

IMPLEMENTING MOTIVATIONAL INTERVIEWING FOR EXERCISE  
WITH DEPRESSED ADULTS

by

Kurt Francis Kristiansen

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A DNP Project Submitted to the Faculty of the

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THE UNIVERSITY OF ARIZONA  
GRADUATE COLLEGE

As members of the DNP Project Committee, we certify that we have read the DNP project prepared by *Kurt Francis Kristiansen*, titled *Implementing Motivational Interviewing for Exercise with Depressed Adults* and recommend that it be accepted as fulfilling the DNP project requirement for the Degree of Doctor of Nursing Practice.

  
\_\_\_\_\_  
*Rene Love, PhD, DNP, PMHNP-BC, FNAP, FAANP* Date: November 16, 2018

  
\_\_\_\_\_  
*Shawn Gallagher, PhD, FNP-BC, PMHCNS-BC* Date: November 16, 2018

  
\_\_\_\_\_  
*Deborah Williams, PhD, MS, MPH* Date: November 16, 2018

Final approval and acceptance of this DNP project is contingent upon the candidate's submission of the final copies of the DNP project to the Graduate College.

I hereby certify that I have read this DNP project prepared under my direction and recommend that it be accepted as fulfilling the DNP project requirement.

  
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DNP Project Director: *Rene Love, PhD, DNP, PMHNP-BC, FNAP, FAANP* Date: November 16, 2018

## ACKNOWLEDGMENTS

To Everyone That Lent a Hand

DEDICATION

*To My Parents*

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## ABSTRACT

**Background:** Depression can negatively impact all aspects of life including physical health, financial stability, and job security. Motivational Interviewing (MI) reflects a counseling style based on five general principles: reflective listening, developing a discrepancy between the patient's goals, values and their current behavior, avoiding argument and direct confrontation, adjusting to client resistance instead of opposing directly, and finally, supporting self-efficacy and optimism. Exercise can improve mood, lessen the course of depression, and can provide benefits in addition to antidepressants. However, many with mental illness do not get enough exercise and this can compound their illness.

**Objective:** The purpose of this DNP project was to determine the barriers and facilitators of employing Motivational Interviewing (MI) for exercise in an outpatient mental health clinic in Northern Arizona

**Methodology:** Patients were interviewed pre and post MI intervention, as well as administered PHQ-9 pre and post MI intervention. Written responses were analyzed for commonalities in their survey questions.

**Setting:** West Yavapai Guidance Clinic in Prescott Valley, AZ.

**Participants:** There were five patients that met project guidelines for depression during the convenience sampling period.

**Results:** Response rate among participants was 60%, with 80% female and 20% male. The PHQ-9 scores was lower at the one month follow up after the MI intervention for two participants and stayed the same for the third. Commonalties that were identified were "relaxed," "peaceful," and "nature," as well as "dogs." Barriers were "time" and "weather."

**Conclusion:** The five participants reported depression and were identified as having depression on the PHQ-9. The three who followed up reported that they thought of exercise more frequently, and linked it to their mental health. With this small sample size there exhibited a positive association between targeting people's behavior via MI on exercise, and subsequent improvement in PHQ-9 scores, as well as positive thoughts regarding mental health and exercise.

## INTRODUCTION

### Background Knowledge

Adolescents and adults both suffer from mental illness. Having poor mental health—either depression, anxiety, and/or suicidal thoughts, negatively impacts all aspects of life, including physical health (Hughes, Connor & Harkin, 2016). According to Dias Porto Chiavegatto Filhom et al. (2015) loss of work days can impact both financial stability and job security, and this, in turn, leads to greater depression and other mental health issues (Choi, 2009). In addition, a recent survey from the World Health Organizations (WHO), World Mental Health (WMH) group, confirmed that depression is a positive predictor for unemployment and disability (Kessler, 2011).

Depression affects one in five Americans, or some 43.8 million persons each year (National Institute of Mental Health, 2015). Depression not only affects mental health but it also influences a person's physical health—for example, the positive association between depression and obesity is robust (Schneider, Baldwin, Mann & Schmitz, 2012). The general public has vastly underestimated the impact depression can have on society, highlighted by the fact that adolescent females who are depressed are approximately two and one half times more likely to be obese than non-depressed females (Schneider et al., 2012). Putting that into context, this effect is stronger than the effect of secondhand smoke in the development of cancers (Vineis et al., 2005). While there is no definitive explanation for how depression causes weight gain, literature points to the impact of emotional eating and lack of exercise (Blaine, 2008). In addition to causing metabolic issues in those affected by depression, those who suffer from a mental

health issue, such as depression, die at a younger age, and lose decades of potential life (Colton & Manderscheid, 2006).

Treatment for depression can consist of talk therapy, such as cognitive therapy (CT), interpersonal psychotherapy (IPT), cognitive behavioral therapy (CBT), and motivational interviewing (MI) (Keely, et al., 2014). Furthermore, pharmacological treatment modalities can be utilized, such as selective serotonin re-uptake inhibitors (SSRI's) (Huibers et al., 2015). Aerobic exercise can also be very beneficial in helping resolve and/or be a supportive adjuvant therapy to the current regimen, according to current research (Blumenthal, Smith & Hoffman, 2013). Engaging in aerobic exercise, such as walking—especially outdoors—can have a compounding effect as well (Barton, Griffin & Pretty, 2011). Current randomized controlled studies have shown that motivational interviewing can be beneficial for depression (Keeley et al., 2014). Those with depression treated with MI had enhanced performance and short-term, clinically relevant positive outcomes, with shorter treatment duration, and fewer reported depressive days (Keeley et al., 2014). Though mental health issues carry a role in every aspect of life, seeking treatment still carries a public burden and stigma (Corrigan, 2004). Only 41% of the above mentioned patients received treatment for any mental health issue in 2014 (Substance Abuse and Mental Health Service Administration- SAMHSA, 2014). As there is no cure, or single most effective treatment for depression and/or poor mental health, it is imperative that practitioners use current best practice evidence to help alleviate the suffering of their patients.

### **Local Problem**

Currently in Arizona, the prevalence of major depression surpasses the national average and the treatment for any mental health issue is in the lowest category (SAMHSA, 2015). In

Yavapai County, where this author conducted clinicals, the rate of depression and/or the feeling of hopelessness most days, for two weeks or more in a row, has been rising (Everett & Montgomery, 2012). In 2009, 34.9% of county residents felt hopelessness most days, for two weeks or more in a row, greater than the national average of 26.1%, (Everett & Montgomery, 2012). The burden of ill health and obesity is not shared equally across the United States, with low-income and rural adults possessing greater rates of obesity (Hill, You & Zoellner, 2014). With that in mind, Yavapai County's most recent Community Health Needs Assessment of 2016, has shown that the obesity rate is 24.90%—lower than that of the State of Arizona at 28.9%, and below the national average of the United States at 27.10% (Yavapai Regional Medical Center, 2016). However, due to clinical experience, the population receiving services for mental health in Yavapai County presents as chronically overweight and obese. The rural setting compounds the issues of depression and obesity as does the economic outlook of Prescott Valley, with the median household income for Prescott Valley being \$43,801- less than the national average of \$61,400 (United States Census, 2018). According to Hastings and Cohn (2013), rural residents have fewer transportation options and have greater distances to travel, which corresponds to greater rates of interrupted mental health services and a higher level of metabolic syndrome (Trivedi, Liu, Probst & Martin, 2013). Additionally, the rates of suicide, alcohol abuse, and disability are higher in rural areas (Hastings et al., 2013). Lastly, rural areas have higher levels of obesity, physical inactivity, and poor diet compared to urban counties (Trivedi, Liu, Probst, Merchant, & Martin, 2015).

Stakeholders for this quality improvement project can be identified as those who work at the outpatient mental health clinic, especially those who engage in direct patient care—

PMHNPs, MDs, RNs, and caseworkers. Furthermore, the organization as a whole, can be viewed as a stakeholder if improvement within the organization helps patients. This can be applied to the Prescott Valley as well. If local residents improve their mental health, then they too have a stake in this quality improvement project.

### **Purpose**

The purpose of this DNP project was to determine the barriers and facilitators of employing Motivational Interviewing (MI) for exercise in an outpatient mental health clinic in Northern Arizona.

### **Study Question**

What were the barriers and facilitators at a community mental health clinic in Northern Arizona for using MI for exercise in depressed adults?

## **THEORETICAL FRAMEWORK AND SYNTHESIS OF EVIDENCE**

### **Theoretical Framework**

For this quality improvement project, the author used Motivational Interviewing (MI) as a theoretical framework, to help guide the project in discerning the barriers and facilitators of using MI to promote exercise in depressed adults.

Motivational Interviewing (MI) is a relatively recent theory and intervention in psychology, first proposed in 1983 (Miller & Rose, 2010). The technique was developed by William R. Miller, a psychologist, who, while on sabbatical in Norway in 1983, interacted with colleagues specializing in behavioral treatment for alcohol problems (Miller & Rose, 2010). During a role-playing process, he was interrupted, and instructed to verbalize what he was doing, where he was going, and what was guiding his practice; this caused him to fully articulate what

had been his model for guiding his personal clinical practice (Miller & Rose, 2010). This further compelled him to be cognizant of what he had not previously been consciously aware, and he realized that what he had communicated differed from other behavior therapies on which he was lecturing (Miller & Rose, 2010). From this experience in the early 1980s, MI has grown exponentially, with the number of publications doubling every three years, and with MI trainers and translators now in more than thirty-eight languages. In addition, the Motivational Interviewing Network of Trainers (MINT) has produced more than fifteen million practitioners of MI (Miller, 2009).

The core tenet of the MI theory reflects a counseling style based on five general principles—expressing empathy through reflective listening, developing a discrepancy between the patient’s goals, values and their current behavior, avoiding argument and direct confrontation, adjusting to client resistance instead of opposing directly, and finally, supporting self-efficacy and optimism (Center for Substance Abuse Treatment, 1999). Miller described MI as “a way of being with a client, not just a set of techniques for doing counseling” (Miller & Rollnick, 1991).

To utilize this framework fully, it is important to understand misconceptions of MI, such as thinking that it is a way of tricking people into doing what they do not what to do. However, MI is grounded, and honors personal autonomy—people generate their own personal behavioral choices (Miller, 2009). In addition, as stated above by Miller (1991), MI is not a technique, but a guiding style for enhancing and encouraging intrinsic motivation to change (Miller, 2009).

Although this theory was developed for treating patients afflicted with substance abuse disorders, it has grown and been applied to numerous other disorders (Miller & Rollnick, 2012).

A large evidence base of MI, comprising more than 200 randomized clinical trials, has shown positive effects across many health problem areas (Miller & Rollnick, 2012). A specific meta-analytic review of MI, utilizing it to encourage exercise, found that it was effective in promoting physical activity (Belanger-Gravel, Godin & Amireault, 2011).

This author used MI theory as a framework to conduct his project, developing a relationship with the client and utilizing the five core beliefs of MI— adopting reflective listening, finding the discrepancy between what the client is currently doing and their future goals, and then supporting their goals through self-efficacy, and most importantly, fostering optimism. Throughout this exchange, direct argument and confrontation were avoided, and the guiding style for enhancing and encouraging motivation to change were used.

From this theory, this author has identified promise in utilizing the MI framework to encourage and educate patients on adopting exercise to help alleviate the symptoms of depression and encourage healthier behaviors.

### **Concepts**

Major depressive disorder (MDD) can be defined as five or more symptoms present over a two-week period that are a change from previous functioning, and one of these symptoms must be either depressed mood, or loss of interest or pleasure (DSM-V, 2013). The other symptoms include weight loss or gain, insomnia or hypersomnia, psychomotor slowing or agitation, fatigue, feelings of worthlessness, diminished ability to think, and recurrent thoughts of death (DSM-V, 2013). In addition, the above mentioned symptoms that cause distress in daily functioning, social or occupational, and the effects, cannot be attributed to a substance or medical condition (DSM-V, 2013).

Support systems can be interchanged with social support. The concept of social integration has a person participating in different social networks where emotional support can be delivered and strengthened (Reblin & Uchino, 2010). Additionally, encouragement is the action of giving support, confidence, or hope to someone (Reblin & Uchino, 2010). Recent findings have shown a robust relationship between social support, encouragement and social systems and a persons health- even so far as to being protective for health (Reblin & Uchino, 2010).

The patient health questionnaire-9 (PHQ-9) was used to detect and measure depression, as well as its severity, in a clinical setting (Smarr & Keefer, 2011). It comprises a total score of 30 with cutoff points indicating mild (5), moderate (10), moderately severe (15), and severe depression (20) (Smarr & Keefer, 2011). Any patient who scores five or higher will be considered depressed, and potentially included in the project. Only adult patients eighteen and above, and capable of making independent decisions, were included.

### **Synthesis of Evidence**

Those diagnosed with a mental health disorder, such as depression, are at an increased risk for obesity, and those who are obese, are at an increased risk for developing depression (Luppino et al., 2010). The use of antidepressants, alone, shows positive improvement in symptoms in only 40-60 percent of persons (National Library of Medicine, 2107). Exercise has been shown to improve, and be as effective as medication, in mild to moderate depression, and in severe depression it can be a valuable adjuvant to pharmacological treatment (Knapen, Vancampfort Morien & Marchal, 2014). Using motivational interviewing (MI) in the treatment of depression has also been shown to improve the overall depressive symptoms as measured by

the Patient Health Questionnaire-9 (PHQ-9) scores (Keely et al., 2016). It is vital that new treatments for depression are studied that can incorporate MI and exercise to improve not only mental health, but overall physical health as well.

To better understand how exercise and MI can be used to influence one's health and depression, a literature search was conducted using PubMed. The following key words were employed: Depression [MESH], Depressive Disorder [MESH], Depressive Disorder, Treatment-Resistant [MESH], Depressive Disorder, Major [MESH], Adjustment Disorders [MESH], Exercise [MESH], Exercise Movement Techniques [MESH], Exercise Therapy [MESH], Motivational Interviewing [MESH], and Motivational Interview. Inclusion criteria for the articles included being published within the last five years and being written in the English language. This search yielded a total of seven articles, with an additional three suggested as similar in the search, retained to the project's purpose (Table 1).

TABLE 1. *Synthesis of evidence.*

Author / Article	Qual: Concepts or phenomena Quan: Key Variables Hypothesis Research Question	Theoretical Framework	Design	Sample (N)	Data Collection (Instruments/tools)	Findings
<p>Nasstasia, Y., Baker, A. L., Halpin, S. A., Lewin, T. J., Hides, L., Kelly, B. J., &amp; Callister, R. (2017). Pilot Study of an Exercise Intervention for Depressive Symptoms and Associated Cognitive-Behavioral Factors in Young Adults With Major Depression. <i>J Nerv Ment Dis</i>, 205(8), 647-655. doi:10.1097/nmd.0000000000000611</p>	<p>To study the feasibility of motivational interviewing with an exercise intervention in young adults who met the criteria for major depressive disorder. This information can be used to integrate MI and exercise into mental health services.</p>	<p>N/A</p>	<p>Pilot Study</p>	<p>12 young adults between the ages of 15-25 and meeting the <i>Diagnostic and Statistical Manuel of Mental Disorders, 4<sup>th</sup> Edition (DSM-IV)</i> definition of major depression disorder MDD.</p>	<p><b>Intervention:</b> Participants underwent a blood sample for IL-6 pre-intervention and post, took a self-report questionnaire along with the Beck Depression Inventory (BDI-II), The Automatic Thoughts Questionnaire (ATQ) and The Behavioral Activation for Depression Scale-Short Form (BADS-SF) , underwent a fitness baseline and again at 12 weeks. After the MI intervention participants commenced the exercise intervention-supervised by an exercise scientist.</p>	<p>Integrating MI with an exercise intervention is feasible and offers insights into the specific effects of exercise on depressive symptoms.</p> <p>Exercise appears to ameliorate somatic symptoms early in treatment and exerts greatest influence in the affective group with potential implications for mitigating anhedonia.</p> <p>Relationship between behavioral activation and inflammation reveals the ability of behavior to influence biological change and suggests</p>

TABLE 1. – *Continued*

Author / Article	Qual: Concepts or phenomena Quan: Key Variables Hypothesis Research Question	Theoretical Framework	Design	Sample (N)	Data Collection (Instruments/tools)	Findings
					<p>Participants were provided gym memberships and encouraged to engage in exercise on their off days for at 30 minutes. They were reassessed with the BDI-II, ATQ, and BADS-SF at weeks 2, 4, 6, 8, 10 and at week 12 post intervention. They were reassessed by a trained independent rater to see if they still met the criteria for MDD.</p> <p><b><u>Main Outcome Measured:</u></b></p> <p>Statistical analyses were conducted using IBM SPSS- To explore trajectory of symptom change.</p>	<p>depression is as much a physical disorder as a psychological one.</p> <p>The high rates of MDD comorbidity, exercise interventions can play an important adjunctive role in improving symptoms and overall functioning.</p>

TABLE 1. – *Continued*

Author / Article	Qual: Concepts or phenomena Quan: Key Variables Hypothesis Research Question	Theoretical Framework	Design	Sample (N)	Data Collection (Instruments/tools)	Findings
Turner, A. P., Hartoonian, N., Sloan, A. P., Benich, M., Kivlahan, D. R., Hughes, C., . . . Haselkorn, J. K. (2016). Improving fatigue and depression in individuals with multiple sclerosis using telephone-administered physical activity counseling. <i>Journal of Consulting and Clinical Psychology, 84</i> (4), 297-309. doi:10.1037/ccp0000086	Evaluate the impact of a physical activity intervention consisting of telephone counseling with home-based monitoring to improve fatigue and depression with multiple sclerosis (MS).	N/A	Single Blind Randomized Controlled Trial	64 participants within the community with MS. Spilt into two groups with one receiving telephone counseling (N= 31) or self-directed physical activity education (N=33).	<p><b><u>Intervention:</u></b> The education condition (EC) consisted of advice to increase physical activity and a DVD with examples of in-home exercises for multiple physical ability levels. The telephone counseling condition (TC) included EC as well as mailed graphic feedback, 6 telephone counseling sessions using motivational interviewing and telehealth to monitor progress on physical activity goals. Assessment was conducted at 3, and 6 month follow up.</p> <p><b><u>Main Outcome Measured:</u></b> Baseline differences in demographics,</p>	<p>TC participants reported significantly reduced fatigue (d= -.70), reduced depression (d= -.72) and increased physical activity (d= -.92) relative to EC participants. Of participants receiving TC 33.3% experienced clinically significant improvement in fatigue (vs. 18.2% in EC).</p> <p>TC was highly feasible participants completed 99.5% of scheduled telephone sessions.</p>

TABLE 1. – *Continued*

Author / Article	Qual: Concepts or phenomena Quan: Key Variables Hypothesis Research Question	Theoretical Framework	Design	Sample (N)	Data Collection (Instruments/tools)	Findings
					disease-related characteristics, fatigue (MFIS), depression (PHQ-9) and physical activity (GLTEQ) were examined to ensure adequacy of randomization.  Fatigue and Depression were the main outcome measures.	
Kratz, A. L., Ehde, D. M., & Bombardier, C. H. (2014). Affective mediators of a physical activity intervention for depression in multiple sclerosis. <i>Rehabilitation Psychology, 59</i> (1), 57-67. doi:10.1037/a0035287	To test positive affect and negative affect as mediators of the effect of the physical activity counseling on depressive symptoms via telephone based motivational interviewing indirect) <i>p</i> value <.001 (MI).	N/A	Randomized Control Trial	92 adults with MS who met criteria for major depression disorder MDD or dysthymia.	<b><u>Intervention:</u></b> Subjects were randomized to a 12-week telephone-based motivational interviewing (MI) intervention to improve physical activity (n=44) or to a 12-week wait-list control group (n=48).	Both positive and negative affect were significant mediators of the effects of the intervention on depressive symptoms; however only positive affect mediated the association between change in physical activity and improved depressive symptoms.

TABLE 1. – *Continued*

Author / Article	Qual: Concepts or phenomena Quan: Key Variables Hypothesis Research Question	Theoretical Framework	Design	Sample (N)	Data Collection (Instruments/tools)	Findings
					<p>Phone calls were given in weeks 1, 2, 3, 4, 6, 8, 10. Each for 30 min- Final in person session was 60 minutes.</p> <p>The Positive and Negative Affect Schedule (PANAS) was used to measure affect. 20-item measure with 10 positive and 10 negative.</p> <p><b><u>Main Outcome Measured:</u></b></p> <p>Positive and Negative Affect.</p>	<p>Total direct effect (Group → depression) <i>p</i> value .68</p> <p>Total effects (Direct +</p>

TABLE 1. – *Continued*

Author / Article	Qual: Concepts or phenomena Quan: Key Variables Hypothesis Research Question	Theoretical Framework	Design	Sample (N)	Data Collection (Instruments/tools)	Findings
Steiner, J. L., Bigatti, S. M., & Ang, D. C. (2015). Trajectory of change in pain, depression, and physical functioning after physical activity adoption in fibromyalgia. <i>Journal of Health Psychology, 20</i> (7), 931-941. doi:10.1177/1359105313504234	Does the trajectory of symptoms of fibromyalgia change related to physical activity adoption and maintenance via motivational interviewing versus education, to increase physical activity.	N/A	Secondary Analysis of a RCT.	Participants (n = 184)	<p><b><u>Intervention:</u></b></p> <p>Participants were randomized to either an MI intervention or an educational attention control (AC) condition. Both received two exercise sessions. 10 minutes of stretching and 10 aerobic. No one received any MI coaching until exercise was completed. Followed by six telephone-delivered intervention sessions.</p> <p><b><u>Main Outcome Measured:</u></b></p> <p>Depression, Pain, and Physical Functioning as measured by the Community Health</p>	<p>CHAMPS: The time by covariate interactions were not significant (<math>p &gt; 0.05</math>) but the time by physical activity group interaction was <math>F(9, 172) = 2.41, p \leq 0.01, \eta^2 = .11</math> suggesting that those who increased their activity differed from non-increasers in trajectory of depression, pain, and physical functioning.</p> <p>Depression: Changes in depression from baseline to week 36 was statistically significant, <math>F(1, 183) = 6.45, p \leq 0.01, \eta^2 = .04</math>. Exercise improves mental wellbeing.</p>

TABLE 1. – *Continued*

Author / Article	Qual: Concepts or phenomena Quan: Key Variables Hypothesis Research Question	Theoretical Framework	Design	Sample (N)	Data Collection (Instruments/tools)	Findings
					Activities Model Program for Seniors, Patient Health Questionnaire-8, Brief Pain Inventory, and the FM Impact Questionnaire-Physical Impairments Subscale	<p>Pain: Between the two groups the difference in pain from baseline to week 36 was statistically significant, <math>F(1, 183) = 6.47, p \leq 0.01, \eta^2 = .04</math>.</p> <p>Physical Functioning: Between the two groups the intervention groups physical functioning from baseline to week 36 was statistically significant, <math>F(1, 183) = 19.02, p \leq 0.01, \eta^2 = .10</math>.</p> <p>Overall, those who increased their activity had a clinically significant</p>

TABLE 1. – *Continued*

Author / Article	Qual: Concepts or phenomena Quan: Key Variables Hypothesis Research Question	Theoretical Framework	Design	Sample (N)	Data Collection (Instruments/tools)	Findings
						difference with improvements in a full clinical category.
Searle, A., Haase, A. M., Chalder, M., Fox, K. R., Taylor, A. H., Lewis, G., & Turner, K. M. (2014). Participants' experiences of facilitated physical activity for the management of depression in primary care. <i>J Health Psychol</i> , 19(11), 1430-1442. doi:10.1177/1359105313493648.	Does facilitated physical activity for depression based on Self-Determination Theory and MI improve symptoms.	N/A	Randomized Control Trial	(n= 19) Participants, aged 19-69 Male (n= 80 Female (n=11).	<p><b><u>Intervention:</u></b></p> <p>Participants received instruction in physical activity (PA), they were then interviewed at four months, with interviews lasting between 30-120 mins. They were then interviewed again at eight months.</p> <p><b><u>Main Outcome Measured:</u></b></p> <p>In line with a Grounded Theory approach, transcripts were read and reread. Emerging themes were</p>	Engaging in PA the participants gained a feeling of competence to engaging in social activities as well as gaining competence and autonomy in skills. In addition, being respected and understood all improved overall mood.

TABLE 1. – *Continued*

Author / Article	Qual: Concepts or phenomena Quan: Key Variables Hypothesis Research Question	Theoretical Framework	Design	Sample (N)	Data Collection (Instruments/tools)	Findings
					identified and verified and then the transcripts were electronically coded by using ATLAS.ti.	
Bombardier, C. H., Ehde, D. M., Gibbons, L. E., Wadhvani, R., Sullivan, M. D., Rosenberg, D. E., & Kraft, G. H. (2013). Telephone-based physical activity counseling for major depression in people with multiple sclerosis. <i>J Consult Clin Psychol</i> , 81(1), 89-99. doi:10.1037/a0031242.	Can a phone counseling intervention coupled with physical activity be a treatment for major depressive disorder (MDD).	N/A	Randomized Control Trial	(n=92) adults. (M(age) = 48 years old; 86% female, 92% White).	<p><b><u>Intervention:</u></b></p> <p>Treatment group received an initial in-person session. They then had seven telephone counseling sessions (1,2,3,4,6,8,10) and finally an in-person session at week twelve.</p> <p><b><u>Main Outcome Measured:</u></b></p> <p>Reduction in the Hamilton Depression Rating Scale (HAM-D).</p>	Compared to those in the control group, those that received phone counseling and physical exercise had significantly lower depression severity on the HAM-D- at 12 weeks that were less likely to meet the criteria for MDD as set by the DSM-IV.

TABLE 1. – *Continued*

Author / Article	Qual: Concepts or phenomena Quan: Key Variables Hypothesis Research Question	Theoretical Framework	Design	Sample (N)	Data Collection (Instruments/tools)	Findings
<p>Chair, S. Y., Chan, S. W., Thompson, D. R., Leung, K. P., Ng, S. K., &amp; Choi, K. C. (2012). Short-term effect of motivational interviewing on clinical and psychological outcomes and health-related quality of life in cardiac rehabilitation patients with poor motivation in Hong Kong: a randomized controlled trial. <i>Eur J Prev Cardiol</i>, 19(6), 1383-1392. doi:10.1177/1741826711425428</p>	<p>Can Motivational Interviewing (MI) be effective in promoting positive health outcome in cardiac rehabilitation patients, including psychological outcomes.</p>	<p>N/A</p>	<p>Randomized Control Trial.</p>	<p>(n=146) subjects. (n=73) in control group and (n=73) In experimental group.</p>	<p>Intervention: (n=73) experimental group received four sessions of MI lasting between 30-45 min. Quality of life was measured at baseline and again at three months.</p> <p>Main Outcome Measured: Hospital Anxiety and Depression Scale.</p>	<p>The experimental group had better aspects of general health (4.74, 95% CI 0.04-9.44; p = 0.048). But, they reported significantly higher anxiety levels in the Hospital Anxiety and Depression Scale (0.96, 95% CI 0.09-1.83; p = 0.030).</p> <p>MI, increased anxiety levels and more evidence is needed to better understand this phenomenon.</p>

TABLE 1. – *Continued*

Author / Article	Qual: Concepts or phenomena Quan: Key Variables Hypothesis Research Question	Theoretical Framework	Design	Sample (N)	Data Collection (Instruments/tools)	Findings
<p>Keeley, R. D., Brody, D. S., Engel, M., Burke, B. L., Nordstrom, K., Moralez, E., . . . Emsermann, C. (2016). Motivational interviewing improves depression outcome in primary care: A cluster randomized trial. <i>J Consult Clin Psychol</i>, 84(11), 993-1007. doi:10.1037/ccp0000124.</p>	<p>Examine the effects of Motivational Interviewing (MI) on rates of improvement over time for depressive symptoms among low-income with newly diagnosed Major Depressive Disorder (MDD).</p>	<p>N/A</p>	<p>Randomized Control Trial</p>	<p>(n=168) (n=88) MI with standard management of depression (SMD) and (n=88) with SMD alone.</p>	<p><b><u>Intervention:</u></b> Patients in experimental treatment were given MI along with SMD and assessed at 6, 12, and 36 weeks with the Patient Health Questionnaire-9 (PHQ-9).  <b><u>Main Outcome Measured:</u></b> PHQ-9 Scores</p>	<p>The experimental group was associated with a more favorable trajectory of PHQ-9 scores than SMD alone.  Training providers to use MI to frame discussions about depression may improve management for depression than the current standard treatment.</p>

TABLE 1. – *Continued*

Author / Article	Qual: Concepts or phenomena Quan: Key Variables Hypothesis Research Question	Theoretical Framework	Design	Sample (N)	Data Collection (Instruments/tools)	Findings
<p>Satre, D. D., Leibowitz, A., Sterling, S. A., Lu, Y., Travis, A., &amp; Weisner, C. (2016). A Randomized Clinical Trial of Motivational Interviewing to Reduce Alcohol and Drug Use among Patients with Depression. <i>Journal of Consulting and Clinical Psychology, 84</i>(7), 571–579. <a href="http://doi.org/10.1037/ccp0000096">http://doi.org/10.1037/ccp0000096</a></p>	<p>The efficacy of Motivational Interviewing (MI) to reduce hazardous drinking and drug use among adults with depression.</p>	<p>N/A</p>	<p>Randomized Control Trial</p>	<p>(n=307) participants aged 18 or older who reported hazardous drinking, drug use (primarily cannabis) or misuse of prescription drugs in the prior 30 days and who scored greater than &gt;5 on the Patient Health Questionnaire (PHQ-9).</p>	<p><b><u>Intervention:</u></b> Participants were randomized to either receive 3 sessions of MI- one in person and two by phone or printed literature about alcohol and drug use risks (control) as an adjunct to usual depression care. Follow up at 3 and 6 months.</p> <p><b><u>Main Outcome Measured:</u></b> Reduction in rate of cannabis and hazardous drinking.</p>	<p>MI was more effective than control in reducing rate of cannabis use (p= .037) and hazardous drinking (p=.060). Depression improved in both conditions as measured by the PHQ-9.</p> <p>MI can be an effective intervention in reducing cannabis use and hazardous drinking in patients with depression.</p>

TABLE 1. – *Continued*

Author / Article	Qual: Concepts or phenomena Quan: Key Variables Hypothesis Research Question	Theoretical Framework	Design	Sample (N)	Data Collection (Instruments/tools)	Findings
<p>Rethorst, C. D., Toups, M. S., Greer, T. L., Nakonezny, P. A., Carmody, T. J., Grannemann, B. D., ... Trivedi, M. H. (2013). Pro-Inflammatory Cytokines as Predictors of Antidepressant Effects of Exercise in Major Depressive Disorder. <i>Molecular Psychiatry</i>, 18(10), 1119–1124. <a href="http://doi.org/10.1038/mp.2012.125">http://doi.org/10.1038/mp.2012.125</a>.</p>	<p>Patients with Major Depressive Disorder (MDD) have elevated inflammatory cytokines but it is not known if exercise affects inflammation in MDD patients and if its clinically relevant.</p>	<p>N/A</p>	<p>Randomized Control Trial</p>	<p>(n=126) participants, (n=105) samples that were available.</p>	<p><b><u>Intervention:</u></b> Exercise groups- low and high. Low had a target energy expenditure of 4 kilocalories and the high 16 kilocalories. Aerobic exercise was completed in a combination of supervised and home-based sessions and logged in a web based system.</p> <p><b><u>Main Outcome Measured:</u></b> 30-Item clinician-rated Inventory of Depressive Symptomatology (IDS-C30).</p>	<p>Higher baseline levels of TNF-a were associated with a greater decrease in depressive symptoms over the 12 week exercise period (p=0.0023). Additionally, positive correlation between the change in IL-1B and depression scores (p=0.0441). No change in exercise dose and mean cytokine level.</p> <p>TNF-a may predict better outcomes with exercise treatment as opposed to antidepressant medication.</p> <p>These results confirm findings from studies of antidepressant medications that tie decreasing IL-1B to positive depression treatment outcomes.</p>

Nasstasia et al. (2017) tested whether using MI to introduce an exercise intervention in young adults who met criteria for major depressive disorder would improve symptoms. Turner et al. (2016) investigated whether employing counseling over the phone to encourage exercise could improve fatigue and depression in those with multiple sclerosis. The results in both of these studies showed that overall mood improved, and that exercise appeared to ameliorate somatic symptoms of depression very early on in treatment (Nasstasia et al., 2017). Connecting with patients, and providing counseling to encourage physical activity also proved to be effective ways to network with patients, as patients completed 99.5% of all scheduled sessions (Turner et al., 2016).

Bombardier et al. (2013) used a telephone counseling intervention to motivate people to be more physically active with major depressive disorder (MDD). Again, this intervention demonstrated that those in the intervention group, compared to the control group were, at the conclusion of the trial, were significantly less depressed as rated by the Hamilton Depression Rating Scale (HAM-D)—so much so that they failed to meet criteria for MDD as set by the Diagnostic Statistical Manual IV (DSM-IV) (Bombardier et al., 2013).

Other studies looked at MI in differing realms of healthcare. Chair et al. (2012) tested whether MI could be used to improve psychological functioning in post-op heart surgery patients who tested positive for depression. It discovered that with the MI intervention, anxiety actually increased compared to the control group (Chair et al., 2012). Further testing needs to be done.

The literature search revealed a gap and a deficiency in large scale randomized control trials that utilize MI to encourage and facilitate exercise in depressed patients, especially across the lifespan. Where studies exist, they comprise small pilot surveys with limited external

validity, due to the small number of participants and limited age span. However, the current studies do reveal a promising intervention—one that combines MI and exercise to facilitate better treatment in those diagnosed with depression. These current studies can point future researchers into the right direction and provide current providers with new insight into its treatment. The information points to a future in which mental health disorders are not disconnected from the physical body, and treatment is more holistic.

## **METHODS**

### **Design**

This DNP project analyzed commonalities among participants in their answers to the survey, both taken at the start of the project, and again at the end. The purpose of the project was to determine barriers and facilitators for utilizing motivational interviewing for exercise with depressed patients in a outpatient mental health environment. The project also educated patients on the definition of exercise as “activity requiring physical effort in an effort to sustain or improve health and fitness” (Johnson & Turner, 2016), on exercise locations, and on scientific knowledge of the benefits of physical activity in regards to mental health. After completing the first round of motivational interviewing, participants were encouraged to engage in physical activity, such as walking, exercising their dog, hiking, swimming, going to the gym, etc. They were to employ information gained in the motivational interview session to engage in lifestyle changes. The timeframe for exercise was four weeks- from the start of the quality improvement project to the conclusion. Prior to the commencement of this project, approval was obtained by the Institutional Review Board of both the University of Arizona (Appendix C), and of the

review board of the project site. This approval ensured that the necessary steps to protect the participant's privacy and safety were taken.

### **Setting**

This project was conducted at an outpatient community mental health clinic in Prescott Valley, Arizona. The setting was chosen for its high volume of patients, and because it serves a rural and underserved community. The community, at large, has high rates of depression, obesity, and poor health habits (Robert Wood Johnson Foundation, 2018). This site was additionally chosen as being centrally located, and well known throughout the area for providing integrative care. Those with a designation of serious mental illness (SMI) can opt to have their primary care done on site by a physician. In addition, the site has its own pharmacy, crisis unit, as well as a patient unit for those needing hospitalization.

### **Participants**

The participants were selected based on their diagnosis—major depressive disorder, either mild, moderate, or severe. If the patients agreed to participate, were given information using motivational interviewing to engage in exercise during their scheduled visit. Motivational interviewing was delivered by a certified psychiatric mental health nurse practitioner, with additional information about the health benefits of exercise, provided by the author. During the visit, the patients completed the PHQ-9 health questionnaire and were provided a sheet to record their activity over the ensuing four weeks, as well as complete questions regarding barriers and facilitators. After four weeks they returned to their scheduled visit to apprise the progress of the past four weeks, and a final patient health questionnaire was administered with the same set of questions. The participants were recruited from the outpatient community mental health clinic

located in Prescott Valley, AZ. They were enrolled via convenience sampling—the process of selecting the most readily available participants (Elfil & Negida, 2017). They had to meet a certain set of criteria: (a) age eighteen or above, (b) English speaking, (c) meet the criteria of major depressive disorder—mild, moderate, severe, and (d) be physically able to engage in exercise as gauged by being able to walk unencumbered, without oxygen into the office. If the participants met these criteria, they were given a standardized script to read (See appendix C), and if willing, were then enrolled into the project. Privacy was ensured by assigning each participant a number. These standards were chosen to open the study to the widest possible group of potential participants, and to educate and engage the widest possible group of clinic patients. To achieve the objectives of this project, the goal was to recruit at least 15 participants.

The key stakeholders involved in this project were nurse practitioners, staff, doctors, and nurses.

### **Resources**

Resources that were essential to this project include the logs of the physical activity, and the handouts of information concerning physical activity and sites for engagement in the physical activity.

### **Data Collection**

Questions were asked at the first and final session in order to assess and to identify facilitators and barriers that existed. The following nine questions were asked at the first visit: (1) Are there any things that made engaging in exercise easy? (2) Was there anything that made engaging in exercise difficult? (3) Was there anything you enjoyed about engaging in exercise? (4) Was there anything you disliked about engaging in exercise? (5) Is there anything that the

Guidance Clinic does that helps you engage in exercise? (6) Is there anything that the Guidance Clinic does that hinders your engagement in exercise? (7) Were there any barriers to engaging in exercise? (8) Were there any facilitators in engaging in exercise? (9) If you could change one thing that would help you stay active what would it be? Question number 10 will be added to the questionnaire during the last visit (10) Is there anything we could have done to help support this project?

During the first visit, the patient was asked the type and amount of exercise that they obtain on a weekly basis. They were given an exercise activity log (See Appendix B) to complete and return on the second visit.

The Patient Health Questionnaire Nine (PHQ-9), which has demonstrated valid and reliable was administered as part of the standard visit for the first visit and then again for the scheduled visit one month later (Manea, Gilbody & McMillan, 2012). The PHQ-9 has diagnostic properties for detecting major depressive disorder with cut-off scores between the scores of 8 and 11 (Manea et al., 2012). Additionally, the PHQ-9 was chosen due to its brief nine questions, its proven validity of diagnosing depression (88% specificity), and assessing said depression (Williams, 2014).

### **Data Analysis**

The answers to the survey questions were analyzed to look for commonalities. From these commonalities, suggestions to the clinic were made. The data from the PHQ-9 and the exercise activity log were analyzed for averages, and recorded between the first and second visits. Data was analyzed to determine if the amount of exercise increased between visits. The data was reported as aggregate statistics among the participants.

### **Ethical Considerations**

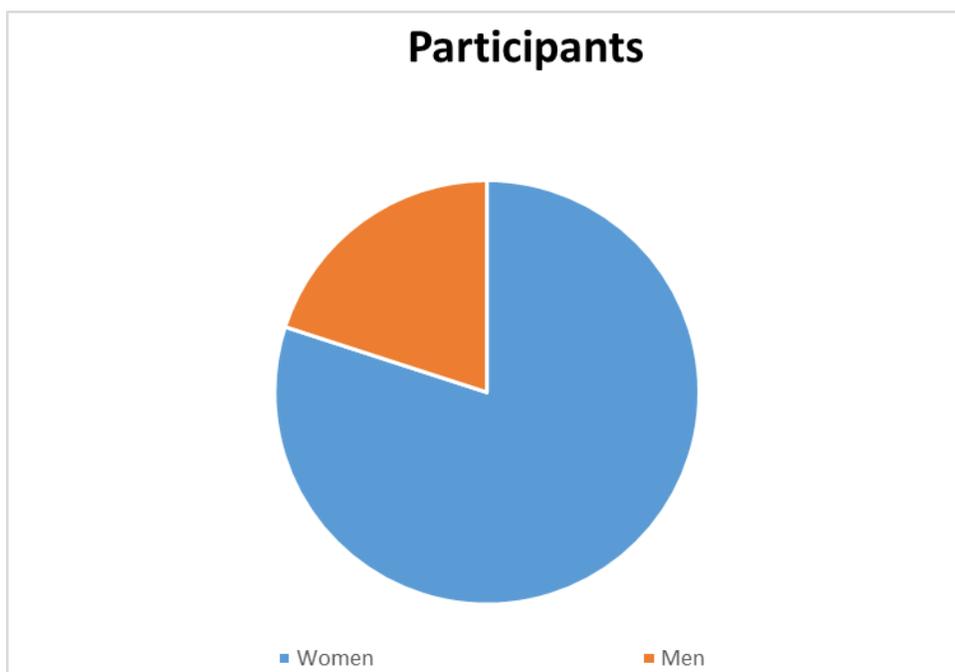
The project that this author conducted has respect for persons by allowing for maximum privacy. All records were kept within the office of the PMHNP, in a password protected computer—no names were used. Each participant was given a unique patient identifier to keep privacy to a maximum, and they were not informed of other subjects. Beneficence was established by keeping safety to a maximum and risks to a minimum, by informing subjects of risks, and by selecting participants that were well enough to begin, and/or continue exercise. Participants were informed of the benefits of exercise and the risks. All vital signs of patients were tracked, and subjects were excluded who had pre-existing conditions that could be aggravated by exercise, such as exacerbated COPD or late stage heart failure. Justice was met by introducing and educating a population that could be improved by the project. It allowed a diverse and wide population to be educated. The test population was vulnerable as they are mental health patients. Due to this, guidelines and instructions were clear, and participants were informed that they could excuse themselves from the study at any time without any impact to their current treatment. Data were reported as an aggregate number to maintain anonymity.

## **RESULTS**

### **Description of the Sample**

The surveys were given to patients who had scheduled follow-ups at the clinic and had met the criteria of having a diagnosis of depression, as well being able to be physically active enough to engage in exercise during the four week intervention. In total, five patients agreed to participate in the study, and of those five, three were able to complete the tasks of answering the questions, completing a PHQ-9, and filling out an exercise log. Of the three participants that

completed both surveys, they were all Caucasian, aged- 53, 61, 58, with two female and one male (Figure 1). The low number of participants was a result of the time constraints in completing the project within the allotted schedule of the University of Arizona. Additionally, the response rate was low due to trends in community mental health of high no-show and no-response rate (Long, Sakauye, Christy & Upton, 2016). The overall response rate was 60%. Of the original five, 80% were female and the remaining 20% were male. All five had a diagnosis of depression and lived within Prescott Valley. In the future, to increase participation I would advertise the study well before it was due to commence, as well as include a longer period of time in which to collect data, rather than a four-week window.



*FIGURE 1.* Participants.

### Findings Related to the Quality Improvement Project

The findings related to the PHQ-9 are shown below (Figure 2). The average score of the PHQ-9 among the five participants was five—suggesting mild depression. The scores ranged from a high of seven (midpoint of mild severity), to a low of one.

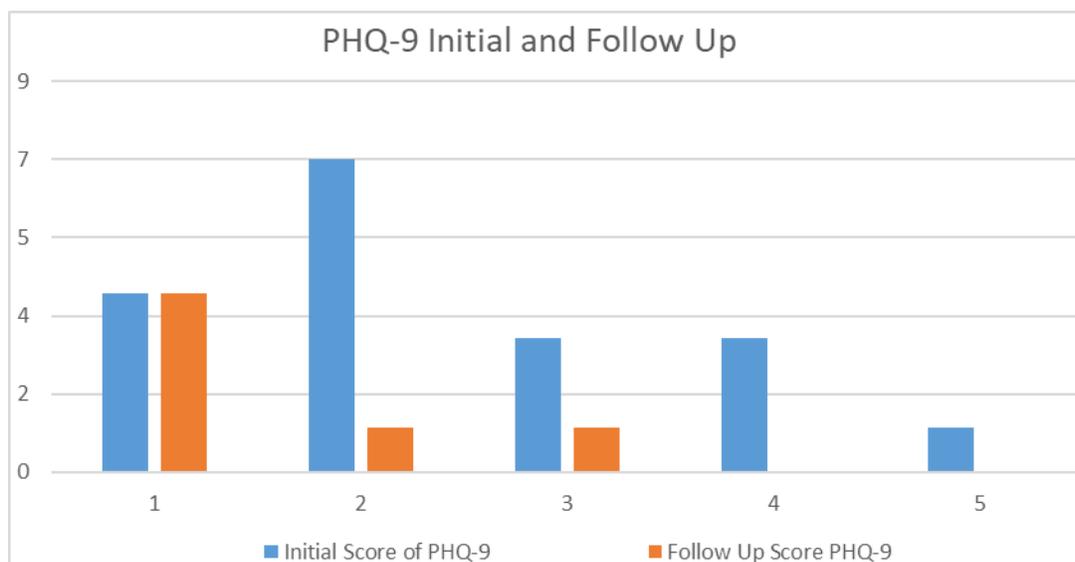


FIGURE 2. PHQ-9 initial and follow up.

Additionally, the questions relating to exercise revealed that weather, time, and the desire to exercise facilitated an ease for getting out and exercising. Commonalities in the answers of the participants were the words, “relaxed,” “peaceful,” and “nature.” Two of the three mentioned their pets (dogs) as a factor in their getting out and walking. In the three responders, two remarked that they increased their exercise by walking more, and by walking their dogs. Of those two, only one returned the exercise log. In this log the participant recorded physical activity every day for a month—either by walking alone, or by walking her dog. The other participant recorded that he did not increase his exercise in any manner, due to the fact that he felt he was already active enough.

In summary, five participants were recruited and three of those five returned to answer the follow-up survey. The questions that the participants answered were analyzed for commonalities. The first question was, “Are there any things that made engaging in exercise easy?” The commonalities were that the two who answered both replied “no.” When asked if there was anything that made engaging in exercise difficult, no commonalities were uncovered. Two participants used the words “peaceful,” “relaxed,” and “nature,” when queried if there was anything they enjoyed about engaging in exercise. To the questions, “Was there anything you disliked about engaging in exercise?”; “Is there anything that the Guidance Clinic does that helps you engage in exercise?”; “Were there any barriers to engaging in exercise?”; “Were there any facilitators in engaging in exercise?”; “If you could change one thing that would help you stay active what would it be?”; and, “Is there anything we could have done to help support this project?” The commonalities to all of the above listed questions was the word, “No.”

## **DISCUSSION**

This project answered the question about barriers and facilitators at a community mental health clinic in Northern Arizona for using MI for exercise in depressed adults. The results of this project illuminated what helped and what areas needed improvement.

The profile of the most common participant demographics was one who experienced depression, and then utilized walking as the most frequent form of exercise. The most common answer to what made engaging in exercise easy, as well as its barriers, was “weather” and “time,” which is concurrent with current literature as published by Glowacki et al. (2017) and Firth et al. (2016) in which socio-ecological issues were identified as barriers to exercise. In addition, participants stated that exercise “helped their mood” and they liked “how it makes me

feel” — again these facilitators are validated by the literature published by Glowacki et al. (2017) and Firth et al. (2016) in where psychological factors were identified as motivating factors for exercise. All participants answered in the negative when asked the question “Is there anything the Guidance Clinic could have done to help you engage in exercise?” Additionally, utilizing MI as a framework for this quality improvement project helped propagate information as identified by Miller et al. (2017) regarding the benefits of exercise and mood to the participants, as well as solidifying the link between movement and mood in the participants.

### **Summary**

This project illuminates that exercise can have a positive effect on the mood of its participants, as scores on the PHQ-9 decreased for the two participants who increased their exercise level equally. Furthermore, the answers to the questions reveal that the participants were aware of the benefits of exercise, and correlated their improved mood to their engagement of exercise. In promoting patients to engage in exercise, interventions should be focused on behavior change techniques such as education — aiding patients to connect mood change to exercise — and motivational interviewing to galvanize them. Behavior change techniques should target these emotions for future interventions (Glowacki et al., 2017). In asking the participants what could be done at the clinic to encourage exercise, all three participants could not theorize an answer. They did not presume that the clinic could do more to help them.

### **Study Strengths**

The project sought to educate and motivate patients to engage in exercise, while being cognizant of their mood. This aim was accomplished by using motivational interviewing,

exercise logs, and the completion of the PHQ-9. The aim was met as it showed a positive benefit in the participants' mood. Again, future interventions should target behavior change techniques.

### **Study Limitations**

Limitations were the response rate and the small sample size. This project was only able to recruit five participants, and then only able to obtain a follow-up of three. The responses of these participants may not be representative of a larger number of patients at the outpatient mental health clinic, which was made aware of the results of the quality improvement project. The limited number of participants was due to time constraints.

### **Conclusion**

The quality improvement project in its limited results, did reflect previous studies such as Bombardier et al., (2013), which showed that MI can facilitate exercise and improve mood in those with depression. Targeting persons' behaviors by utilizing motivational interviewing, and educating them regarding the positive benefits of exercise can help augment current treatment for depression. The high no show rate for patients made it difficult to follow up on participants and evaluate progress regarding MI and exercise. Additionally, having a trained MI practitioner on site helped facilitate introducing MI into sessions. There is a positive association between exercise and movement, and outpatient mental health clinics should utilize this association. Lastly, behavior modification techniques should be utilized to target patients in future interventions

APPENDIX A:  
RECRUITMENT SCRIPT

Hello, my name is Kurt Kristiansen and I am a graduate student at the University of Arizona in the psychiatric mental health program. I am conducting a project on using motivational interviewing for depression and exercise here at the West Yavapai Guidance Clinic. I am inviting you to participate because you use the clinic and have a diagnosis of depression.

Participation in this project involves a session with myself and Patricia White. We will use motivational interviewing to inform you of the benefits of exercise and you will complete the PHQ-9. I will also be asking questions to understand and identify the barriers and facilitators to getting exercise. The project will require approximately 30 minutes of your time. You will be asked to record the times in which you engage in exercise and to come back in four weeks to discuss and once more to take the PHQ-9 and the survey questions. I will ask for your record on the times you engaged in exercise. I will also ask questions once again on barriers and facilitators to getting exercise over the previous four weeks. Each session will last approximately 30 minutes.

If you participate the total time commitment will be approximately one hour. Participation is completely voluntary. Your care at the clinic will not be impacted in any way whether you decide to participate or not.

This project hopes to provide West Yavapai Guidance Clinic information to optimize treatment for its patients.

APPENDIX B:  
PATIENT QUESTIONNAIRE-9 (PHQ-9)

PATIENT QUESTIONNAIRE	PHQ-9
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Patient Name: \_\_\_\_\_ Provider: \_\_\_\_\_ Date: \_\_\_\_\_

1. Over the last 2 weeks, how often have you been bothered by any of the following problems?

	Not at all	Several days	More than half the days	Nearly every day
	0	1	2	3
a. Little interest or pleasure in doing things	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Feeling down, depressed, or hopeless	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. Trouble falling/staying asleep, sleeping too much	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. Feeling tired or having little energy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. Poor appetite or overeating	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f. Feeling bad about yourself – or that you are a failure or have let yourself or your family down.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g. Trouble concentrating on things, such as reading the newspaper or watching television.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h. Moving or speaking so slowly that other people could have noticed. Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i. Thoughts that you would be better off dead or of hurting yourself in some way.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. If you checked off any problem on this questionnaire so far, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all	Somewhat Difficult	Very Difficult	Extremely Difficult
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3. If these problems have caused you difficulty, have they caused you difficulty for two years or more?

\_\_\_\_\_ Yes, I have had difficulty with these problems for two years or more.

\_\_\_\_\_ No, I have not had difficulty with these problems for two years or more.

Number of Symptoms: \_\_\_\_\_

Total Score for first 9 Questions: \_\_\_\_\_

Function Score (Question 2): \_\_\_\_\_

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday

Please write the amount of estimated time spent exercising and the activity under the day it occurred - i.e. 7/23- Walked Dog 30 min.

Please identify the estimated exercise you already engage in at the bottom of this sheet.

APPENDIX C:  
THE UNIVERSITY OF ARIZONA INSTITUTIONAL REVIEW BOARD (IRB) APPROVAL  
LETTER


 Human Subjects  
 Protection Program

 1618 E. Helen St.  
 P.O. Box 245137  
 Tucson, AZ 85724-5137  
 Tel: (520) 626-6721  
<http://hgw.arizona.edu/compliance/home>

**Date:** August 21, 2018

**Principal Investigator:** Kurt Kristiansen

**Protocol Number:** 1808865453

**Protocol Title:** Impact of Exercise on Adults with Depressive Symptoms

**Determination:** Human Subjects Review not Required

**Documents Reviewed Concurrently:**

**Data Collection Tools:** *DNP-Exercise\_Log.pdf*

**Data Collection Tools:** *PHQ-9.docx*

**HSPF Forms/Correspondence:** *IRB-August\_Final\_1.pdf*

**Other Approvals and Authorizations:** *Advisor Confirmation Email.pdf*

**Other Approvals and Authorizations:** *Site Authorization Template (Yavapai) Signed.pdf*

**Recruitment Material:** *Recruitment Script\_Disclosure.docx*

**Regulatory Determinations/Comments:**

- Not Research as defined by 45 CFR 46.102(d): As presented, the activities described above do not meet the definition of research cited in the regulations issued by U.S. Department of Health and Human Services which state that "research means a systematic investigation, including research development, testing and evaluation, designed to contribute to generalizable knowledge."

The project listed above does not require oversight by the University of Arizona.

If the nature of the project changes, submit a new determination form to the Human Subjects Protection Program (HSPF) for reassessment. Changes include addition of research with children, specimen collection, participant observation, prospective collection of data when the study was previously retrospective in nature, and broadening the scope or nature of the study activity. Please contact the HSPF to consult on whether the proposed changes need further review.

The University of Arizona maintains a Federalwide Assurance with the Office for Human Research Protections (FWA #00004218).

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