care with shrinking resources, shorter appointment times, and limited tool box of therapeutic options.

Problem and Purpose

Rescue medications such as benzodiazepines are frequently employed to manage distressing symptom exacerbations as first line treatment. Using rescue meds in this fashion

increases polypharmacy with all its requisite complications and concerns (Bry, Chou, Miguel, & Comer, 2017). Large gaps in therapeutic success, patient satisfaction, cost effectiveness, and patient empowerment exist (Rathbone, Clarry, & Prescott, 2017). Medication dependence and abuse is common (Shuman-Olivier, Noordsy, & Brunette, 2013). Patients are reliant on medication versus being aware of symptom triggers thereby removing an opportunity for non-pharmacologic management. Inclusion of effective, ongoing, and evidenced based therapy in treatment plans has been challenging given cost and time constraints in most mental health clinics.

The purpose of this project was to review the problem of polypharmacy as it related to national trends, healthcare systems, and clinical outcomes with the goal of implementing a technology-based solution to improve mental health treatment, empower patients to recognize and self-manage distressing symptoms, and decrease polypharmacy.

Background and Significance

Negative outcomes are associated with polypharmacy. Lack of treatment success, patient dissatisfaction, poor symptom relief, and lack of control over treatment outcomes have snowballed into a concerning clinical practice challenge. Rescue meds are being prescribed as a front-line treatment with less than optimal outcomes rather than patient directed, self-management therapies that reduce the need for additional medication (Zhao, Freeman, & Li, 2016).

Cognitive Behavioral Therapy

Patients living with anxiety, panic, depression, and moodiness are treated in an outpatient setting with medication alone or a combination of evidenced based therapy such as Cognitive Behavioral Therapy (CBT) (Os et al, 2017). The purpose of CBT is to teach patients to monitor

and adjust to distressing cognitive, emotional, and behavioral reactions underlying depression and anxiety (Barlow et al, 2014). CBT has four main elements and can be employed in practice through the use of the Unified Protocol (Barlow et al, 2014; Bakker, Kazantzis, Rickwood, & Rickard, 2016). The Unified Protocol is an individual CBT protocol designed by Barlow et al to treat anxiety and anxiety related symptoms. The four elements are: 1) increase present focused emotional awareness, 2) improve cognitive flexibility, 3) identify and prevent patterns of emotional avoidance and mal-adaptive emotion driven behaviors, and 4) promote exposure (Barlow et al, 2014; Bakker, Kazantzis, Rickwood, & Rickard, 2016).

Innovative Mobile Technology

Mental health experts are encouraged that new technologies have the potential to transform care compared with standard treatments. Mobile technologies are a promising tool to improve patient management, decrease polypharmacy, empower patients through self-efficacy and symptom management, enhance patient outcomes, and change future standards of practice (Bakker, Kazantzis, Rickwood, & Rickard, 2016; Mistler, Ben-Zeev, Carpenter-Song, Brunette, & Friedman, 2017; Zhao, Freeman, & Li, 2016). From a systems perspective, decreasing polypharmacy with the use of mobile technologies may reduce the overall healthcare burden, prescription drug costs, and improve practice efficiencies on a national, local, and individual level (Rathbone & Prescott, 2017). Mobile self-help applications have the potential to curb billions of dollars in annual prescription drug costs and minimize decreased productivity losses. Evidence supports improved outcomes, symptom relief, and empowerment with the use of mobile mindfulness apps (Rathbone, Clarry, & Prescott, 2017). Mobile phone ownership is ubiquitous as 95% of Americans own a mobile phone with 77% owning a smart phone (Pew Research Center, 2016). Additional research shows lower income families often use smartphones

as their only internet access point (Alfano & Beidel, 2014; Pew Research Center, 2016 ; Zhao, Freeman, & Li, 2016).

Internal Evidence

Information collected in an Arizona mental health clinic provides further internal evidence of a practice gap. The Clinical Practice Manager reports approximately 75% of their patients take more than one med, with greater than 50% of patients taking at least two meds prescribed by clinic NPs. The practice has a mixed payer profile with 40% Medicare/Medicaid patients, 55% private insurance, and 5% self-paying patients. Therapists and NPs here treat a significant number of patients living with anxiety, panic, and elevated stress levels as primary or secondary mental health diagnosis. Rescue medications such as lorazepam, alprazolam, or hydroxyzine are first line treatments. Providers prefer to follow clinical practice guidelines limiting the number of medications, particularly rescue medications when possible while encouraging non-pharmacologic coping behaviors. The clinic provides on-site licensed therapists as well as a professionally led exercise program and nutritional coaching in support of this effort. Research shows increased patient engagement in positive coping behaviors improves treatment outcomes (Hartin et al, 2016). Presumably, patient satisfaction levels would rise accordingly. While many patients report symptom relief, taking additional medication leads to added side effects and complications. Multiple medications are expensive for the patient and the healthcare system. For these reasons, polypharmacy is a challenge that needs to be addressed.

PICOT

The background and significance of increased polypharmacy as well as the identified problem and practice gap lead to the following PICOT question. In persons with mental health

issues receiving care at an outpatient mental health clinic, does engaging in mindfulness practice versus no mindfulness practice change polypharmacy use over a 3 month period?

Exhaustive Search Strategy

An exhaustive search to extract the highest quality research from PubMed, PsycINFO, CINHAL, Science Direct, and Academic Search Premier extends from the PICOT question. Searches included the terms “mobile,” “smartphone,” “CBT,” “mindfulness,” “polypharmacy,” “anxiety,” “mHealth,” and “RCT.” Inclusion criteria were randomized controlled trials within the last 5 years, mobile technology or on-line intervention for improvement in polypharmacy or symptom management, mindfulness-based, and designed for clinical application with mental health patients.

The strategy is detailed as follows. A search of PubMed Central yielded 753 studies with the terms mobile smartphone AND CBT AND mindfulness AND anxiety AND RCT. This was narrowed to 59 studies with using AND versus OR in search parameters, and filtering results to the last five years. Additionally, the first search phrase was changed from mobile AND smartphone to mobile smartphone (Appendix A). Three relevant studies in the evaluation table were included from this search (Appendix F). A search of PsycINFO with terms anxiety AND mindfulness AND RCT AND mobile app yielded zero results. Changing the terms to anxiety AND mindfulness AND RCT OR mobile app resulted in 32 studies. Additional limiters included English language and peer reviewed (Appendix B). One relevant study was included in the evaluation table (Appendix F). CINHAL was searched using a variety of terms including smartphone, mobile, app, mindfulness, polypharmacy, self-help, and mhealth. Mindfulness AND mhealth returned one relevant result (Appendix C). The search was further expanded to 46 results by changing search terms to mobile apps AND behavior change, but no relevant studies

were found. OR and AND were used as links in all search permutations. Using all previous searches linked with OR yielded 12 results. One relevant study is included (Appendix F). Science Direct was searched using the terms mindfulness AND online AND RCT in article titles. Four results were returned (Appendix D). One study was evaluated and selected (Appendix F). A search of Academic Search Premier using the terms mobile apps AND self-help yielded 100 results. The search was further refined with the filter full text available providing 43 results (Appendix E). One relevant study was selected from these results (Appendix F). Two remaining studies were hand searched (Appendix F).

Critical Appraisal and Synthesis

The strength of available evidence for effectiveness of mobile mindfulness apps at eliciting individual behavior change is moderate (Appendix G). A number of randomized controlled trials exist but are of somewhat limited quality as attrition rates and sample sizes are not ideal. Populations are relatively heterogenic, ranging from general non-clinical participants to purposefully self-selected samples. Self-selection is expected and desired because the primary goal of mindfulness app use is decreased medication use through improved self-efficacy. Mean ages and populations in the studies selected are appropriate for the outpatient population of interest as all studies were limited to adults over 18 years of age and included willing participants. Reliability across all studies ranges from reliable to somewhat reliable. Most commercially available apps are developed for profit in some way. Bias in several studies exists to the extent that researchers are involved in app development or have similar apps in the open marketplace. Interestingly, two studies disclosing this bias reported the weakest overall evidence for symptom improvement with mobile apps. Similar conclusions exist across studies in

symptom improvement, user behavior changes, and the value of adjunctive technology-based mindfulness therapy.

Conclusions/Discussion

Mobile application technology is evolving and developing daily. The pace of research simply cannot keep up with development. Research on mobile apps with specific clear-cut guidelines for use and outcome measurements was not located. Extrapolating evidence from the best available studies supports the use of mindfulness-based therapies both in-person and via mobile apps and could be generalized to an outpatient mental health setting. Practicing mindfulness was shown to positively impact various vital signs such as heart rate and blood pressure as well as psychological factors like mood, depression, and anxiety. Mindfulness-based therapies also impacted patient behaviors such as decreasing psychomotor agitation, improve coping, and create synergistic effects with adjunct anti-depressant medications. Mindfulness, regardless of delivery method, was shown across multiple studies to improve coping mechanisms as well as improve depressive symptoms. Evidence supports improved therapeutic engagement via mobile mindfulness apps increases self-efficacy and provides immediate relief from symptoms such as anxiety, agitation, depression, and stress.

Based on the evidence at hand, incorporating a protocol for mobile mindfulness apps in an outpatient setting to decrease symptoms of anxiety, depression, agitation, and stress might be effective at reducing these symptoms in patients. A decrease in undesirable symptoms could reduce use of rescue medications achieving a primary goal of the outpatient facility. Piloting the use of mobile mindfulness apps is warranted.

Chapter 2

Contribution of theory to utility of the evidence

Albert Bandura's Theory of Self Efficacy (1977) is the framework on which this project and research is based (Appendix H). One of the central themes of self-efficacy is the understanding a patient who engages in a treatment or intervention will further begin to self-promote and more fully utilize the intervention over time as individual engagement increases (Bandura, 1977). The same foundation of self-efficacy is present throughout most of the selected research. Examining the research question at hand, one can see how polypharmacy may be reduced with mobile technology, but even more so with increased self-efficacy and a desire to use mobile apps as a vehicle for improved coping and reducing personal medication usage.

Evidence Based Practice Model

Implementing an evidence-based practice change works congruently with the nursing process; assess, diagnose, plan, implement, and evaluate. As such, a comprehensive approach to internal needs analysis, evidence gathering, critical appraisal, planning and implementation is necessary. The Iowa Model of Evidence-Based Practice to Promote Quality Care was the working model used to guide research and decision making (Appendix I; Rycroft-Malone & Bucknall, 2010).

Both problem and knowledge focused triggers have led to an understanding that a NP led polypharmacy reduction effort is necessary. NPs at a local community health clinic have noticed an unfortunate increase in polypharmacy across their patient population. Recommendations for minimizing the use of controlled medications are becoming more stringent as the negative effects of polypharmacy is increasingly under the microscope (Kouladjian, Gnjidic, Chen, Mangoni, & Hilmer, 2014). The organization's philosophy of care advises limiting unnecessary medication

and supports including evidenced based non-pharmacologic treatment adjuncts in an effort to provide holistic patient centered interventions. The company's CEO has tasked NPs with implementing efficiencies and practice improvements through technology. The clinical management created a team to meet this organizational priority yielding the research and analysis presented here.

Sufficient evidence existed to pilot a practice change to reduce polypharmacy and encourage greater patient autonomy and self-efficacy through mobile apps. Goals of a pilot program included reducing total polypharmacy individually in patients identified as utilizing rescue medications, minimizing the number of prescriptions refilled as a comparative percentage from baseline, and eliciting patient feedback on the use of mobile apps as a treatment adjunct and effectiveness compared with rescue medications. Guidelines were developed below for patient inclusion in the pilot mobile app polypharmacy reduction program. Methods, outcome measures, data analysis and results are presented below determining effectiveness and sustainability recommendations for a company-wide roll out.

Project Purpose

In order to combat polypharmacy at a local community mental health clinic, the research team selected a mobile mindfulness meditation app called Insight Timer to help patients manage distressing symptoms and decrease polypharmacy. The team chose Insight Timer because the app allowed for individual accommodation for time constraints, diagnosis, and/or target symptoms treatment. The project purpose was to evaluate the effectiveness of Insight Timer Mobile App at helping patients self-manage distressing symptoms and reduce PRN medication use. Patients would benefit from increased mindfulness, treatment control, and positive coping behaviors related to managing distressing symptoms with Insight Timer. The clinic and NPs would benefit

by including an inexpensive, easily accessible, technology-based intervention in their therapeutic repertoire.

Methods

Recruitment, protection of human subjects, and patient privacy

The study population included adults identified by the NPs and clinical manager who were using PRN prescriptions and were amenable to using Insight Timer mobile mindfulness app as an adjunct non-pharmacologic symptom management tool. NPs provided the patient with a recruitment flyer. If they chose to participate, they met with the co-investigator regarding expectations of the study and consented in writing after all questions were answered. The research team instituted the following inclusion and exclusion criteria. The primary inclusion requirements were: 1) patients had to be age 18 years or older, 2) had to own a smart phone; 3) had to be taking at least one PRN med; 4) and were agreeable to using Insight Timer mobile mindfulness app as part of their current treatment. Minors, adults who were unable to consent, prisoners, and pregnant women were excluded from participation. Race and citizenship status were not relevant to the study and were not tracked. All participants were English speaking.

After obtaining IRB approval a variety of protections were put in place to ensure human rights were maintained during this project (Appendix J). First, patients participated in an informed consent process. Participants consented in writing after meeting with the co-primary investigator to learn about the project. Completing beginning surveys and downloading Insight Timer was considered consent to participate. Second, participants were provided as long as needed to review consent and ask questions related to the study prior to agreeing to participate. Finally, risks and benefits were reviewed. Risks were noted to be no greater than those associated with everyday types of activity. If symptoms worsened or a participant felt unsafe

they were informed they could schedule and emergency appointment or be referred to the emergency department. Benefits of participation were also discussed such as research indicating mindfulness therapies have been shown to result in increases in positive coping behaviors which may include decreasing use of PRNs when possible. The primary benefit of the pilot program for participants is to improve mindfulness, individual empowerment over symptoms, and non-pharmacologic symptom management by using a mobile mindfulness application.

Privacy measures for participant data were also implemented. The co-primary investigator had data access and was responsible for data security. The questionnaires were stored in a locked file cabinet at the facility. Participants developed their own unique identification code at the initial meeting. This code was not connected to their name or other personal identifying information. A master list of participants with their ID code was stored on a password protected computer at the facility. Data was destroyed after analysis was completed.

Setting, Culture, and Innovative Leadership

The project setting was a local community mental health clinic in Arizona. The patient population at this clinic is general mental health patients with a variety of common psychiatric diagnosis. Approximately five or six NPs provide medication management and multiple therapists and counselors provide therapy services. Nutritional coaching and personal training services are also on site. Services are available to adults over the age of 18. The payer mix is varied with 40% Medicare/Medicaid patients, 55% private insurance, and 5% self-pay patients. The project site is unique. The philosophy of the CEO and providers is to deliver patient-centered, individually tailored, and multifaceted psychiatric services to their patients. Clinic staff strive to exceed expectations by providing a full complement of mind-body services to assist patients on their road to mental health and wellness. This philosophy is evidenced by the

incorporation of therapists specializing in modalities such as Eye Movement Desensitization and Reprocessing (EMDR), Cognitive Behavioral Therapy (CBT), and Dialectical Behavioral Therapy (DBT), as well as counselors, nutritional coaches, personal trainers, and a non-pharmacologic pain management program in addition to the NP provided medication and therapy options. Each provider individualizes care through a unique lens. They are well supported in their autonomy to deliver the best evidence-based treatments possible.

The CEO supports and values innovative use of technology and efficiencies across all service lines. This project grew out of a directive from him to have the NP staff incorporate technology more robustly into their work flows. In addition to psychiatric services, this company offers crisis services, trauma services, and disaster relief. The executive leadership has a clear vision of delivering an exceptional health and wellness product and is nimble in their response to changing complexities in healthcare delivery.

Collaborators and Research Team Members

The co-investigator worked with the NPs, Clinical Manager, and medical assistants to enroll the patients in the project. Site employees were helpful assisting the co-investigator meet the goals of recruitment and providing adequate space for patient meetings and consent. The NPs and Clinical Manager were engaged in identifying patients that could benefit from the Insight Timer intervention. The medical assistants (MAs) were invaluable in making sure there was adequate time scheduled for meeting and completing study questionnaires.

Intervention Process

Following IRB approval, a 10-week evidence-based practice (EBP) project was implemented at an Arizona outpatient mental health clinic using Insight Timer mobile app. Over three weeks, NP's recruited patients (n=12) over age 18 for participation. The co-investigator

worked with the NPs and MAs to enroll and educate the patients on the purpose of the mobile app project, their role in reporting information on their next visit, and assist in downloading and brief instruction of Insight Timer to use as a mindfulness improvement tool until their next visit. Consenting participants downloaded the mobile app, and completed a brief questionnaire measuring PRN use at the start of app use (Appendix K), and PRN use at their next visit (Appendix L). The 45-item Outcomes Questionnaire 45.2 (OQ-45.2) was administered simultaneously to measure total score (TS) as well as 3 functional domains; symptom distress (SD), interpersonal relations (IR), and social role (SR) before and after starting the app (Lambert et al, 2013) (Appendix M).

Outcome Measures

Outcome measurements were taken at the participant's next visit (within 10 weeks). These included a post-intervention demographic questionnaire and post OQ-45.2 assessment. Additional qualitative data including personal satisfaction with Insight Timer, reasons for non-completion or switching to a different app, and general self-reported experiences with app use were also analyzed. Quantitative outcome measures included number of PRN doses taken before and after Insight Timer use. The number of times the app was used in place of PRN medication was also measured.

Validity and Reliability

The OQ-45.2 Inventory is a valid and reliable (r= .94) 45-item questionnaire. The OQ-45.2 measures total score (TS) as well as 3 functional domains; symptom distress (SD), interpersonal relations (IR), and social role (SR) before and after starting the app. Cronbach's alphas for each domain and TS are: SD (.93), IR (.78), SR (.70), and TS (.94). Correlations indicate strong support for the validity of the OQ-45.2 TS and SD domain (Lambert et al, 2013).

Data Collection, Analysis, and Budget

The co-researcher coded pre and post intervention questionnaires and the OQ-45.2 instrument. Over 10-weeks, the research team collected data at the outpatient clinic with care to maintain data security and patient privacy according to the recruitment, protection of human subjects, and patient privacy protocol previously noted. Data was then analyzed using IBM SPSS Statistics 23. The project was funded by the co-investigator. Costs were minimal; less than $50 for photocopy and printing services. Office space to conduct participant meetings was provided free of charge by the outpatient clinic.

Methodology

Descriptive statistics were used to describe the sample and outcome variables. Mean doses of PRNs pre and post intervention did not meet the assumptions of the normal distribution of scores after running tests for normalcy, therefore the non-parametric Wilcoxon signed rank test was performed. Paired t-tests were used to analyze pre and post intervention OQ-45.2 data. The critical value was set at $p < .05$ and a two tailed test was run.

Results

Twelve participants (11= female, 1= male), with an average age of 38 completed the study (M=38, SD=13.08). Ages ranged from 20 to 62 years of age. A Wilcoxon signed rank test revealed a 10-week mindfulness app trial did not significantly lower average post app PRN doses compared with pre-app dosing ($Z = -.534$, $p = .693$). A paired t-test was calculated to compare mean pre-app use 65.16 (M=65.16, SD= 28.64) versus post app use 67.75 (M=67.75, SD= 20.22) OQ45.2 total life functioning scores as well as pre versus post app use scores for the three instrument domains. Average pre-app life functioning total scores ranged from 29 to 115 while average post app life functioning total scores ranged from 29 to 96. Pre mean app use scores for

Symptom Distress (*M*=39.12, *SD*=19.75), Social Role (*M*=10.08, *SD*=5.47), and Interpersonal Relations (*M*=15.67, *SD*=7.08) were compared with post app use scores for each domain SD (*M*=44.67, *SD*=13.23), SR (*M*=8.92, *SD*=3.99), IR (*M*=14.14, *SD*=7.58). No significant change in OQ45.2 life functioning total scores was seen pre (*M*= 65.17, *SD* = 28.64) versus post (*M*= 67.75, *SD*= 20.22) app use. ($t(11)= -.420$, $p>.05$). ($d= .121$). Similarly, no significant changes were seen in pre vs post domain scores.

Clinically significant results included 83.3% of patients taking greater than nine PRN doses over the study period used the app six times or more in place of medication. This finding illustrated high PRN users employed the app frequently in place of medication.

Unintended findings included a patient report of app use as a replacement for alcohol in the evenings. A PTSD patient reported app use for AM focus and concentration versus sleep hygiene and reduced propranolol PRNs. Another patient reported anxiety exacerbation, increasing both PRN lorazepam use and app sessions.

Chapter 3

Discussion and Practice Implications

High PRN users employed the mobile mindfulness app frequently in place of medication potentially out of need and/or desire to reduce PRN use. Active patient directed mindfulness app use suggests increased treatment engagement illustrating Self-Efficacy Theory at work on an individualized basis. Incidental findings such as utilizing Insight Timer for additional mindfulness needs like reducing nightly alcohol intake; or treating additional distressing symptoms not initially identified as the primary focus of app use further support the use of patient directed mindfulness therapies across a wide range of diagnosis. Increased levels of app use in high PRN users support conclusions these participants derived substantial benefits from Insight Timer possibly because symptoms were particularly distressing. High PRN users are high need as evidenced by greater than 80% using the app regularly in place of medication.

This project is not without limitations. A longer study period, such as six months or a year with multiple points of patient contact might yield statistically significant findings. Additional patient experience questions on the demographic questionnaires may be useful as well. For example, it would be helpful to know how the patients perceive the severity of their symptoms, and if app use was more effective for mild, moderate, or severe symptoms. The project sample size is limited as is consistent with most studies of this kind. A larger sample might reveal results representative of broader mental health treatment experiences. Additionally, a two group study design with an app use group and a control group may provide more concrete conclusions.

Recommendations and Sustainability

Findings from this project indicate app use appears particularly beneficial for high need patients. Treatment plans of high PRN users should include mindfulness apps as first line non-

pharmacologic therapy to reduce reliance on rescue medications where appropriate. Identifying patients who are receptive to mindfulness therapies as an adjunct treatment modality is useful for improving treatment engagement. Educating future clinic NP's on the tangible benefits of mindfulness apps in reducing polypharmacy and easing symptom distress will encourage implementation of this intervention on an ongoing basis.

Conclusion

Use of mobile mindfulness apps results in positive behavior changes and increased treatment engagement as evidence by the results of this project. Implementing a patient directed mindfulness app intervention has the potential to reduce individual PRN use well as overall polypharmacy. Greater patient self-efficacy and participation in self-care may lead to reduced depression and anxiety scores over time. Further research is needed on efficacy of mindfulness apps on polypharmacy reduction in clinical practice and among broader mental health populations. Mindfulness app use in this clinical setting illustrated the potential of technology to improve measurable patient outcomes, decrease PRN use, and advance the overarching goal of improving mental health treatments.

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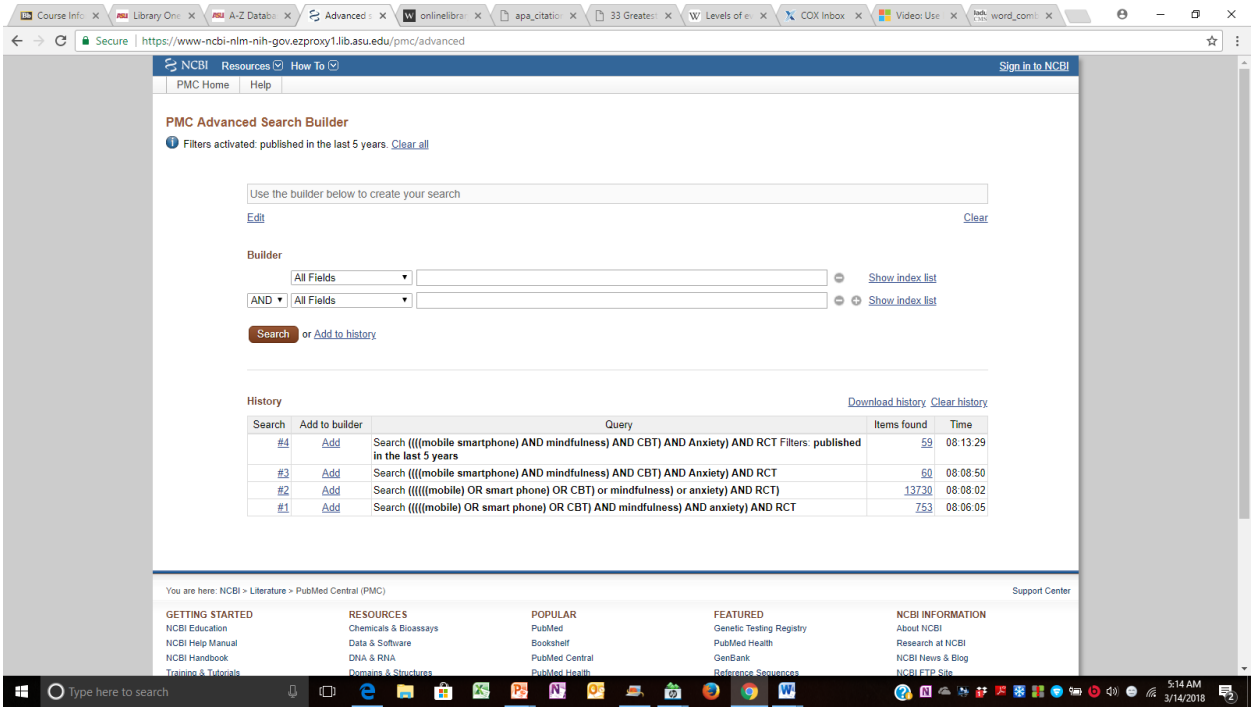
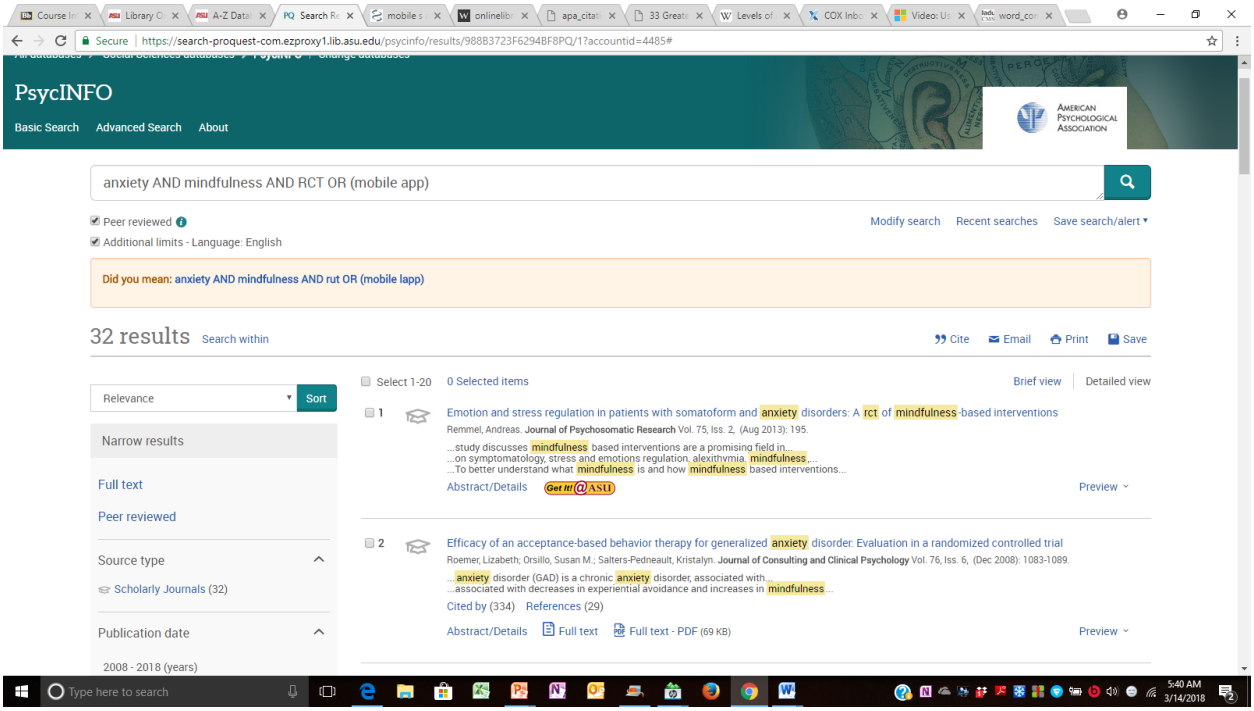
Appendix A

PubMed Database Search



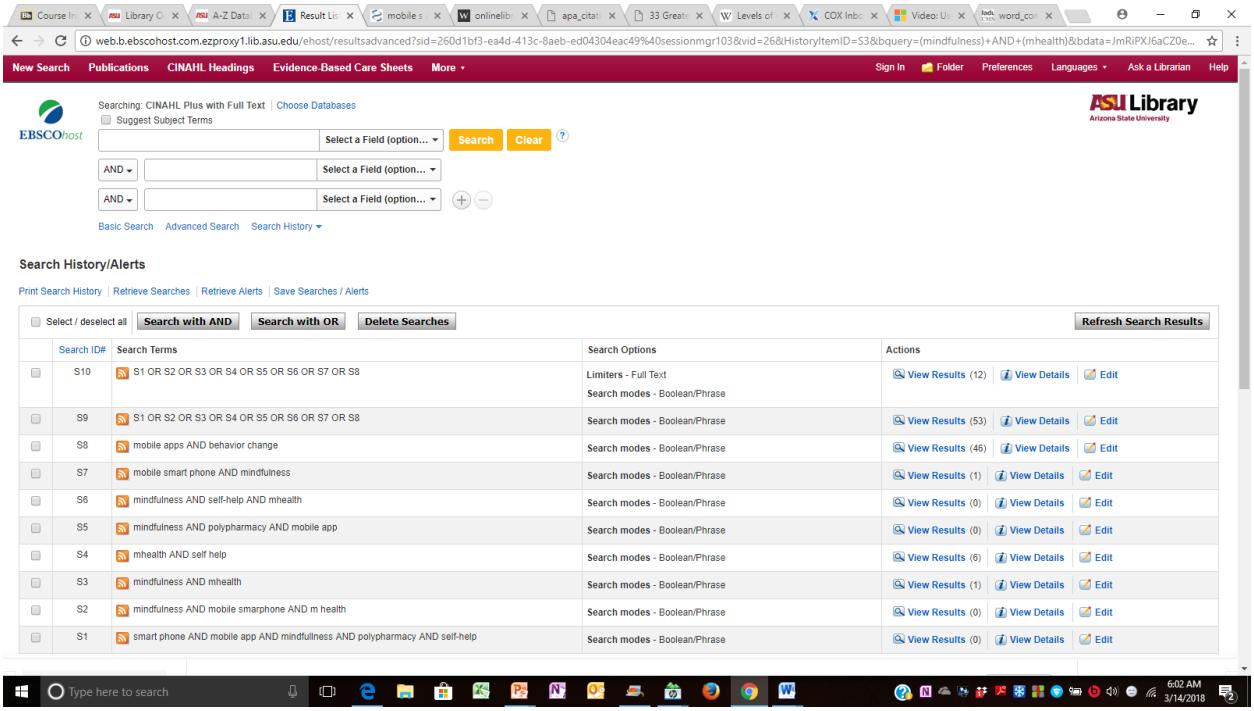
Appendix B

PsycINFO Database Search



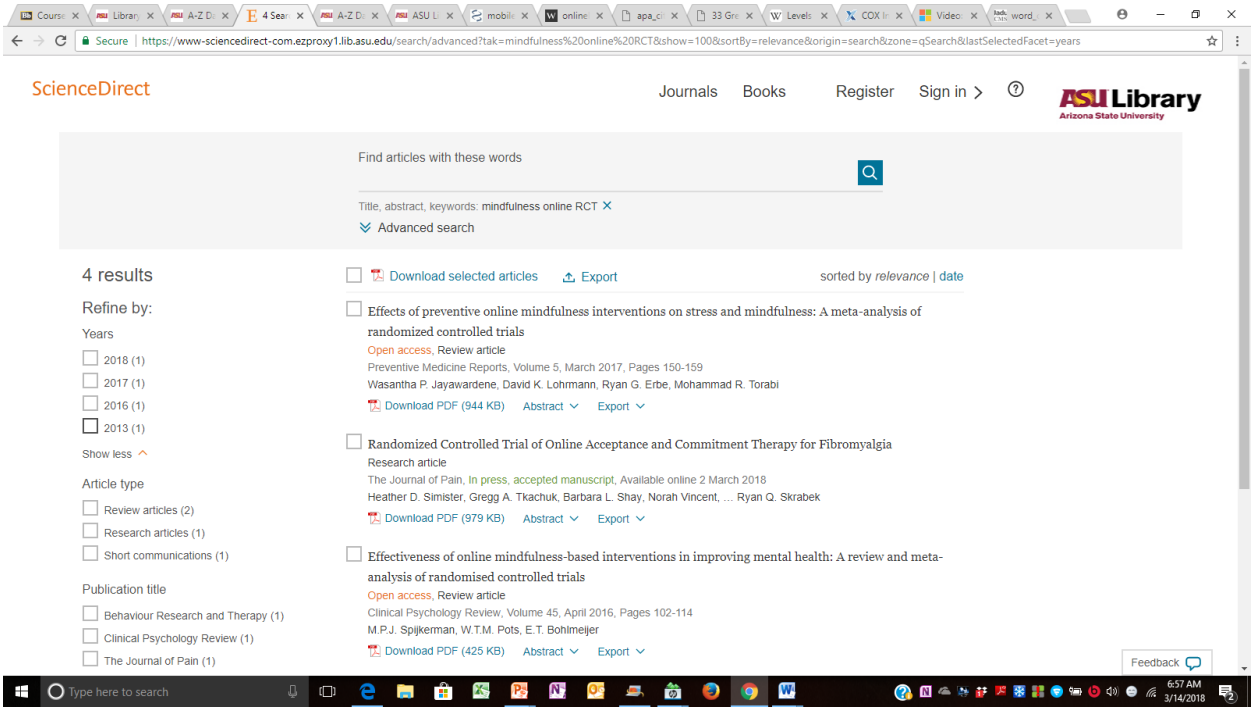
Appendix C

CINHAL Database Search



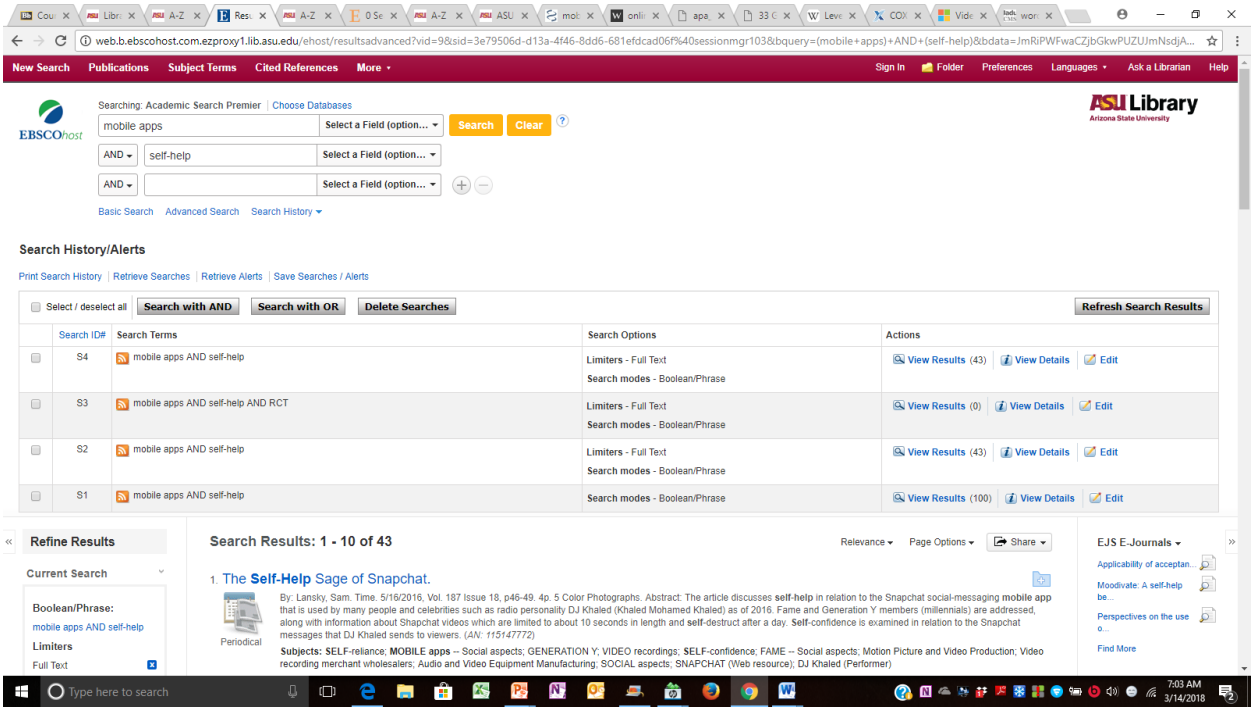
Appendix D

Science Direct Database Search



Appendix E

Academic Search Premier Database Search



Appendix F

Table 1

Evaluation Table

Citation	**Theory/ Conceptual Framework**	**Design/ Method**	**Sample/ Setting**	**Major Variables & Definitions**	**Measurement/ Instrumentation**	**Data Analysis (stats used)**	**Findings/ Results**	**Level/Quality of Evidence; Decision for practice/ application to practice**
Carissoli, C. et al 2015 Does a meditation protocol supported by a mobile application help people reduce stress? Suggestions from a controlled pragmatic trial Funding: None Conflict/bias:	Health Belief Model Purpose: Examine effectiveness of MDF android app on stress reduction and perceived stress reduction in adults over 3 weeks	RCT 56 participants randomly assigned to one of 3 groups App group, Music Group, Wait list group Reported beginning and end perceived stress and HR after 2 MDF	n= 56 Purposeful self-selection via flyers 56 Italian workers Age 20-52 36 women 24 men 66.1% hold college degree >95% HS diploma	IV= MDF app group n=20 Control= Music group Group n=18 DV2=wait list Group n=18	Self-report Likert scale MSP Cronbach's alpha of validated Italian Version is 0.95 Heart rate	One way ANOVA	No difference between app vs music group Wait list group increased MSP scores App and music group self-report improved stress reduction App group = less hyperactivity, accelerated behaviors	Level II Small SS, number of subjects per tx group not available, marginal true participation rate 55.3% fully participated 18.4% irregular participation Low AR=0% MDF practice has positive physical results

Key: **DV**-dependent variable; **IV**- independent variable; **N**-number of studies; **n**- number of participants; **SRC**- Swedish Research Council; **ECSFP**- European Commission Seventh Framework Programme; **BDI-II**- Beck Depression Inventory; **PHQ-9**- Patient Health Questionnaire Depression Scale; **FFMQ**-Five Facet Mindfulness Questionnaire; **MINI-** Mini International Neuropsychiatric Interview; **PSS** – Perceived Stress Scale; **QOLI**- Quality of Life Inventory; **C-scale**- Credibility of analogue therapy rationales; **AUDIT**- Alcohol Use Disorders Identification Test; **DTS**- Danger to self; **ITT**- Intention to treat; **BOCF** – baseline observation carried forward method; **CI**- confidence interval; **SS**- small sample size; **AR**- Attrition rate; **MDF** –Mindfulness; **AD**- Anxiety & Depression; **PS**- Perceived Stress; **NOSRC**- Netherlands Organization for Scientific Research; **HAM-D**- Hamilton Depression Rating Scale; **ESM**- experience sampling method; **JFNMH**- Japan Foundation for Neuroscience and Mental Health; **JMHLW**- Japanese Ministry of Health, Labor, & Welfare; **CBT**- cognitive behavioral therapy; **FIBSER-** Frequency, Intensity, and Burden of Side Effects Ratings; **MSP**- Mesure du Stress Psychologique; **NIMH**- National Institute of Mental Health; **MBCT**-Mindfulness-based cognitive therapy; **MBSR**- Mindfulness-based stress reduction; **HRSD-21**- Hamilton Rating Scale for Depression, 21 item; **RSQ**- Response Styles Questionnaire; **HPQ**- Mindfulness Homework Practice Questionnaire; **BAI**- Beck Anxiety Inventory; **QOLI**- Quality of Life Inventory; **AAQ-II**- Acceptance & Action Questionnaire; **MMSQ**-Multidimensional Mood State Questionnaire; **ABBT**- Acceptance-based behavioral therapy; **ADIS-IV**- Anxiety Disorders Interview Schedule per DSM-IV; **PSWQ**-Penn State Worry Questionnaire; **DASS**- Depression Anxiety Stress Scales; **MAAS**- Mindfulness Attention Awareness Questionnaire, SWR-Somewhat Reliable

None Country: Italy		app session daily					Music group = less pain Decreased HR in both app and music group	
Citation	**Theory/ Conceptual Framework**	**Design/ Method**	**Sample/ Setting**	**Major Variables & Definitions**	**Measurement/ Instrumentation**	**Data Analysis (stats used)**	**Findings/ Results**	**Level/Quality of Evidence; Decision for practice/ application to practice**
Cavanagh et al. 2013 A randomized controlled trial of a brief online mindfulness-based intervention. Funding: NHS Foundation Trust Conflict/bias: none Country: United Kingdom	Self-Efficacy Purpose: Use an adequately powered RCT to evaluate the impact of n online mindfulness based self-help intervention	RCT Participants randomly assigned via computer immediate intervention condition group or wait list group after completing baseline questionnaires Inactive waiting list	n=104 92 female Age 19-51 University Students in S. Wales Self-selected via recruitment poster or email Purposeful selection	IV- Immediate intervention n =52 DV-2 week wait list intervention n = 52 Same intervention, 2 weeks apart	Mindfulness FFMQ scores perceived stress PSS scores anxiety & depression PHQ-4 scores	IBM SPSS 19 ITT with BOCF ANOVA Two-tailed t-test 95%CI	high AR, almost 50% did not complete Significant incrs in MDF, Decrs in PS and AD in immediate intervention group	Level II AR 46%, >90% female participants On-line based MDF interventions are effective at reducing PS and AD in student populations

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		control condition						
Citation	**Theory/ Conceptual Framework**	**Design/ Method**	**Sample/ Setting**	**Major Variables & Definitions**	**Measurement/ Instrumentation**	**Data Analysis (stats used)**	**Findings/ Results**	**Level/Quality of Evidence; Decision for practice/ application to practice**
Hartin, P. J. et al. 2016 The empowering role of mobile apps in behavior change interventions: The gray matters randomized controlled trial Funding: Utah State University, N. Ireland Dept. for Employment & Learning Conflict/bias: None Country: USA	Theory of Planned Behavior and Health Belief Model Purpose: To examine effectiveness of mobile apps on biological health markers as wells psychologic measure ments of well-being compared with usual treatment	RCT 144 subjects randomly assigned to treatment or control groups Method: Treatment group prescribed app delivered instruction and treatments requiring participant input and response. Controls received treatment as unusual over 6 months	n=144 Purposeful self-selection via email, word of mouth, flyers, health fairs Age 40-60 BMI < 42 Own a smart phone or tablet Fluent in English Live in Cache County	IV= no strict regimen n= 102 DV= strictly prescribed regimen n= 42	Primary: BMI, Blood based biomarkers, cognitive testing, behavior in targeted domains Secondary: Cognition, readiness for change, sleep, motivation, social engagement, depression, couple satisfaction Exit surveys	Independent t-test, one way ANOVA CI= 95%	Use of app corresponds to changes in clinical and bio markers No correlation between achieving recommende d values and actual clinical or bio markers Sustained improvement to clinical bio markers can be seen with sustained app use	Level I Under powered Participants >96% white and rural Power increased by increasing treatment group App use improves clinical and biologic marker outcomes with increased use Improved depression/anxiet y, BP, individual functional behaviors

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			Not currently diagnosed pregnant, dementia, unmanaged diabetes, uncontrolled major depression					
Citation	**Theory/ Conceptual Framework**	**Design/ Method**	**Sample/ Setting**	**Major Variables & Definitions**	**Measurement/ Instrumentation**	**Data Analysis (stats used)**	**Findings/ Results**	**Level/Quality of Evidence; Decision for practice/ application to practice**
Hawley, L. et al. 2014 Mindfulness practice, rumination and clinical outcome in mindfulness-based treatment Funding: NIMH Conflict/bias: None Country:	Health Belief Model Purpose: Determine whether rumination & distraction were affected and/or decreased with mindfulness, if so, does mindfulness type affect depressive symptoms	Mixed methods Correlate and Compare 2 data sets from 2 previous RCT's	n=32 Age 18-65 Mean 44.1 60% female 83.3% white Experience remission of depression as measured by 50% decrease in HRSD-21 AND	MBCT grp n=18 MBSR grp n= 14	Structure Clinical Interview for DSM-IV HRSD-21 RSQ HPQ	IBM SPSS 20 Bootstrapping Multiple regression analysis	No significant assoc between distraction and depression Decreased rumination = decreased depression Distraction beneficial but not as much as MDF for depression	Level 1 First study examining specific forms MDF and symptom alleviation Distraction beneficial but not for depression symptoms MDF effective for depression

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Canada			HRSD-21 <8 for 8 weeks Excluded: bipolar, schizophrenia, PTSD, substance abuse, Borderline personality, ECT in last 6 mos, currently doing yoga or meditation				Frequency of formal and total MDF decreased depressive sympt. Informal MDF not assoc. with depression sympt. change	MDF engages rumination habits and emotionally charged thoughts allowing disengagement with distressing thoughts Distraction did not relieve depression symptoms
Citation	**Theory/ Conceptual Framework**	**Design/ Method**	**Sample/ Setting**	**Major Variables & Definitions**	**Measurement/ Instrumentation**	**Data Analysis (stats used)**	**Findings/ Results**	**Level/Quality of Evidence; Decision for practice/ application to practice**
Ly, K.H. et al. n.d. Smartphone-supported versus full behavioural activation for depression: A randomised controlled trial	Self-Efficacy Purpose: Examine whether blended smart app and in-person tx was not inferior to	RCT True random number service Method: Compared effectiveness of blended tx of 4 in person	n= 93 Age 18 or > Consumed none or fixed dose of medication for depression and anxiety	IV- Smart app and in person blended n = 46 DV- In-person only tx n = 47	Primary = BDI-II Secondary = PHQ-9, BAI, QOLI Clinician administered: MINI	IBM SPSS 20 Indept. Samples t-test Chi-square Cohen's d	n=93 16 (25.8%) did not submit self-report measures 88 completed all in person tx.	Level II Small sample size, bias, attrition >25% Blended tx almost as effective as full in-person, more efficient

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Funding: SRC, ECSFP, Wemind Psykiatari Stockholm Conflict/bias: Ly, K.H. develops version of app for open market Country: Netherlands	100% in-person tx.	sessions and smart app vs full in person behavioral tx	Depression diagnosed via DSM-IV > 5 on PHQ-9 scale No comorbid psychiatric diagnosis, i.e, bipolar No severe alcohol problems >8 on AUDIT test No medical problems requiring treatment No DTS per MINI		Credibility & working alliance measurement: C-Scale		Avg. therapist time blended = 321 min In-person =600min 47% less BDI-II scores dropped 12.75 pts overall. No significant difference between groups Blended tx almost as effective as full in-person, more efficient	
Citation	**Theory/ Conceptual Framework**	**Design/ Method**	**Sample/ Setting**	**Major Variables & Definitions**	**Measurement/ Instrumentation**	**Data Analysis (stats used)**	**Findings/ Results**	**Level/Quality of Evidence; Decision for practice/ application to practice**

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Ly, K. et al. 2014 Behavioural activation versus mindfulness-based guided self-help treatment administered through a smartphone application: A randomized controlled trial. Funding: SRC Conflict/bias: Ly, K. has a related version of the app on the open market Country: Sweden	Self-Efficacy Purpose: Compare effectiveness of CBT vs MDF smart phone app	Parallel randomized control, open, trial 2 groups randomized to CBT app group and MDF app group. Results reported and examined after 8 weeks.	n=81 Purposeful self-selection via Swedish mass media Mean age=36 Confirmed diagnosis of major depression >18 yrs old, PHQ-9>5, unchanged med doses over last month, no concurrent psych tx., no comorbid psych diagnosis, no medical problems needing tx., no severe alcohol prob., no DTS	IV=MDF app n=40 IV=BA app n=41	BDI-II PHQ-9 BAI QOLI AAQ-II MINI	IBM SPSS 20 Independent t-test Chi-square Mixed effects models Power analysis (89%) Cohen's d	15.9% AR MDF more effective in less severe initial depression Recovery rates similar across both BA and MDF groups 82.4% BA less severe sympt. recovered vs 92.3% MDF less severe sympt.	Level II Underpowered, recruited via mass media, generalizable to clinic??, most participants college educated First completely app only delivered therapy MDF more effective in less severe initial depression

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Citation	Theory/ Conceptual Framework	Design/ Method	Sample/ Setting	Major Variables & Definitions	Measurement/ Instrumentation	Data Analysis (stats used)	Findings/ Results	Level/Quality of Evidence; Decision for practice/ application to practice
Mantani, A. et al. 2017 Smartphone cognitive behavioral therapy as an adjunct to pharmacotherapy for refractory depression: Randomized controlled trial. Funding: JMHLW, JFNMH, received donations from major drug companies including Eli Lilly, GSK, Janssen, and Pfizer Conflict/bias:	Self-Efficacy Purpose: Evaluate effectiveness of app in anti-depressant treatment resistant depression	RCT Method: Evaluate effectiveness of app in medication change group versus medication change and app group in treatment resistant depression.	n=164 20 Japanese psychiatric clinics Primary diagnosis of depression Anti-depressant refractory after 1 or more anti-depressants at adequate dose for > 4 weeks Score >10 on BDI-II Randomized to med switch alone vs med	IV= med change and app CBT n= 81 DV= med change alone n= 83	Interview PHQ-9, BDI-II, FIBSER	SAS version 9.4 Linear mixed model with a 95%CI	Med switch & App group n=57 scored 1.77 pts lower on PHQ-9, 3.2 pts lower on BDI-II, 0.75 pts lower on FISBER. 95% CI Measurable results up to week 17	Level I Bias moderate Results specific to Kokoro app Improved depression in multiple assessment scales short term and at 17 wk follow up. Apps work as adjunctive treatment in anti-depressant treatment resistant depressed persons. Short and long term benefits seen at 17wk follow up

Key: **DV**-dependent variable; **IV**- independent variable; **N**-number of studies; **n**- number of participants; **SRC**- Swedish Research Council; **ECSFP**- European Commission Seventh Framework Programme; **BDI-II**- Beck Depression Inventory; **PHQ-9**- Patient Health Questionnaire Depression Scale; **FFMQ**-Five Facet Mindfulness Questionnaire; **MINI-** Mini International Neuropsychiatric Interview; **PSS** – Perceived Stress Scale; **QOLI**- Quality of Life Inventory; **C-scale**- Credibility of analogue therapy rationales; **AUDIT**- Alcohol Use Disorders Identification Test; **DTS**- Danger to self; **ITT**- Intention to treat; **BOCF** – baseline observation carried forward method; **CI**- confidence interval; **SS**- small sample size; **AR**- Attrition rate; **MDF** –Mindfulness; **AD**- Anxiety & Depression; **PS**- Perceived Stress; **NOSRC**- Netherlands Organization for Scientific Research; **HAM-D**- Hamilton Depression Rating Scale; **ESM**- experience sampling method; **JFNMH**- Japan Foundation for Neuroscience and Mental Health; **JMHLW**- Japanese Ministry of Health, Labor, & Welfare; **CBT**- cognitive behavioral therapy; **FIBSER-** Frequency, Intensity, and Burden of Side Effects Ratings; **MSP**- Mesure du Stress Psychologique; **NIMH**- National Institute of Mental Health; **MBCT**-Mindfulness-based cognitive therapy; **MBSR**- Mindfulness-based stress reduction; **HRSD-21**- Hamilton Rating Scale for Depression, 21 item; **RSQ**- Response Styles Questionnaire; **HPQ**- Mindfulness Homework Practice Questionnaire; **BAI**- Beck Anxiety Inventory; **QOLI**- Quality of Life Inventory; **AAQ-II**- Acceptance & Action Questionnaire; **MMSQ**-Multidimensional Mood State Questionnaire; **ABBT**- Acceptance-based behavioral therapy; **ADIS-IV**- Anxiety Disorders Interview Schedule per DSM-IV; **PSWQ**-Penn State Worry Questionnaire; **DASS**- Depression Anxiety Stress Scales; **MAAS**- Mindfulness Attention Awareness Questionnaire, SWR-Somewhat Reliable

Many authors receive drug company funding, two authors developed Kokoro app Country: Japan			switch and app CBT					
Citation	**Theory/ Conceptual Framework**	**Design/ Method**	**Sample/ Setting**	**Major Variables & Definitions**	**Measurement/ Instrumentation**	**Data Analysis (stats used)**	**Findings/ Results**	**Level/Quality of Evidence; Decision for practice/ application to practice**
Meinlschmidt, G. et al. 2016 Smartphone-based psychotherapeutic micro-interventions to improve mood in a real-world setting Funding: University of Surrey and Canterbury Christ Church University	Self-Efficacy Purpose: To test effectiveness of smartphone MDF and CBT apps and their effect on mood in a healthy, non-clinical, population	Mixed methods study Men selected from a larger study group used smart apps and were exposed to multiple different types of mindfulness, transcendental meditation, and CBT therapies and reported	n=27 All males, Age 18-65, Right handed, not color-blind, no hx of cardiac, neuro, mental health disorders, English speaking, smart phone familiar	IVa= psychotherapeutic technique IVb=viscerosensory attention IVc=other DV=no intervention	MMSQ	R Project for Statistical Computing Two-tailed t-test	Mood improved pre to post micro intervention. p=0.022 Increase in mood across days not significant. p=0.276 Subjects calmer pre-post intervention, but not across days	Level III Small SS, all male, highly selected candidates App use positively affects mood and level of relaxation immediately

Key: **DV**-dependent variable; **IV**- independent variable; **N**-number of studies; **n**- number of participants; **SRC**- Swedish Research Council; **ECSFP**- European Commission Seventh Framework Programme; **BDI-II**- Beck Depression Inventory; **PHQ-9**- Patient Health Questionnaire Depression Scale; **FFMQ**-Five Facet Mindfulness Questionnaire; **MINI-** Mini International Neuropsychiatric Interview; **PSS** – Perceived Stress Scale; **QOLI**- Quality of Life Inventory; **C-scale**- Credibility of analogue therapy rationales; **AUDIT**- Alcohol Use Disorders Identification Test; **DTS**- Danger to self; **ITT**- Intention to treat; **BOCF** – baseline observation carried forward method; **CI**- confidence interval; **SS**- small sample size; **AR**- Attrition rate; **MDF** –Mindfulness; **AD**- Anxiety & Depression; **PS**- Perceived Stress; **NOSRC**- Netherlands Organization for Scientific Research; **HAM-D**- Hamilton Depression Rating Scale; **ESM**- experience sampling method; **JFNMH**- Japan Foundation for Neuroscience and Mental Health; **JMHLW**- Japanese Ministry of Health, Labor, & Welfare; **CBT**- cognitive behavioral therapy; **FIBSER-** Frequency, Intensity, and Burden of Side Effects Ratings; **MSP**- Mesure du Stress Psychologique; **NIMH**- National Institute of Mental Health; **MBCT**-Mindfulness-based cognitive therapy; **MBSR**- Mindfulness-based stress reduction; **HRSD-21**- Hamilton Rating Scale for Depression, 21 item; **RSQ**- Response Styles Questionnaire; **HPQ**- Mindfulness Homework Practice Questionnaire; **BAI**- Beck Anxiety Inventory; **QOLI**- Quality of Life Inventory; **AAQ-II**- Acceptance & Action Questionnaire; **MMSQ**-Multidimensional Mood State Questionnaire; **ABBT**- Acceptance-based behavioral therapy; **ADIS-IV**- Anxiety Disorders Interview Schedule per DSM-IV; **PSWQ**-Penn State Worry Questionnaire; **DASS**- Depression Anxiety Stress Scales; **MAAS**- Mindfulness Attention Awareness Questionnaire, SWR-Somewhat Reliable

Conflict/bias: None Country: S. Korea		mood at start of day and end of day.	Purposeful self-selection from broader study participant					
Os, J. et al. 2017 The experience sampling method as an mHealth tool to support self-monitoring, self-insight, and personalized health care in clinical practice. Funding: NORSC, ECSFP, Weijerhorst Stichting Conflict/bias: none Country: Netherlands	Self-Efficacy Purpose: To examine large scale patient reported experiences to improve app personalization and effectiveness	Large Mixed methods qualitative and quantitative Method: Review & analysis of auto-correlation of experience sampling methodology applied via smart apps to support greater app personalization and efficacy in clinical practice	Large university maintained database with comparable experiencing monitoring lists Controls n = 276, Healthy twins n = 601, relative of pt with psychotic disorder n = 178, pts with psychotic disorder n = 293, depression n = 115, residual depression n = 129, risk for psychotic	Report of Feeling Down Controls n = 251, residual depression n=n 129, depression n = 45 Report of feeling down via location Controls n = 251, residual depression n=n 129, depression n = 45 Report of feeling suspicious paranoia Controls n = 212, residual depression n=n 129, psychotic disorder n = 293 Report of Positive effect vs no effect after 6 weeks of	Self-report beep counter Auto-correlation over successive lags of ESM Interview HAM-D	Mean of self-report (10 random measurements per day over 6 days)	Self-monitoring increased resiliency and decreased low mood, paranoia Self-monitoring increased personalization in psych med dosing, accuracy in dosing	Level I Large SS, Generalizable across multiple populations Self-monitoring data can be used to improve med prescribing, monitor effect, improve dosing and accuracy

Key: **DV**-dependent variable; **IV**- independent variable; **N**-number of studies; **n**- number of participants; **SRC**- Swedish Research Council; **ECSFP**- European Commission Seventh Framework Programme; **BDI-II**- Beck Depression Inventory; **PHQ-9**- Patient Health Questionnaire Depression Scale; **FFMQ**-Five Facet Mindfulness Questionnaire; **MINI-** Mini International Neuropsychiatric Interview; **PSS** – Perceived Stress Scale; **QOLI**- Quality of Life Inventory; **C-scale**- Credibility of analogue therapy rationales; **AUDIT**- Alcohol Use Disorders Identification Test; **DTS**- Danger to self; **ITT**- Intention to treat; **BOCF** – baseline observation carried forward method; **CI**- confidence interval; **SS**- small sample size; **AR**- Attrition rate; **MDF** –Mindfulness; **AD**- Anxiety & Depression; **PS**- Perceived Stress; **NOSRC**- Netherlands Organization for Scientific Research; **HAM-D**- Hamilton Depression Rating Scale; **ESM**- experience sampling method; **JFNMH**- Japan Foundation for Neuroscience and Mental Health; **JMHLW**- Japanese Ministry of Health, Labor, & Welfare; **CBT**- cognitive behavioral therapy; **FIBSER-** Frequency, Intensity, and Burden of Side Effects Ratings; **MSP**- Mesure du Stress Psychologique; **NIMH**- National Institute of Mental Health; **MBCT**-Mindfulness-based cognitive therapy; **MBSR**- Mindfulness-based stress reduction; **HRSD-21**- Hamilton Rating Scale for Depression, 21 item; **RSQ**- Response Styles Questionnaire; **HPQ**- Mindfulness Homework Practice Questionnaire; **BAI**- Beck Anxiety Inventory; **QOLI**- Quality of Life Inventory; **AAQ-II**- Acceptance & Action Questionnaire; **MMSQ**-Multidimensional Mood State Questionnaire; **ABBT**- Acceptance-based behavioral therapy; **ADIS-IV**- Anxiety Disorders Interview Schedule per DSM-IV; **PSWQ**-Penn State Worry Questionnaire; **DASS**- Depression Anxiety Stress Scales; **MAAS**- Mindfulness Attention Awareness Questionnaire, SWR-Somewhat Reliable

			disorder n = 106	initiation of imipramine in 26 pts 50% reduction in HAMD at 6 wks				
Citation	**Theory/ Conceptual Framework**	**Design/ Method**	**Sample/ Setting**	**Major Variables & Definitions**	**Measurement/ Instrumentation**	**Data Analysis (stats used)**	**Findings/ Results**	**Level/Quality of Evidence; Decision for practice/ application to practice**
Roemer, L. et al. 2008 Efficacy of an acceptance-based behavior therapy for generalized anxiety disorder: Evaluation in a randomized controlled trial Funding: NIMH Conflict/bias:	Self-Efficacy Purpose: Decrease anxiety and avoidance in anxiety pts. via in-person exposure therapy and mindfulness training.	RCT Method: 16 in-person sessions focused on exposure, habitual anxious responding, mindfulness and self-monitoring	n=31 25 participants completed study Age 18> Primary diagnosis GAD referred by provider Excluded: bipolar, substance abuse,	IV=treatment group n=16 DV=wait list group n=15	ADIS-IV PSWQ DASS BDI-II QOLI AAQ MAAS	Hierarchical Linear and Nonlinear Modeling software Multilevel regression analysis Means Standard errors Between-groups t-test	ABBT therapy decreased anxiety in all measurement instruments Positive anxiety results seen at 9 mos.	Level I AR= 22%, Small SS, customized ABBT, underpowered ABBT decreased anxiety in all measures Positive anxiety results seen at 9 mos.

Key: **DV**-dependent variable; **IV**- independent variable; **N**-number of studies; **n**- number of participants; **SRC**- Swedish Research Council; **ECSFP**- European Commission Seventh Framework Programme; **BDI-II**- Beck Depression Inventory; **PHQ-9**- Patient Health Questionnaire Depression Scale; **FFMQ**-Five Facet Mindfulness Questionnaire; **MINI-** Mini International Neuropsychiatric Interview; **PSS** – Perceived Stress Scale; **QOLI**- Quality of Life Inventory; **C-scale**- Credibility of analogue therapy rationales; **AUDIT**- Alcohol Use Disorders Identification Test; **DTS**- Danger to self; **ITT**- Intention to treat; **BOCF** – baseline observation carried forward method; **CI**- confidence interval; **SS**- small sample size; **AR**- Attrition rate; **MDF** –Mindfulness; **AD**- Anxiety & Depression; **PS**- Perceived Stress; **NOSRC**- Netherlands Organization for Scientific Research; **HAM-D**- Hamilton Depression Rating Scale; **ESM**- experience sampling method; **JFNMH**- Japan Foundation for Neuroscience and Mental Health; **JMHLW**- Japanese Ministry of Health, Labor, & Welfare; **CBT**- cognitive behavioral therapy; **FIBSER-** Frequency, Intensity, and Burden of Side Effects Ratings; **MSP**- Mesure du Stress Psychologique; **NIMH**- National Institute of Mental Health; **MBCT**-Mindfulness-based cognitive therapy; **MBSR**- Mindfulness-based stress reduction; **HRSD-21**- Hamilton Rating Scale for Depression, 21 item; **RSQ**- Response Styles Questionnaire; **HPQ**- Mindfulness Homework Practice Questionnaire; **BAI**- Beck Anxiety Inventory; **QOLI**- Quality of Life Inventory; **AAQ-II**- Acceptance & Action Questionnaire; **MMSQ**-Multidimensional Mood State Questionnaire; **ABBT**- Acceptance-based behavioral therapy; **ADIS-IV**- Anxiety Disorders Interview Schedule per DSM-IV; **PSWQ**-Penn State Worry Questionnaire; **DASS**- Depression Anxiety Stress Scales; **MAAS**- Mindfulness Attention Awareness Questionnaire, SWR-Somewhat Reliable

None Country: USA			psychotic disorders, DTS					Mindfulness is core tenet of ABBT

Key: **DV**-dependent variable; **IV**- independent variable; **N**-number of studies; **n**- number of participants; **SRC**- Swedish Research Council; **ECSFP**- European Commission Seventh Framework Programme; **BDI-II**- Beck Depression Inventory; **PHQ-9**- Patient Health Questionnaire Depression Scale; **FFMQ**-Five Facet Mindfulness Questionnaire; **MINI-** Mini International Neuropsychiatric Interview; **PSS** – Perceived Stress Scale; **QOLI**- Quality of Life Inventory; **C-scale**- Credibility of analogue therapy rationales; **AUDIT**- Alcohol Use Disorders Identification Test; **DTS**- Danger to self; **ITT**- Intention to treat; **BOCF** – baseline observation carried forward method; **CI**- confidence interval; **SS**- small sample size; **AR**- Attrition rate; **MDF** –Mindfulness; **AD**- Anxiety & Depression; **PS**- Perceived Stress; **NOSRC**- Netherlands Organization for Scientific Research; **HAM-D**- Hamilton Depression Rating Scale; **ESM**- experience sampling method; **JFNMH**- Japan Foundation for Neuroscience and Mental Health; **JMHLW**- Japanese Ministry of Health, Labor, & Welfare; **CBT**- cognitive behavioral therapy; **FIBSER-** Frequency, Intensity, and Burden of Side Effects Ratings; **MSP**- Mesure du Stress Psychologique; **NIMH**- National Institute of Mental Health; **MBCT**-Mindfulness-based cognitive therapy; **MBSR**- Mindfulness-based stress reduction; **HRSD-21**- Hamilton Rating Scale for Depression, 21 item; **RSQ**- Response Styles Questionnaire; **HPQ**- Mindfulness Homework Practice Questionnaire; **BAI**- Beck Anxiety Inventory; **QOLI**- Quality of Life Inventory; **AAQ-II**- Acceptance & Action Questionnaire; **MMSQ**-Multidimensional Mood State Questionnaire; **ABBT**- Acceptance-based behavioral therapy; **ADIS-IV**- Anxiety Disorders Interview Schedule per DSM-IV; **PSWQ**-Penn State Worry Questionnaire; **DASS**- Depression Anxiety Stress Scales; **MAAS**- Mindfulness Attention Awareness Questionnaire, SWR-Somewhat Reliable

Appendix G

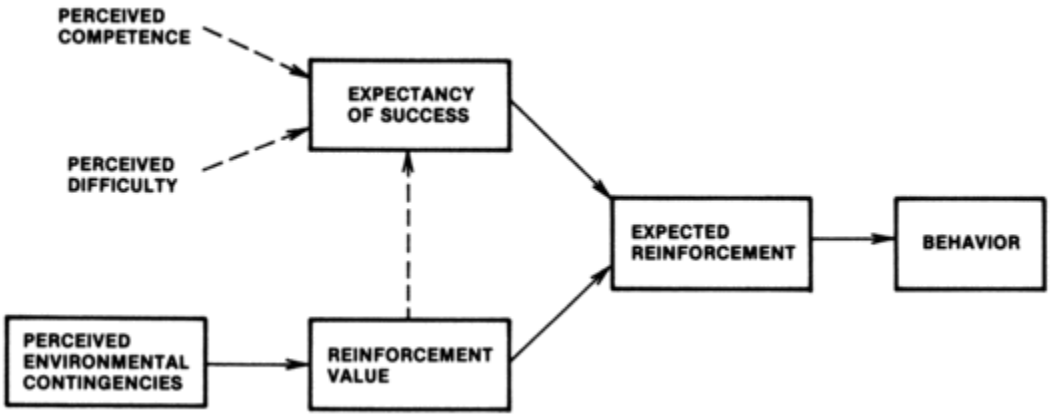
Table 2

Synthesis Table

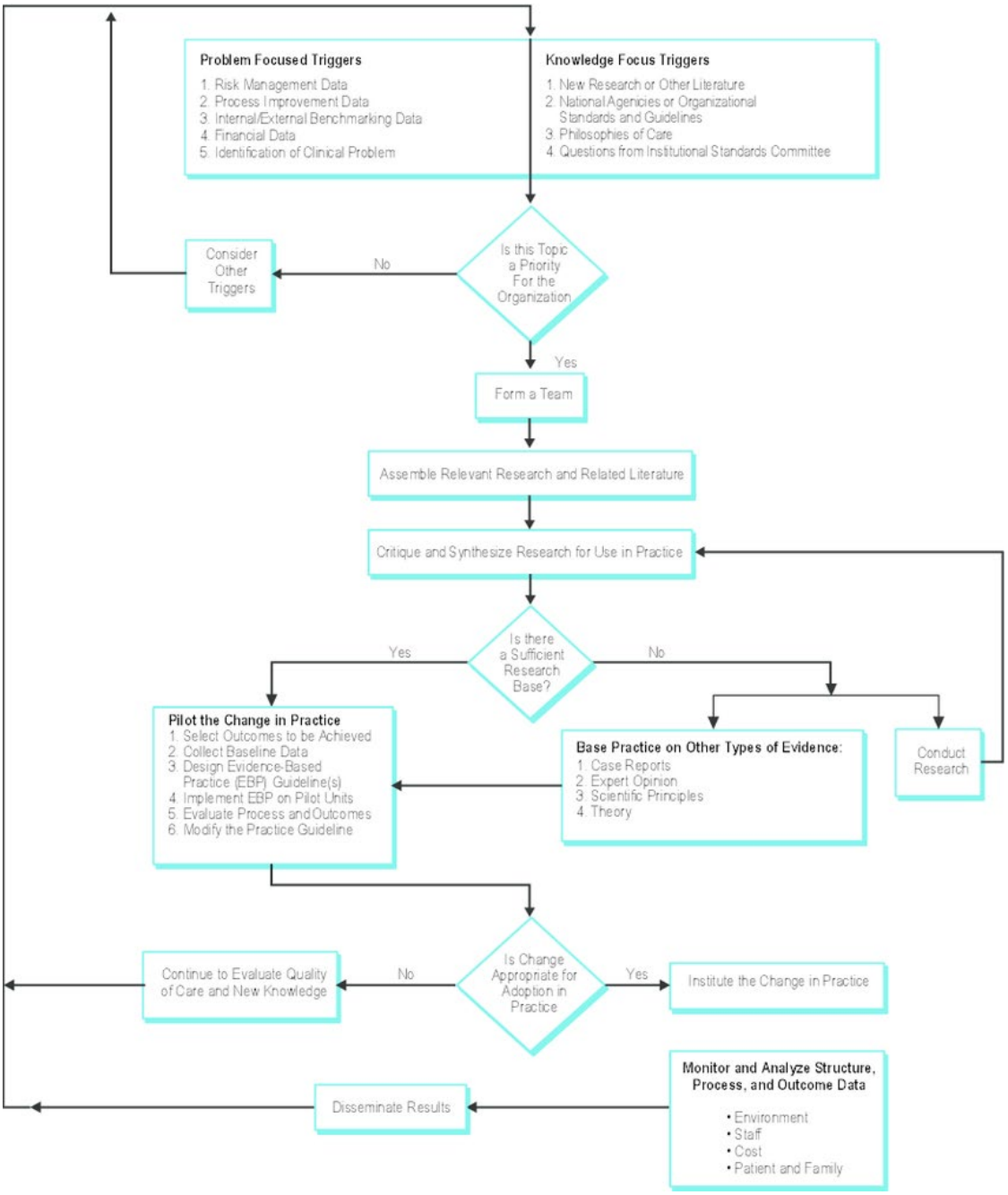
Studies		Carissoli, C. et al.	Cavanagh et al.	Hartin, P.J. et al.	Hawley, L. et al.	Ly, H.K. et al.	Ly, K.H. et al.	Mantani, A. et al.	Meinlschmidt, G. et al.	Os, J. et al.	Roemer, L. et al.
Basics	Year	2015	2013	2016	2014	n.d.	2013	2017	2016	2017	2008
	LOE	II	II	I	I	II	II	I	III	I	I
	Design	RCT	RCT	RCT	MM	RCT	RCT	RCT	MM	MM	RCT
	Mean Age	38.1	24.7	40-60	44.1	30.6	36	40.2	24.3	N/A	33.9
	Attrition	0%**	46%	0%	N/A	25.8	21%	2%	N/A	N/A	22%
	Bias	None	None	None	None	***	***	M	M	None	None
	# of participants	56	104	144	32	93	81	164	27	1592	31
	Reliability	MR	MR	R	R	MAR	MR	R	MR	R	R
Interventions	BA&IPMDFT					X					
	ABBT										X
	ET										X
	In-person MBT*				X	X					X
	MDF/CBT App	X		X		X	X	X			
	Education			X							X
	On-line MBT		X								
	Self-lead MBT				X						
	Medication Chng							X			
Major findings	Stress/ PS	↓	↓								
	Coping/Mood	↑							↑		
	HR and/or BP	↓		↓							
	Anxiety		↓								↓
	Depression		↓	↓	↓*		↓	↓			
	Mindfulness		↑		↑*						↑
	QOL		↑								
	Agitation	↓							↓		↓
	Efficiency					↑				↑	
	IFB			↑							↑
	IR	↓		↑				↑	↑		↑
	SR			↑				↑		↑	↑

ABBT-Acceptance Based Behavior Therapy, IR-Immediate Response, SR – Sustained Response at follow-up, IFB- Individual Functional behavior, ET-Exposure Therapy, MBT- Mindfulness Behavior Therapy, MDF- Mindfulness, MR-Mostly Reliable, MAR- Marginally Reliable, R-Reliable, BA&IPMDFT- Blended App and In-person Mindfulness Based Therapy, PS- Perceived Stress, ***- Ly, K.H. develops an app for the open market, M-Moderate Bias, MM-mixed methods, NA- not applicable, QOL – Quality of life, R – Reliable, RCT – Randomized Controlled trial, ↓ - Reduced, ↑ - Increased, ** - for primary outcome

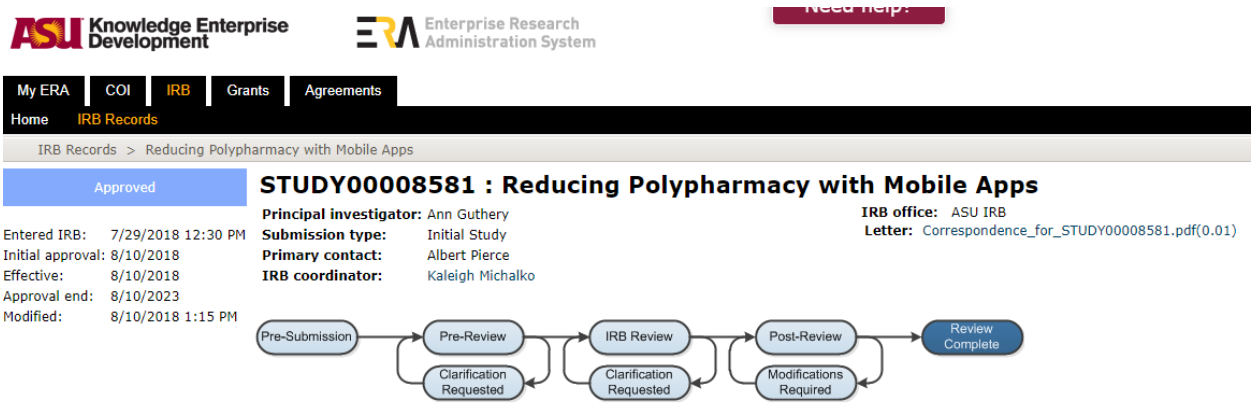
Appendix H


PERCEIVED COMPETENCE
PERCEIVED DIFFICULTY
EXPECTANCY OF SUCCESS
EXPECTED REINFORCEMENT
BEHAVIOR
PERCEIVED ENVIRONMENTAL CONTINGENCIES
REINFORCEMENT VALUE

Appendix I


Problem Focused Triggers
1. Risk Management Data
2. Process Improvement Data
3. Internal/External Benchmarking Data
4. Financial Data
5. Identification of Clinical Problem
Knowledge Focus Triggers
1. New Research or Other Literature
2. National Agencies or Organizational Standards and Guidelines
3. Philosophies of Care
4. Questions from Institutional Standards Committee
Is this Topic a Priority For the Organization
No
Consider Other Triggers
Yes
Form a Team
Assemble Relevant Research and Related Literature
Critique and Synthesize Research for Use in Practice
Is there a Sufficient Research Base?
Yes
No
Pilot the Change in Practice
1. Select Outcomes to be Achieved
2. Collect Baseline Data
3. Design Evidence-Based Practice (EBP) Guideline(s)
4. Implement EBP on Pilot Units
5. Evaluate Process and Outcomes
6. Modify the Practice Guideline
Base Practice on Other Types of Evidence:
1. Case Reports
2. Expert Opinion
3. Scientific Principles
4. Theory
Conduct Research
Is Change Appropriate for Adoption in Practice
No
Yes
Continue to Evaluate Quality of Care and New Knowledge
Institute the Change in Practice
Monitor and Analyze Structure, Process, and Outcome Data
• Environment
• Staff
• Cost
• Patient and Family
Disseminate Results

Appendix J


Knowledge Enterprise Development
Enterprise Research Administration System
My ERA
COI
IRB
Grants
Agreements
Home
IRB Records
IRB Records > Reducing Polypharmacy with Mobile Apps
Approved
STUDY00008581 : Reducing Polypharmacy with Mobile Apps
Principal investigator: Ann Guthery
Submission type: Initial Study
Primary contact: Albert Pierce
IRB coordinator: Kaleigh Michalko
IRB office: ASU IRB
Letter: Correspondence_for_STUDY00008581.pdf(0.01)
Entered IRB: 7/29/2018 12:30 PM
Initial approval: 8/10/2018
Effective: 8/10/2018
Approval end: 8/10/2023
Modified: 8/10/2018 1:15 PM
Pre-Submission
Pre-Review
Clarification Requested
IRB Review
Clarification Requested
Post-Review
Modifications Required
Review Complete

Appendix K

ID_____ Date _____ 1

Reducing Polypharmacy with Mobile Apps

Demographics:

Instructions:

Please write in answers to the following questions.

1. Age_____ (write in age in years)
2. Gender
   Male (0) _____
   Female (1) _____
3. Diagnosis_____ (write in primary diagnosis)
4. Name of as needed medication(s) _____ (write in medication names)
   _____
   _____
5. How many doses of as needed medication have you taken since your last visit? _____ (number of doses)

Official Use Only
Data Entry_____ Data Validation_____ Data Analysis_____

Appendix L

ID_____ Date _____ 1

Reducing Polypharmacy with Mobile Apps

Demographics:

Instructions:

Please write in answers to the following questions.

1. How satisfied were you with using your app? Very Somewhat Not at all
2. If you stopped using your app, what was the primary reason for stopping?

   _____
3. Did you switch to using a different app? If yes, which one?

   _____
4. How many doses of your as needed medication have you taken since you started using your app?

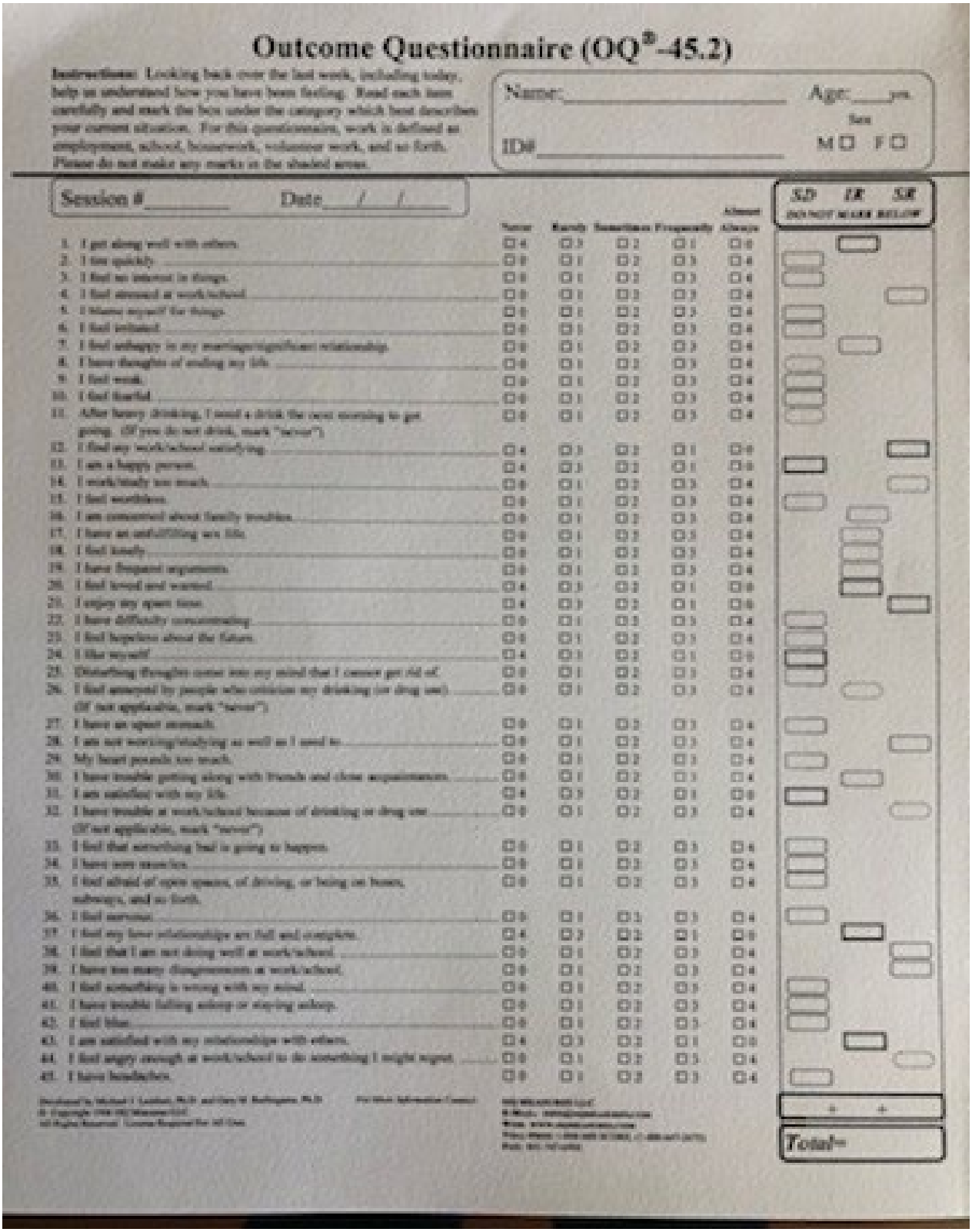
   _____ (write number of doses here)
5. How many times do you think you used your app instead of taking a dose of as needed medication?

   _____ (write number of times app used instead of medication)

Official Use Only

Data Entry_____ Data Validation_____ Data Analysis_____

Appendix M



Outcome Questionnaire (OQ®-45.2)

Instructions: Looking back over the last week, including today, help us understand how you have been feeling. Read each item carefully and mark the box under the category which best describes your current situation. For this questionnaire, work is defined as employment, school, housework, volunteer work, and so forth. Please do not make any marks in the shaded areas.

Name:_____ Age:___yrs.

Sex M☐ F☐

ID#_____

Session #_____ Date___/___/_____

	Never	Rarely	Sometimes	Frequently	Almost Always
1. I get along well with others.	☐4	☐3	☐2	☐1	☐0
2. I tire quickly.	☐0	☐1	☐2	☐3	☐4
3. I feel no interest in things.	☐0	☐1	☐2	☐3	☐4
4. I feel stressed at work/school.	☐0	☐1	☐2	☐3	☐4
5. I blame myself for things.	☐0	☐1	☐2	☐3	☐4
6. I feel irritated.	☐0	☐1	☐2	☐3	☐4
7. I feel unhappy in my marriage/significant relationship.	☐0	☐1	☐2	☐3	☐4
8. I have thoughts of ending my life.	☐0	☐1	☐2	☐3	☐4
9. I feel weak.	☐0	☐1	☐2	☐3	☐4
10. I feel fearful.	☐0	☐1	☐2	☐3	☐4
11. After heavy drinking, I need a drink the next morning to get going. (If you do not drink, mark "never").	☐0	☐1	☐2	☐3	☐4
12. I find my work/school satisfying.	☐4	☐3	☐2	☐1	☐0
13. I am a happy person.	☐4	☐3	☐2	☐1	☐0
14. I work/study too much.	☐0	☐1	☐2	☐3	☐4
15. I feel worthless.	☐0	☐1	☐2	☐3	☐4
16. I am concerned about family troubles.	☐0	☐1	☐2	☐3	☐4
17. I have an unfulfilling sex life.	☐0	☐1	☐2	☐3	☐4
18. I feel lonely.	☐0	☐1	☐2	☐3	☐4
19. I have frequent arguments.	☐0	☐1	☐2	☐3	☐4
20. I feel loved and wanted.	☐4	☐3	☐2	☐1	☐0
21. I enjoy my spare time.	☐4	☐3	☐2	☐1	☐0
22. I have difficulty concentrating.	☐0	☐1	☐2	☐3	☐4
23. I feel hopeless about the future.	☐0	☐1	☐2	☐3	☐4
24. I like myself.	☐4	☐3	☐2	☐1	☐0
25. Disturbing thoughts come into my mind that I cannot get rid of.	☐0	☐1	☐2	☐3	☐4
26. I feel annoyed by people who criticize my drinking (or drug use). (If not applicable, mark "never").	☐0	☐1	☐2	☐3	☐4
27. I have an upset stomach.	☐0	☐1	☐2	☐3	☐4
28. I am not working/studying as well as I used to.	☐0	☐1	☐2	☐3	☐4
29. My heart pounds too much.	☐0	☐1	☐2	☐3	☐4
30. I have trouble getting along with friends and close acquaintances.	☐0	☐1	☐2	☐3	☐4
31. I am satisfied with my life.	☐4	☐3	☐2	☐1	☐0
32. I have trouble at work/school because of drinking or drug use. (If not applicable, mark "never").	☐0	☐1	☐2	☐3	☐4
33. I feel that something bad is going to happen.	☐0	☐1	☐2	☐3	☐4
34. I have sore muscles.	☐0	☐1	☐2	☐3	☐4
35. I feel afraid of open spaces, of driving, or being on buses, subways, and so forth.	☐0	☐1	☐2	☐3	☐4
36. I feel nervous.	☐0	☐1	☐2	☐3	☐4
37. I feel my love relationships are full and complete.	☐4	☐3	☐2	☐1	☐0
38. I feel that I am not doing well at work/school.	☐0	☐1	☐2	☐3	☐4
39. I have too many disagreements at work/school.	☐0	☐1	☐2	☐3	☐4
40. I feel something is wrong with my mind.	☐0	☐1	☐2	☐3	☐4
41. I have trouble falling asleep or staying asleep.	☐0	☐1	☐2	☐3	☐4
42. I feel blue.	☐0	☐1	☐2	☐3	☐4
43. I am satisfied with my relationships with others.	☐4	☐3	☐2	☐1	☐0
44. I feel angry enough at work/school to do something I might regret.	☐0	☐1	☐2	☐3	☐4
45. I have headaches.	☐0	☐1	☐2	☐3	☐4

SD IR SR
DO NOT MARK BELOW

+ +

Total=