

Mood Lifters: Increasing Accessibility to Mental Health Care through a Novel Peer-Led Approach

by

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DEDICATION

This dissertation is dedicated to my late grandmother, Mercedes Flórez, who led by example and taught me that, through hard work, anything is possible.

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ABSTRACT

Nearly one in two people will experience a mental illness over the course of their lifetime and only 43% of individuals requiring care will access it (Kessler et al., 2005; National Institute of Mental Health [NIMH], 2017). New interventions, such as e-therapy, mobile applications and workplace wellness programs, have been developed to address barriers to care; however, they have inconsistent support and many introduce new barriers to care (Barak et al., 2008; Lui et al., 2017; Ivandic et al., 2017). A new program, Mood Lifters, an intervention with peer-led skills-based group meetings, was developed to further address barriers to care. Study 1 tested the feasibility of the program and future study structure in a series of pilot studies. Results suggested that the program and study structure were feasible. Study 2 explored the results of the semi-randomized, to treatment or waitlist conditions, control trial to determine the efficacy of the program. Multiple imputation was used to account for unexpected attrition. Results indicated that individuals in the program, when compared to the waitlist control condition, saw statistically significant improvements in anxiety, and that individuals who completed more homework saw statistically significant improvements in anxiety and perceived stress. Study 3 examined the efficacy of peer leaders compared to professional leaders. Results showed that there were no differences between leader types for attendance, homework completion or mood improvement. Overall, the findings from these studies suggest that the Mood Lifters program is feasible, that individuals engaged with the Mood Lifters program experience reductions in anxiety symptoms and perceived stress, and that the program is effectively delivered by peer leaders. Taken

together, this dissertation suggests that Mood Lifters may offer hope to millions of individuals struggling with anxiety, depression and problems in living.

CHAPTER I: Overview

In the most recent data from the National Institute of Mental Health (NIMH, 2017), researchers estimated that 44.7 million American adults had experienced a form of mental illness in the last year. When expanding the scope to lifetime prevalence, nearly 50% of American adults will experience some form of mental illness (Kessler et al., 2005). Further, individuals may experience common stressors and hassles, such as loss of a loved one, a pandemic, or financial difficulties that may contribute to subclinical symptoms or general suffering. All of these individuals would likely benefit from some type of mental health support or care in order to reduce symptoms and distress.

Unfortunately, research suggests that the current mental health care system in the United States (U.S.) is not effectively addressing the current mental health care need, with only 43% of the 44.7 million Americans affected by mental illness receiving mental health care in the last year (NIMH, 2017). Other studies have produced even lower estimates (38% of individuals with any mental illness receiving care; Walker et al., 2015). Even when individuals are referred for mental health care treatment within the “general medical sector,” they often do not receive treatment or drop out early; research shows that approximately 60% of this group eventually drop out of treatment (Olfson et al., 2009).

Those in the mental health care field may remain hopeful that at least some individuals in need of care are receiving treatment. However, out of those individuals who sought out mental health care, 22% dropped out of treatment early and those who dropped out attended a median of four to six appointments for specialty mental health services (i.e., psychiatrist/mental health

professional). The number of attended appointments was even less if individuals were receiving care in the general medical sector (three appointments; Olfson et al., 2009). This is much less than the recommended number of sessions for most evidence-based psychotherapies, with even the briefest treatments lasting approximately 12 sessions. Further, even when individuals find, stay in and receive care, the majority do not receive evidence-based or guideline concordant care (González et al., 2010). Taken together, despite the need for mental health care in the U.S., services are underutilized and individuals are not receiving care.

Based on this under-utilization of mental health care in the U.S., researchers have sought to identify barriers that prevent individuals from seeking care. Unfortunately, researchers have found that nearly 45% of individuals with a DSM-IV disorder simply do not perceive that they need treatment for their symptoms, which results in them not seeking services (Mojtabai et al., 2011). However, the majority of respondents felt that they would benefit from services, but did not seek them out due to a variety of barriers. These researchers found that barriers fell into two categories: attitudinal (i.e., barriers relating to beliefs or ideas about mental health and care seeking) and structural (i.e., barriers relating to the care system or physical access). In this study, attitudinal barriers were endorsed by 97% of individuals and structural barriers were endorsed with less frequency, at 22% (Mojtabai et al., 2011). These data suggest that both attitudinal and structural barriers prevent individuals from seeking needed mental health care and could explain the under-utilization of our current mental health care system.

Attitudinal barriers

The most commonly reported barrier to receiving mental health care, attitudinal or structural, is the desire to resolve one's symptoms on one's own with one study reporting that 73% of respondents endorsed this barrier (Mojtabai et al., 2011). Other studies examining

barriers to care also reported it as the most commonly endorsed barrier (Andrade et al., 2014; Walker et al., 2015; Sareen et al., 2007). Unlike any other barrier examined by Mojtabai et al. (2011), this barrier was statistically more likely to be endorsed by individuals with mild or moderate psychopathology than by individuals with severe psychopathology (approximately 78%, 74%, and 63%; mild, moderate, and severe, respectively). Unfortunately, even when individuals are initially able to overcome this barrier, it continues to prevent individuals from receiving full care. The same study reported that 42% endorsed “wanted to handle on own” as a reason for dropping out of care (Mojtabai et al., 2011). This research suggests that, aside from perceiving one does not need care, the desire to improve one’s symptoms on one’s own in the biggest barrier to mental health care in the U.S.

Stigma is another important attitudinal barrier, endorsed by 9% of respondents with perceived need for care in the Mojtabai et al. (2011) study. Stigma is defined as negative thoughts, attitudes or beliefs about mental illness or seeking mental health care that can result in discrimination or negative consequences (Rüsch et al., 2005; Corrigan et al., 2014). Research suggests that stigma of mental illness increased between the 1950s and the 2000s, but plateaued in the late 2000s (Rüsch et al., 2005; Parcesepe & Cabassa, 2013). Despite the plateau, and the increase in visibility of mental health difficulties in the media and pop culture, stigma continues to be widespread in the U.S. with adults with mental illness being perceived as more dangerous and less competent (Parcesepe & Cabassa, 2013). Unfortunately, these negative attitudes significantly contribute to individuals not receiving care. One meta-analysis found that stigma was the fourth most endorsed barrier to care (Clement et al., 2015). Unlike previously discussed attitudinal barriers, individuals with severe psychopathology are the most likely to endorse stigma as a barrier to seeking mental health care, followed by individuals with moderate

psychopathology and mild psychopathology (21%, 7% and 3%, respectively; Mojtabai et al., 2011). Based on this research, stigma surrounding mental illness still exists and continues to act as a barrier for individuals seeking treatment, particularly for individuals with more severe psychopathology.

Structural Barriers

While structural barriers are less frequently endorsed than attitudinal barriers, they are still reported by approximately a quarter of individuals with a mental illness who felt they needed care, but did not receive it (Mojtabai et al., 2011). Financial burden is the most frequently reported structural barrier; in one study; approximately 15% of respondents endorsed financial barriers as a reason for not seeking care and 17% of respondents endorsed financial barriers as a reason for dropping out of care prematurely (Mojtabai et al., 2011). Unfortunately, financial barriers are disproportionately endorsed by individuals with severe forms of psychopathology with 26% of severely mentally ill respondents endorsing financial barriers compared to 9% of mildly mentally ill respondents (Mojtabai et al., 2011). This research suggests that the financial cost of mental health care in the U.S. can be burdensome. In a study by Crane and Payne (2011), researchers found that the average cost for one “episode of care” was \$340.05 for approximately seven sessions. Further, they found that cost and number of sessions attended varied by education level of the provider. Data from this study showed that treatment with a psychologist was the most expensive (approximately \$398.58 for seven sessions) followed by treatment with a social worker (approximately \$327.36 for seven sessions). Care provided by a psychiatrist was the least expensive, but was also for fewer sessions averaging out to the highest cost per session (approximately \$317.10 for four sessions). Taken together, cost for mental health care services,

regardless of education level of provider, is high and individuals report it as a reason for not seeking care.

Recent laws in the U.S. have attempted to increase health insurance coverage including coverage for mental health treatment. Unfortunately, research suggests that individuals with mental illness are less likely to have insurance than individuals without mental illness. One study found that 22% of individuals with any mental illness lacked insurance compared to 19% of individuals with no mental illness. Further, this study found that individuals with no insurance and mental illness were significantly less likely to obtain mental health care when compared to individuals with health insurance (Walker et al., 2015). And of those who have insurance, individuals still receive out-of-network mental health care at a greater rate than out-of-network physical health care (Melek et al., 2017). This means that despite insurance, the financial burden still lands on the individual seeking care. Ultimately, this data suggests that, while there was an attempt to increase accessibility by increasing health care coverage, increased coverage has not contributed to an increase in accessibility to mental health care services through reduced cost.

The second most endorsed structural barrier to mental health care in the U.S. is availability of providers with 13% of respondents in one study endorsing this barrier (Mojtabai et al., 2011). Similar to other structural barriers, lack of availability disproportionately affects individuals with severe psychopathology compared to individuals with moderate or mild psychopathology (24%, 11% and 7%, respectively; Mojtabai et al., 2011). Research on this barrier has found that availability of providers differentially impacts rural and urban communities. Studies have shown that, across the U.S., nearly three fourths of “small rural counties” had no psychiatrists and only half of those counties had a master’s or doctoral level psychologist (Gamm et al., 2010). This is not due to lack of need as research also shows that

need for mental health care is equal in rural and urban communities. In fact, suicide rates are higher in rural communities than in urban communities (Gamm et al., 2010). Even in urban communities, where there are more providers, lack of availability is still a problem due to a greater need for services than the total number of providers. This often results in individuals seeking care being placed on waiting lists until the next available appointment. In one simulated-patient study, researchers found that the average time before a first appointment, when they were able to reach a psychiatrist, was 25 days, with a range of 0-93 days depending on the site (Malowney et al., 2014). Taken together, it is clear that lack of availability of providers poses a significant problem for individuals seeking mental health care across the U.S.

Even after individuals are able to overcome other barriers to care, research suggests that they are not always receiving the most up-to-date psychotherapies or, at least, evidence based psychotherapy. One study investigating therapists' clinical orientations in the U.S. found that one third of respondents, all practicing psychotherapists, reported a non-evidence based psychotherapy as part of their theoretical orientation (Cook et al., 2010). Further, much of psychotherapy that is being practiced in the U.S. does not meet basic guidelines and standards set by the American Psychological Association (APA). A study by González et al. (2010) found that only 21% of patients received care consistent with the guidelines set by the APA. This study also found that this disproportionately affects patients of color with African American and Mexican Americans receiving guideline consistent care 14% and 12% of the time, respectively. Of those individuals who are receiving evidence-based care, research suggests that this care may be out of date as many studies show that it can take up to 17 years for healthcare research to be translated into clinical care (Morris et al., 2011).

Thus, it is clear that a new solution is needed. More specifically, a solution that addresses many of the current barriers to mental health care in the U.S. in order to increase access beyond what is being provided by the traditional psychotherapy and self-help markets. This solution needs to reduce the cost per session, increase the total number of providers (in both rural and urban locations), increase accessibility to evidence-based care with the ability to update quickly, reduce stigma and empower individuals to manage their own symptoms. A new program, Mood Lifters, offers a solution to some of these barriers by offering peer-based psychoeducation meetings in a group setting that encourages participants to learn and practice skills on their own. We developed this novel program to address the barriers described above.

Mood Lifters relies on trained peer leaders to address barriers of cost, stigma and accessibility. Peer leaders have the potential to reduce the cost of sessions because they are paid less per hour than master's or doctoral level psychotherapists. Additionally, there are more potential leaders, as individuals who have already been through the program can become leaders without going through years of education. Research also suggests that receiving services from peers decreases stigma towards mental illness, increases feelings of hope and empowerment, and increases self-esteem, empathy and self-confidence (Repper & Carter, 2011). Further, in direct comparison with traditional psychotherapy, Sells et al. (2006) found that individuals in programs led by peers felt more understood, accepted and liked than individuals in traditional psychotherapy. Overall, evidence suggests that using peer leaders in a program does address significant accessibility barriers and provides additional benefits. However, an important question remains: can a program be effectively delivered by peers? Will participants benefit as much from a program led by peers as they would from the same program led by professionals?

The literature addressing this question is mixed. Some studies show equivalent or more improvement for peer led groups compared to professionally led groups, but other researchers highlight the limitations of these studies. However, most reviews agree that peer delivered mental health services (regardless of the type of service) are at least as effective as professionally delivered services (Repper & Carter, 2011; Chinman et al., 2014). Studies in these reviews found that patients in peer led care saw reduced symptoms and in-patient hospital stays and improved overall functioning. What was less clear from these studies, is whether these results went beyond improvements seen with patients in traditional programs. One specific type of peer led program, “peers delivering curricula,” which Mood Lifters would be categorized as, had very promising results. Research on these types of programs has found that they were more effective than treatment as usual (i.e., Wellness Recovery Action Plans, Building Recovery of Individual Dreams and Goals, Health and Recovery Peer; Chinman et al., 2014). One limitation of these studies is that they have not directly tested peer led programs with the same program led by professionals, so it is not clear if improvements are the result of the program itself or the peer leaders. Overall, research suggests that peers are equally as effective as professional leaders at delivering certain types of mental health care and function as one potential solution to significant barriers to mental health care.

Mood Lifters also uses meetings held in groups to address structural barriers. Group therapy addresses availability difficulties by allowing multiple individuals to be seen by one leader, thus increasing accessibility. Similarly, it allows for the cost of service to be reduced because multiple individuals are receiving care. In fact, one review found that group therapy saved patients up to 42% of the cost of individual therapy (McDermut et al., 2001). Thus, group therapy does, in fact, address structural barriers to care. However, a question remains: is group

therapy as effective as individual psychotherapy? Fortunately, research shows that, for depressive symptoms, group therapy does improve depressive symptoms compared to waitlist conditions (McDermut et al., 2001). However, the research on its efficacy in comparison to individual therapy is mixed, with some studies suggesting group therapy is more effective and other studies suggesting individual therapy is more effective. Despite this, it is clear that using a group based program does address some current barriers to mental health care accessibility and appears to improve mental health.

Finally, Mood Lifters is evidence-based with meetings on a variety of skills from the most recent evidence-based psychotherapies. Mood Lifters takes a comprehensive approach to mood improvement by including meetings from five categories: biology (Body), cognition (Mind), relationships (Social), behavior (Behavior), and emotions (Mood). Meetings include topics and strategies from cognitive behavioral therapy (CBT), acceptance and commitment therapy (ACT) and dialectical behavior therapy (DBT). All of these therapies have significant empirical support in the form of randomized control trials and meta-analyses (Hofmann et al., 2012; Powers et al., 2009; Robins & Chapman, 2004). While Mood Lifters does not include all strategies/topics from these psychotherapies, every effort was made to include strategies with the most empirical support. Further, Mood Lifters includes topics and skills that are not from traditional psychotherapies, but have been shown to empirically improve mood (e.g., character strengths or exercise; Niemiec, 2013; Bryne & Bryne, 1993).

The following studies were designed to establish the feasibility and efficacy of Mood Lifters in order to address and at least partially resolve many of the current barriers to mental health care in the U.S. Study 1 examines the feasibility of implementing the new program in a small pilot feasibility study. Study 2 examines the efficacy of the program in a semi-randomized

controlled trial with a waitlist condition. Study 3 examines whether or not peers are as effective as professional leaders for the Mood Lifters program.

In Study 1, we assess the feasibility of implementing the Mood Lifters program in a small pre-pilot group. This feasibility study seeks to examine whether participants attend meetings, participate in the program outside of the meetings (i.e., homework/points) and see improvements in mood after completing the program. Data was collected pre-and post-completion of the pilot program with twice weekly meetings for eight weeks. We expect to find that participants attend meetings and are able to integrate what they've learned in meetings at home, by completing "homework" assignments and tracking "points" outside of the meetings. Additionally, we hope to find that participants improve on a variety of mood and clinical measures after completing the group. By establishing the feasibility of the Mood Lifters pilot program, it will allow us to move forward and begin the semi-randomized control trial (RCT) for the Mood Lifters program.

Study 2 outlines the semi-randomized control trial of the Mood Lifters program, where study participants were assigned to either a waitlist control group, or one of two Mood Lifters group conditions. In this study, we measure the efficacy of the program by analyzing pre-and post-group differences between individuals who completed the Mood Lifters program and individuals in a waitlist control condition. Data was collected pre-and post-completion of the Mood Lifters program with weekly meetings for 15 weeks. In this trial, three "rounds" of groups were run, so participants in the waitlist control condition could complete the program after being on the waitlist. Groups were run in February 2018, May 2018 and September 2018. We expect to find that participants in the Mood Lifters program improve on mood, clinical and other relevant measures compared to a wait list control condition. This is important because it would provide

evidence that Mood Lifters effectively improves participants' conditions and addresses important barriers to accessibility.

In Study 3, we measure whether peers (i.e., individuals who had completed the Mood Lifters program) are as effective as professionals (i.e., individuals with clinical psychology training) in leading the Mood Lifters program. For this study, we examine data from the RCT to determine group differences in program outcomes between participants in groups led by peers and participants in groups led by professionals. Data was collected pre- and post-completion of the 15-week Mood Lifters program for the RCT. We expect to find that participants in peer led Mood Lifters groups improve as much or more than participants in professionally led Mood Lifters groups. This is important because this would indicate that peers can be used to effectively deliver the program, reducing cost and increasing availability of providers if Mood Lifters is launched nationwide.

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CHAPTER II: The Development and Feasibility of the Mood Lifters Program

Introduction

In the United States (U.S.), approximately one in two people will experience a mental illness in their lifetime (Kessler et al., 2005). Therefore, nearly every person in the United States will be affected by mental illness over the course of their life, either their own or that of a loved one. According to the National Institute of Mental Health (NIMH, 2017), in 2016 alone, 44.7 million American adults suffered from any mental illness. Even more critical, since 1999, the suicide rate in the U.S. has increased by 28% (NIMH, 2018). Despite the need for care, only 43% of those affected by mental illness received some type of treatment in the past year (NIMH, 2017). Unfortunately, even if individuals seek care, they attend a median of three appointments and 22% of people drop out of treatment early (Olfson et al., 2009). These data suggest that there is a large unmet need for mental health care in the United States.

The literature on access to mental health care refers to two types of barriers that prevent individuals from seeking out care: attitudinal and structural (Andrade et al., 2014). Attitudinal barriers describe thoughts or attitudes people have that prevent them from seeking care. For example, attitudinal barriers include stigma, perceived ineffectiveness of care, beliefs that people can get better on their own or that symptoms will resolve on their own. In contrast, structural barriers are described as healthcare system problems that prevent people from receiving care. These include barriers such as cost, availability of providers, transportation difficulties and receiving non-evidence based care. Research suggests that individuals endorse experiencing both

attitudinal and structural barriers that prevent them from seeking care; however, attitudinal barriers are the most commonly reported (Andrade et al., 2014).

Attitudinal Barriers

Several studies suggest that the desire to manage symptoms on one's own is the most commonly reported attitudinal barrier to receiving care (Andrade et al., 2014; Walker et al., 2015; Sareen et al., 2007). One study of a nationally representative U.S. sample found that approximately 73% of respondents who perceived an unmet need for mental health care endorsed this barrier (Mojtabai et al., 2011). Additionally, this study found that while this belief was most commonly reported by individuals with mild psychopathology, it was also endorsed across mild, moderate, and severe psychopathology (78%, 74% and 63% respectively). This suggests that the desire to treat one's own symptoms decreases the likelihood of receiving mental health care and acts as the most significant barrier to mental health care in the U.S at any level of psychopathology.

Another critical attitudinal barrier is stigma, or negative attitudes towards mental illness or seeking care, often based on misconceptions that can result in discriminatory experiences (Corrigan et al., 2014; Rüsçh et al., 2005). While speaking about mental health has become more commonplace, including public figures coming forward with their own experiences, negative stereotypes of individuals with mental illness and of seeking mental health care remain. Research suggests that stigmatizing beliefs of individuals with mental illness increased between the 1950s and the 2000s and plateaued through the late 2000s (Rüsçh et al., 2005; Parcesepe & Cabassa, 2013). Further, a meta-analysis on stigma by Parcesepe and Cabassa (2013) suggested that a variety of stigmatizing beliefs are widespread in the U.S. Unfortunately, stigma prevents individuals from reaching out to care, therefore reducing access to mental health treatment for

individuals who need it. In a recent meta-analysis, researchers found that stigma was the fourth most endorsed barrier to seeking mental health care (Clement et al., 2015). Other researchers found that it acted as a barrier for respondents regardless of degree of psychopathology (severe, moderate, and mild; 21%, 7% and 3% respectively; Mojtabai et al., 2011). Thus, stigma is another barrier to consider when attempting to improve accessibility to mental health care as it prevents individuals from seeking care in the first place. While recovery can occur without mental health care, a review of population based longitudinal studies on the course of depression show that an average of only 48% of individuals recovered and did not experience another depressive episode across the follow up period (Steinert et al., 2014). Although individuals with depression are only a fraction of individuals struggling with mental health difficulties, these studies can act as an example of recovery for other mental illnesses. With more access to care, the speed of recovery and the number of individuals who recover and experience stable recovery may increase.

Structural Barriers

Structural barriers also pose a significant problem for individuals seeking mental health care. One of these barriers is cost. Based on a study by Crane and Payne (2011), the average cost of therapy for one “episode of care” in the U.S. was \$340.05, with an average coverage of approximately seven sessions. They also found that average cost and number of sessions varied by provider type (i.e., psychologist versus social worker versus medical doctor). Individuals seeing psychologists incurred the highest cost of care with an average cost of \$398.58 for an average of seven sessions; individuals seeing social workers had an average cost of care of \$327.36 with an average of seven sessions; finally, individuals seeing medical doctors had an average cost of care of \$317.10 with an average of approximately four sessions (Crane & Payne,

2011). Due to the high cost, recent laws have attempted to increase the availability of psychotherapy through insurance coverage; however, individuals still receive out-of-network mental health care at a much higher rate than out-of-network physical health care (Melek et al., 2017). Even if individuals have insurance that covers psychotherapy, they have to pay a copay or pay out of pocket until they reach their deductible posing a significant financial burden for many Americans. In fact, one study showed that 15% of individuals reported cost as a significant barrier to receiving care (Mojtabai et al., 2011). Further, it also impacts the rate at which individuals drop out of therapy with this same study showing that 17% endorsed a financial burden as a reason for dropping out of care. It is clear that cost poses a significant problem for individuals looking for mental health care in the U.S.

In addition to cost, there are often not enough providers to serve the number of people seeking care. This often impacts rural and urban communities differently. Mental health providers often prefer to live in more populated areas like urban and suburban communities, and that impacts the distribution of providers. Researchers found that, in the U.S., almost three fourths of “small rural counties” did not have a psychiatrist and only half of these had a master’s or doctoral level psychologist (Gamm et al., 2010). This is despite the fact that research shows that the need for mental health care is similar across rural and urban communities and suicide rates are higher in rural communities (Gamm et al., 2010). Despite equal need, there are fewer providers in rural communities, posing a significant barrier to individuals living in those communities. Unfortunately, in more urban communities, despite greater proportion of therapists per capita, there is still a greater need for services than there are providers. When an individual seeks care and there is no available provider, they are often put on wait list until the next appointment is available. This results in long wait list times, with one simulated-patient study

finding that the average time before a first mental health care appointment with a psychiatrist to be 25 days (Malowney et al., 2014). Research on barriers to mental health care suggests that the difficulty in finding an available therapist is reported as a significant structural barrier. One study reported that up to 17% of people across all levels of psychopathology who sought care were unable to find it (Mojtabai et al., 2011).

Even when individuals are able to schedule and pay for their appointments, they do not always receive the most up-to-date evidence based care. One study on therapists' clinical orientation found that approximately one third of the therapists sampled reported a non-empirically supported therapy as part of their theoretical orientation (Cook et al., 2010). And while the American Psychological Association (APA) has guidelines and standards for evidence-based care, research has found that individuals often receive care that is not consistent with these guidelines. In one study of 15,762 patients, researchers found that only 21% of patients received guideline concordant care (González et al., 2010). Unfortunately, this disproportionately affects disadvantaged populations with African American and Mexican Americans receiving guideline concordant care only 14% and 12% of the time, respectively. To further compound on this problem, one review found that many researchers converged on an average time of 17 years for the translation of current health care research into clinical care (Morris et al., 2011). Unfortunately, this results in individuals receiving ineffective and out-of-date care even when they are able to overcome other barriers to care.

What do we do?

Based on current evidence, there is a need for low-cost, evidence based mental health interventions that are non-stigmatizing and give individuals a sense of efficacy. A team at the University of Michigan developed such an intervention to address some of these barriers and

conducted a feasibility study on this new intervention. The following paper reports on the development and pilot results of this novel program, Mood Lifters.

Why Mood Lifters?

Mood Lifters consists of evidence-based, skills focused weekly group meetings. Based on the biopsychosocial model first proposed by Engel (1977), Mood Lifters takes this approach with mental health, recognizing that a person cannot be fully understood from a health/psychopathological perspective without considering their entire context and the many factors influencing them, including their biology, cognition, affect, social relationships and behavior. Research suggests that these areas differentially impact individual's mental health and that incorporating and including these topics in a single intervention can lead to more personalization and benefits for participants (Álvarez et al., 2012; Babalola et al., 2017; Smith et al., 2013). As such, it was critical that Mood Lifters work from a biopsychosocial model to be comprehensive, inclusive and personalizable.

Beyond the biopsychosocial model, the program has three key components: “check-in”, meeting content and planning/homework. The “check-in” includes two parts: (1) a brief questionnaire and (2) a brief interaction with one of the group leaders to review homework completed and barriers that arose over the week between meetings. The first part of the “check-in” process is to complete a brief questionnaire that assesses mood, relationships and behavior. Weekly assessments allow for regular testing of efficacy of the program, frequent review of participant's mental health and a place to intervene if a participant is worsening (Colla et al., 2015). This assessment is paired with a brief discussion with the program leader that facilitates connection and develops accountability for practicing skills outside of the program. Accountability is rarely considered in adherence to mental health interventions, but recent

models suggest that supportive accountability, accountability that occurs with someone perceived as trustworthy and knowledgeable, can benefit participants and promote behavioral change (Oussendik et al., 2017; Mohr et al., 2011). The meeting content, as described in more detail below, is taken from the most recent literature on mental health and previously supported mental health interventions (e.g., Beck, 2011; Hayes et al., 2012; Linehan, 2015). Finally, the program includes regular homework and tracks homework through a “points” based system. Homework has been shown to be an important mechanism of change in therapeutic interventions (Kazantzis et al., 2016). Several meta-analyses on cognitive behavioral therapy (CBT), another skill focused intervention, show that individuals who complete more homework improve significantly more than individuals who complete less homework with small to moderate effect sizes (Kazantzis et al., 2000; Mausbach et al., 2010; Kazantzis et al., 2017). Additionally, research shows that CBT with homework produces change with larger effect sizes than CBT without homework (Kazantzis et al., 2010). Further, this area of research suggests that homework adherence is predictive of maintaining therapy gains a year after completion (Kazantzis et al., 2000). To better capitalize on the potential benefits of homework, Mood Lifters gamifies homework through a “points” based system. Research suggests that gamification is beneficial for adherence to and, subsequently, outcome, in behavioral health interventions, although more research specific to mental health interventions is needed (Cugelman, 2013; Brown et al., 2016). As homework is an important mechanism of change in psychological interventions, each meeting incorporates time to plan for homework that will be completed over the week between meetings (Kazantzis et al., 2016). By combining accountability at each meeting and distinct planning time, Mood Lifters intends to set participants up for success in practicing newly learned skills that will improve participants’ mental health. Taken together,

these components integrate a variety of concepts and models in the literature to create a unique personalizable and accessible mental health intervention.

Initial Mood Lifters Program Development

The Mood Lifters program was developed by Dr. Patricia Deldin and colleagues at the University of Michigan. Due to the barriers to mental health care outlined above, the goal was to create a peer-led, low-cost, evidence-based program similar to “Weight Watchers” but for mental health. The program, as described briefly above, consists of weekly meetings reviewing topics and skills that are critical for improving mental health. It also includes a points-based system in order to hold participants accountable for engaging with the material outside of the meetings.

In the first stage of development, the Mood Lifters team researched relevant skills/topics that have been shown to have a significant impact on mental health. Team members included graduate and undergraduate psychology students under Dr. Deldin’s mentorship. Team members took a comprehensive biopsychosocial approach focusing on biology, behavior, cognition, emotion and relationships. A list of meeting topics was first developed by Dr. Deldin. This list was then added to and further refined by the team and approved by Dr. Deldin. After the list of topics for the meetings was finalized, each member was responsible for completing a literature search on one or two meeting topics (e.g., exercise in the biology area). Once the literature search was complete, each member presented the findings of their literature search to the other team members. Next, members developed a rough draft of the psychoeducational components of the participant materials based on their literature search. Members were also encouraged to review established psychotherapy materials for activities or worksheets for participants to complete during relevant meetings. These activities were included with the drafts of psychoeducational materials in order to engage participants in the material during the meetings.

At the end of this process, a rough draft of the “Participant Manual” was produced from the psychoeducational material drafts and worksheets/activities for all the included topics.

After the completion of the rough draft of the “Participant Manual,” the study team rationally and when possible, based on specific evidence based “dosage information,” or quantity of intervention needed for therapeutic effect, determined what would count for a “point” for each week and how many points were earned per section, each week. Specifically, these became the homework assignments for a given week. For example, research on exercise and mental health suggests that engaging in aerobic exercise for 30 minutes, five times a week leads to improvement in mental health outcomes (Bryne & Bryne, 1993). Thus, it was determined that a “point” for the Exercise meeting would be 30 minutes of exercise and that a participant should earn 5 “points” a week (Blumenthal et al., 2007). Additionally, to follow with a comprehensive approach, it was decided that participants would earn points in all areas as meeting topics built upon each other (i.e., sleep, body, social, mind, mood, behavior). In order to personalize treatment, and make it precisely geared for each individual, participants could choose which activities they would do to earn their points. For example, they could do Zumba instead of jogging to meet their weekly body point goal. Additionally, team members also developed a “Leader Manual” for meeting leaders to follow for each meeting. This contained additional readings on the topic of the meeting and an example “script” of how a leader would facilitate the meeting.

Once the program structure and “Participant Manual” were complete, the Mood Lifters Team completed the full program over eight weeks with members rotating through leading different meetings. Members were encouraged to engage with the material and the program as participants. All team members gave feedback on participant materials and meeting flow. At the

end of the eight weeks, the “Participant Manual” was edited based on the feedback provided by the team. Additionally, the “Leader Manual” was updated to reflect the “Participant Manual” edits and expanded into a script that leaders could follow. The Leader and Participant Manuals were the materials used in this feasibility study.

Study A

Goal

The goal of Study A was to test the feasibility of the Mood Lifters program. Researchers were most interested in the following questions: were people able to attend meetings regularly, did participants engage with different parts of the Mood Lifters program (e.g., check-in, points, meeting content), what were participants reactions to the program, and did participants benefit from the program?

Methods

Participants. Participants were adults 18 years and older and were recruited using an online posting on Facebook encouraging participation in a new program, Mood Lifters. Participants were not compensated for participating in the groups; participation was entirely voluntary. 13 participants responded to the post on Facebook via email before it was closed and were sent the screening measures. Exclusion criteria for this study were psychosis, severe suicidal ideation and current mania and participants were screened for these difficulties using measures described below. Of the 13 participants who responded and completed the screener, two participants were excluded for psychosis and suicide, one participant did not respond to further emails and three participants dropped out prior to attending the first meeting. Two of these participants dropped out due to timing conflicts and asked to be considered for future studies and, notably, one participant dropped due to the length of the pre-measures. Seven

participants completed the pilot study. Two participants only completed post measures and, thus, are not included in the analyses. The study protocol was approved by the University of Michigan Institutional Review Board. Demographic information is presented in Table 1.

Materials & Procedure. Interested participants contacted the study team by email to express interest in the group. Then, they were given more details about the group and asked to complete a screening questionnaire on the survey hosting website Qualtrics. Participants who endorsed psychotic, manic or suicidal symptoms were contacted by a study team member to determine eligibility. Two participants were excluded because they did not meet eligibility criteria. Eligible participants were sent a longer series of questionnaires on Qualtrics that served as the pre-group measures. These took approximately two hours to complete. All questionnaires were completed in a randomized order in order to reduce fatigue effects (see Table 2 for full list of measures).

Participants attended a total of 13 meetings across eight weeks; groups were not held for one week due to a national holiday. Each meeting lasted approximately one hour. At the first meeting, participants were given a consent form, a participant manual and an introduction to the program. They were given time to review the consent form, ask any questions and decline to participate, again, at that time. Participants attended bi-weekly meetings for the entirety of the program. Prior to the final meeting, participants were asked to again complete the series of questionnaires on Qualtrics. At the final meeting, participants were given feedback about their progress in the program based on the measures they completed.

Mood Lifters Meeting Structure. Meetings were led by two trained peer-leaders (i.e., had completed the program themselves). For this feasibility group, the leaders were the authors of this paper (PJD, CMV), both had professional clinical training. At the beginning of each

meeting, participants completed a brief “check-in” questionnaire on paper. This questionnaire included visual analog scale questions asking about activity level, mood, negative thoughts, relationships and sleep. Additionally, the questionnaire asked about psychotic, manic and suicidal symptoms. If participants endorsed any of these symptoms, the meeting leader would discuss their responses with them at the end of the meeting. If a participant had become ineligible (i.e., high-level suicide risk or significant disruptive psychotic or manic symptoms), the meeting leader would have followed risk protocol and referred the participant to the appropriate resources. This did not occur during Study A.

After completing the “check-in” questionnaire, participants briefly talked to one of the leaders about the “points” that were earned that week and any barriers they had with understanding or engaging with the material from the previous meeting. The first 10-15 minutes of each meeting were reserved for these conversations, that lasted approximately two to five minutes depending on participant comments and questions. Next, all participants came together as a group and spent approximately five minutes discussing barriers to earning “points” or engaging with the material outside of the meeting. During this time, participants could share how they had overcome barriers, for example, having difficulty managing time for exercise with other priorities, and leaders shared evidence-based strategies for overcoming barriers (if applicable).

After these discussions, leaders introduced the topic for that meeting. Topics for the meetings were as follows (in chronological order): Introduction to Mood Lifters & Behavioral Change, Sleep, Thought Changes, Exercise, Emotional Awareness, Emotion Regulation, Making Connections, Values in Action, Problem-Solving, Repairing Relationships (Forgiveness), Nutrition & Hydration, Character Strengths and Wrap-Up. Leaders shared basic psycho-

education about and the most recent research on the topic of the meeting. Participants followed along with the material in their participant manual and engaged with various activities and worksheets related to the topic. After reviewing the material and completing the activities, leaders specifically outlined how to earn “points” for the meeting to encourage participants to practice what was learned outside of the meeting. Lastly, participants had time to plan out when they would earn their points before the next meeting.

Measures.

Altman Mania Scale (AMS). The AMS is a five-question screening measure for manic symptoms (Altman et al., 1997). This measure was used as a screening measure for this study. Participants in this study were contacted by the research study team if they scored greater than five on the AMS. The validation paper for this study reported an 85.5% sensitivity and 87.3% specificity at this cutoff for identifying active mania suggesting that this was an appropriate cutoff for this study (Altman et al., 1997). The AMS shows good internal reliability, with the validation paper reporting a Cronbach’s α of .65-.79 (Altman et al., 1997).

Community Assessment of Psychic Experiences (CAPE). The CAPE is a 42-item screening questionnaire assessing positive, negative and depressive symptoms and those at risk for psychotic disorders (Mossaheb et al., 2012). The study team modified the CAPE for length and to focus on positive symptoms that may be particularly disruptive to a group setting and might indicate a need for a higher level of care. Clinical staff made decisions about contacting participants based on the profile of participants responses. Importantly, participants were immediately contacted if they endorsed any type of perceptual disturbance (i.e., hallucinations).

Patient Health Questionnaire-9 (PHQ-9). The PHQ-9 is a nine-question module taken from the Primary Care Evaluation of Mental Disorders (PRIME-MD) designed to determine

clinical levels of depressive symptoms (Spitzer et al., 1999). The PHQ-9 shows good internal reliability, with the validation paper reporting a Cronbach's α of .86-.89 (Kroenke et al., 2001). In this sample, the Cronbach α was .86. The final item on this measure assesses respondent's suicidal ideation. This item was used as a screening item for the study. If participants scored above zero on this item, they were contacted by a study team member, who followed the team's suicide assessment protocol.

Generalized Anxiety Disorder-7 (GAD-7). The GAD-7 is a seven-question measure developed to identify clinical levels of generalized anxiety symptoms (Spitzer et al., 2006). The GAD-7 shows good internal reliability, with the validation paper reporting a Cronbach's α of .92 (Spitzer et al., 2006). In this sample, the Cronbach α was .88.

Differential Emotions Scale (DES-MOD). The DES-MOD is a 19-question measure developed to examine levels of positive and negative affect (Fredrickson et al., 2003). Our study used a modified version of this measure that removed two questions (i.e., "felt inspired, uplifted, elevated" and "felt stressed, nervous, overwhelmed") and added three questions (i.e., "felt sexual, desiring, flirtatious," "felt surprised, amazed, astonished" and "felt sympathy, concern, compassion"). This resulted in a 20-question version; this measure provides two subscale scores: negative and positive emotions. The DES-MOD shows good internal reliability, with a Cronbach's α of .79 for positive emotions and .69 for negative emotions (Fredrickson et al., 2003). In this sample, for positive and negative sub-scales, the Cronbach α were .94 and .98, respectively.

Analyses. As the purpose of this study is to examine the feasibility of the Mood Lifters program, analyses will include qualitative and quantitative examinations. These examinations will focus on feasibility of study structure (e.g., feasibility of measures) and program structure

(e.g., attendance). First, researchers examined the average number of meetings attended to determine whether and how frequently participants attended the program. Next, researchers examined outside program engagement by reviewing “points” earned in the program. Additionally, researchers reviewed participant feedback about the program. Finally, researchers completed paired samples t-tests to examine differences between pre-and post-scores on clinical, mood and other relevant measures to get a preliminary understanding of whether the program was effective for the small sample size. In order to estimate effect size, researchers calculated corrected hedges g scores, due to the small sample size.

Results

Study Structure. Study components included measures (conducted at pre-and post-group and weekly) and 13 twice weekly skills-focused group meetings. Participants were able to complete both pre-and post-measures for the study. However, several participants reported that the measures were cumbersome and took too long ($N = 4$). They stated that it was challenging to complete them in one sitting. Participants seemed to find the weekly measures more palatable due to their shorter length despite the fact that they were completed more frequently than the pre/post measures. Every participant who came to a meeting was able and willing to complete the weekly measure at every meeting. However, participants stated that it may be easier if they were able to complete these weekly measures online rather than on paper. Overall, the measures appeared to be feasible, but there were concerns about the length of the pre/post measures.

Participants were able to attend meetings. Some participants attended all meetings and others missed several meetings. On average, participants each attended 10.71 out of 13 total meetings ($SD = 1.7$). Two participants attended all meetings and three participants missed only a single session. It is important to note that the low average was significantly impacted by one

participant who only attended seven meetings. Additionally, no participants dropped out after attending at least one meeting. All dropouts occurred prior to attending a meeting. Finally, participants commented that, while they were able to find parking due to free street parking during the time of their meeting, if the meeting time was earlier, parking may have been difficult.

Program Structure. Most participants were able to complete points weekly in each category (i.e., body, sleep, behavior, mood, mind and social). However, participants differentially struggled to earn points in each area. It appeared that participants had “weak” areas that were most challenging for them to earn points (e.g., one participant struggled to earn “body” points consistently, while another participant consistently met the “body” points goal). Additionally, in areas where participants consistently earned points, they often acted as “experts” offering support and recommendations to participants who were struggling in those areas. Finally, the majority of participants appeared to enjoy receiving stickers for “points” that were earned (N = 6). These participants reported that this motivated them to continue earning points and helped them track progress.

Participants appeared engaged with the content that was presented in all of the meetings. However, participants did respond differentially to the meetings, with participants favoring some meetings over others, although there was no consistent “favorite meeting.” For example, Character Strengths was the most popular meeting, receiving two endorsements for favorite meeting, and Thought Changes, Emotion Awareness, Sleep and Values in Action all receiving one endorsement for favorite meeting. Of note, favorite meeting was not consistent with meetings participants rated as most helpful, Emotion Regulation and Behavioral Activation were

rated as the most helpful meetings, with Thought Changes rated as the second most helpful meeting. No information was gathered on least popular meeting.

In each meeting, participants were able to engage with the material, activities and discussions. Participants stated that they would have preferred meetings to occur weekly rather than bi-weekly, as they found that they did not have as much time as they would like between meetings to process and apply material. All participants responded that they would recommend the group to others.

Outcomes. Although the focus of this study was on the feasibility of the Mood Lifters program, researchers assessed for depressive symptoms, anxiety symptoms and positive and negative affect to examine potential post-group effects. Prior to the program, the average PHQ-9 score was 10.20 and, after the program, this average was 3.80 ($N = 5$). The standard deviation was 5.89 and 2.28, respectively. This change was significant at $p = .047$ (Hedges' $g = .807$). The average GAD-7 score, prior to beginning the program, was 6.20 and following the program was 2.80 ($N = 5$). The standard deviation was 4.82 and 2.17, respectively. This finding was not significant ($p = .179$). The average DES positive affect score, prior to beginning the program, was 2.47 and, after the program, was 3.83. The standard deviation was .89 and .41, respectively. This change trended towards significant at $p = .078$ (Hedges' $g = 1.114$). Lastly, the average DES negative affect score, prior to beginning the program, was 2.38 and, following the program, was 1.63. The standard deviation was 1.24 and .28, respectively. This change was not significant ($p = .256$).

Study B

Goal

The goal of Study B was to continue to test the feasibility of the Mood Lifters program after changes, including manual and meeting content changes (described in more detail below), were made after Study A given participant feedback. Again, researchers were interested in examining meeting attendance and engagement and participant reactions, feedback and preliminary outcomes. Additionally, an important change between studies was the introduction of non-clinically trained peer leaders into the program. The use of peer leaders for structured mental health interventions has the potential to address many of the current barriers to mental health care (e.g., lowering cost, increasing accessibility). An important goal of Study B was to test the feasibility of peer leaders for the Mood Lifters program.

Methods

Participants. Similar to Study A, participants were all adults who were 18 years or older, who were not psychotic, manic or severely suicidal. Participants were recruited using an online posting on Facebook encouraging participation in a new program, Mood Lifters. Participants were also recruited through UM Health Research, an online posting service through the University of Michigan for health-related studies. Participants were not compensated for participating in the groups; however, participants were compensated for completing follow-up measures at one month and six months post program (20 and 30 dollars, respectively). Participants were sent an email with information about the pilot program after initial interest; this email contained a link to the screening measure. Participants were screened for psychotic, manic and suicidal symptoms and given group information prior to completing the baseline measures. Of the participants who completed the screening measures, 21 participants attended at least one meeting. Notably, one group was closed after one meeting due to low attendance (only three participants attended the first meeting). One reason for the low attendance is that participants

were assigned to a group immediately after expressing interest and completing screening, and recruitment was then closed once groups met maximum capacity (15 people). Unfortunately, the majority of individuals who did not complete the full initial measures prior to the start of group never showed up to a meeting, artificially inflating attrition rates as less than 15 people would show up to the first meeting. In subsequent studies, participants were not assigned to a group until they had completed the initial measures. Thus, only 10 participants completed this pilot study. Of note, only nine participants completed both pre-and post-measures. Thus, analyses have an N of nine. No comparison group was included as the study was still examining the feasibility of the program, in particular, the feasibility of peer-led groups. The study protocol was approved by the University of Michigan Institutional Review Board. Demographic information is presented in Table 3. Note: due to an error, only some participants provided age information.

Material & Procedures. Similar to Study A, interested participants contacted the study team by email to express interest in the program. Then, they were given more details about the group and asked to complete a screening questionnaire on the survey hosting website Qualtrics. Participants who endorsed psychotic, manic or suicidal symptoms were contacted by a study team member to determine eligibility. Eligible participants were sent the same series of questionnaires on Qualtrics as Study A; these served as pre-group measures and took approximately two hours to complete. All questionnaires were completed in a randomized order in order to reduce fatigue effects (see Table 2 for full list of measures).

Participants attended a total of 14 meetings across 15 weeks (mean = 11.25 meetings, standard deviation = 1.82). All but two participants attended more than 10 meetings. Each meeting lasted approximately one hour. At the first meeting, participants were given a consent form, a participant manual and an introduction to the program. Prior to the final meeting,

participants were asked to again complete the series of questionnaires on Qualtrics. At the final meeting, participants were privately given feedback about their progress in the program based on the measures they completed.

Measures. The screening and pre-and post-measures for Study B were identical to Study A and included the PHQ-9, GAD-7 and DES-MOD (Kroenke et al., 2001; Spitzer et al., 2006; Fredrickson et al., 2003). In this sample, the PHQ-9 had a Cronbach α of .866. The GAD-7 had a Cronbach α of .864. Finally, the DES, for positive and negative sub-scales, had Cronbach α of .926 and .885, respectively.

Mood Lifters Meetings Structure. Meeting structure was unchanged from Study A. Participants attended each meeting, completed a paper “check-in” form and discussed points with the leader or helper. The bulk of the meeting was devoted to content and discussion. At the end of the meeting, participants were given time to plan how they would earn “points” for the program over the coming week. If participants missed a meeting, they were given an opportunity at the end of the next attended meeting to review any material or questions they had with the leader.

Between Study A and Study B, the developers of the program reviewed the background literature on mood improvement and various clinical interventions in order to ensure that the program continued to reflect the most recent research. As a result of this review, some changes to order and content of meetings was changed between Study A and Study B. First, two meetings were each split into two separate meetings: Thought Changes became Thought Awareness and Thought Changes and Repairing Relationships became Forgiveness and Apologizing. It appeared, in Study A, that participants were struggling with concepts introduced in Thought Changes (i.e., brought up to leaders in multiple meetings after its introduction with questions)

and would benefit from more time spent discussing and learning about cognitive restructuring. Thus, Thought Changes was split into two meetings which allowed participants more time to process and integrate this topic (i.e., Cognitive Behavioral Therapy's cognitive restructuring). Additionally, our team noticed that the number of meetings addressing social topics was less than meetings addressing other areas of mental health (e.g., thoughts, behaviors) despite the importance of social relationships for optimal mental health (Harandi et al., 2017). Thus, Repairing Relationships was split into two meetings (i.e., Forgiveness & Apologizing). Note that one participant from Study A mentioned that giving more time per topic may be helpful for future groups, allowing them to discuss and digest information for more time. Two meetings were collapsed into one meeting deemed "Physical Health" (Exercise & Nutrition) due to short content length in both meetings. Finally, two other small content changes were made. After a review of the literature, hydration was removed from the Physical Health meeting, due to insufficient support for its impact on mood improvement (i.e., no new literature and less support than other discussed topics). Additional content on relapse and prevention was added to the final Wrap-Up/Feedback Meeting as this is a common important psychoeducation piece of clinical intervention termination that was missing from the first version of the program.

Program/Content Changes. After the experiences in Study A, some changes were considered and made to both the study structure and the Mood Lifters program. First, study staff attempted to make the weekly measures available online for participants; however, this was not possible due to technical complications. Thus, this change was made in later studies. Measures were consistent between Study A and Study B, but researchers asked for feedback about measure length at the end of the study. At this point, no significant changes were made to the study structure for Study B. However, some changes were made to the Mood Lifters program. First,

leaders were not constrained to trained professionals. Of the three groups, two were led by peer leaders who had completed the program in Study A. Peer leaders included a male and female in their 40s. The remaining group was led by a professional leader, one of the two leaders in Study A. This leader was a female graduate student in her 20s. After engaging with the program as participants, these “peer leaders” completed an eight hour clinical skills and content training, held by the director of clinical training at the University of Michigan, to become certified “peer leaders” in the Mood Lifters program. The training included a thorough review of all topics covered in the Mood Lifters program and relevant clinical skills (e.g., empathetic responding, open ended questions). Another change to the program was that meetings were scheduled for once a week, rather than bi-weekly meetings. Additionally, all three groups were held in different locations (i.e., in a university meeting space, in a mental health clinic and in a public-school after-hours). Finally, several changes were made to the content contained in the meetings. As described above, some meetings were split into two separate meetings and research discussed in the program was updated.

Analyses. Similar to Study A, the purpose of Study B was to build further evidence of the feasibility of the Mood Lifters program. Thus, analyses will again include both qualitative and quantitative analyses of both study and program structure. Quantitative analyses will include number of attended meetings and preliminary outcome measures. These preliminary examinations of outcomes will include t-tests to examine differences between pre-and post-scores on baseline measures. Qualitative considerations will be examinations of feedback from participants and observations of the study.

Results

Study Structure. Study structure was very similar to Study A, aside from the changes described above. Thus, Study B provided more feedback about a similar study structure. Similar to Study A, nine out of 10 participants were able to complete the pre- and post- measures for the study; however, again, several participants complained about the length of the pre-and post-study measures. All participants were able to complete the weekly measures for meetings that they attended; no participants complained about the length or frequency of these measures. However, similar to participants in Study A, they stated that it may have been easier if they were able to complete these measures online (e.g., on a tablet, laptop or mobile device). Overall, study measures were feasible, but participants stated that pre-and post-measures were too lengthy and weekly measures would have been made easier if they were completed online.

Once groups were established, participants were able to attend meetings regularly. On average, participants who completed pre-and post-measures attended a mean of 12 meetings (SD = 1.32). However, one group, held in a public school, was closed after the first meeting due to low attendance (i.e., three individuals at the first meeting). These participants were invited to the other running groups, but none were able to attend due to scheduling differences. In addition to the closed group, attendance appeared to be slightly worse compared to Study A. On average, participants who completed pre-and post-measures missed a mean of two meetings (SD = 1.32). There was also more drop out than Study A, with 11 participants dropping out of these groups after attending at least one meeting; this left a total of 10 participants in the remaining two groups. Lastly, participants also commented on the availability of parking with participants finding parking difficult and expensive in both group locations.

Program Structure. Participants were able to complete weekly points and reach weekly point goals (i.e., body, sleep, behavior, mood, mind and social). Similar to Study A, participants

often had one or two categories that they were more inconsistent in earning points. However, they often had strengths and had one or two areas in which they always earned points. These categories (i.e., strength versus weakness) differed by participant. In areas where participants were more comfortable and earned points, they often shared recommendations with others in the group about their habits in these areas. Most participants enjoyed earning stickers, similarly to Study A. However, not all participants enjoyed receiving stickers for their achieved goals; these participants did appreciate tracking points and still used the point system to achieve their goals.

Participants enjoyed and engaged with the content that was covered in the meetings according to group leader observations. Similar to point tracking, participants favored some meetings over others. However, again, there was no favorite meeting or topic which was assessed by a single feedback question. Participants appreciated weekly rather than bi-weekly meetings. They felt they were better able to understand the material at this slower pace and more effectively integrate the weekly topic into their lives through the point system.

A major change between these groups and the group in Study A was that one out of two groups in Study B were led by peer leaders rather than trained professionals. To clarify, all leaders of the Mood Lifters program are “peers” in the sense that all leaders have previously completed the program. However, some of the “peers” have also had professional clinical psychology training; these leaders are referred to as “professional” leaders, even though they are also “peers.” During this study, we had two “peer” leaders and two “professional” leaders. At one group, the leader was a “peer” with a “professional” acting as a helper (i.e., backup who observed all meetings) and, at the other group, the leader was a “professional” with a “peer” leader acting as a helper. No participants made comments about their leader’s ability, style or efficacy during the program or when given the opportunity to provide anonymous feedback

about the program. Thus, it was determined that there were no qualitative differences between the group led by the professional and the group led by the trained peer leader. Based on leader observation, participants appeared equally engaged across groups.

Outcomes. Again, the focus of Study B was feasibility, yet, researchers assessed for depressive symptoms, anxiety symptoms and positive and negative affect to examine potential treatment-related effects. The average PHQ-9 score, at the start of the program, was 5.78 and, after the program, was 4.33 (N = 9). The standard deviation was 4.32 and 4.24, respectively. This change was not significant at $p = .182$. Prior to the start of the program, the average GAD-7 score was 4.00 and, following the program, was 3.89 (N = 9). The standard deviation was 3.24 and 3.52, respectively. This finding was not significant ($p = .933$). The average DES positive affect score, prior to starting the program, was 3.06 and, after the program, was 3.29 (N = 9). The standard deviation was .86 and .62, respectively. This change was not significant at $p = .257$. Finally, the average DES negative affect score, prior to beginning the program, was 1.83 and, following the program, was 1.67 (N = 9). The standard deviation was .74 and .77, respectively. This change was not significant ($p = .339$).

Discussion

Mood Lifters is a novel mental wellness intervention that was designed to address several of the most endorsed barriers to care including empowerment, stigma, cost and availability of providers (Mojtabai et al., 2011). Importantly, the Mood Lifters program integrates effective theoretical and clinical components such as the biopsychosocial model, weekly assessments, evidence-based skills, accountability, and gamified homework (i.e., “points”) to produce a holistic evidence-based program to improve mental health (Babalola et al., 2017; Smith et al., 2013; Álvarez et al., 2012; Oussedik et al., 2017; Mohr et al., 2011; Beck, 2011; Hayes et al.,

2012; Linehan, 2015; Kazantzis et al., 2016; Colla et al., 2016; Brown et al., 2016; Cugelman, 2013).

The above studies address the feasibility of the Mood Lifters program. In Study A, we found that participants were able to engage in all meetings, were able to earn points and, overall, benefitted from the program. Caution is needed to interpret any results given this small sample size. However, preliminary outcome analyses for Study A showed some promise with significant reduction in depressive symptoms across the group. However, participants did recommend some changes to improve both the study and the program. In Study B, several changes were made to the program and study structure. Specifically, meetings were moved from bi-weekly to weekly meetings, one group had a peer rather than professional leader, and some content changes were made (i.e., splitting three meetings into six meetings and removal/addition of content in two other meetings). In general, these changes were received well by the participants. Importantly, there were no qualitative differences between peer and professional groups, indicating that participants are open to peer led programs, although efficacy differences will need to be tested in future studies. Participants came to the weekly meetings, although there were slightly poorer attendance rates, and participants were able to complete homework (points) across the program. Unfortunately, while the results from Study B were not statistically effective, they do suggest a similar pattern of change as Study A. Non-significant findings may be due to the small sample size, high rate of attrition for this study or lower pre-levels of psychopathology in Study B compared to Study A. Overall, most participants in both programs felt that the program was beneficial to them and that they were able to participate in the program and the study, confirming the feasibility of this program and study and providing initial evidence to take Mood Lifters to a

larger trial. In combination, these studies add to the existing literature by offering initial feasibility evidence for a new accessible alternative to traditional mental health care.

In order to ensure the feasibility of a larger scale study, future studies should make the following changes. First, participants recommended a significant reduction of measures to make the measures less cumbersome. Additionally, participants would appreciate the ability to fill out weekly measures online rather than on paper. Participants would also appreciate the researchers' consideration of location and parking for future studies. Most importantly, the program needs to be compared with a no treatment comparison group. These changes were made in the future semi-randomized control trial of the Mood Lifters program.

These studies had several limitations. First, the sample size of both studies was small ($N = 5$ and $N = 10$, respectively). In Study A, this was intentional as the first pilot study of the program. However, Study B had more attrition than Study A. The majority of attrition was a direct result of a location shift, but the groups that continued also experienced attrition. Attrition also may have been high because the group was weekly rather than twice weekly, like Study A. This meant that participants had to commit to the program for a total of 15 weeks, rather than eight, increasing the likelihood of travel or other conflicts. Additionally, neither study included a comparison group for this study, so we are unable to make comparisons with treatment as usual or no treatment. Finally, in both studies, all participants were Caucasian, as were the peer leaders, and the majority were middle class, therefore, generalizability was limited.

The Mood Lifters program was developed in order to test alternative treatments to traditional psychotherapy that address common barriers to mental health care. Some of these barriers include the desire to manage one's own symptoms, stigma, cost, availability and lack of evidence-based care (Mojtabai et al., 2011; González et al., 2010). The program addresses these

barriers by using peers as leaders, delivering treatment in a group setting, and focusing on the most recent literature in mood improvement (including psychopathology and positive psychology research). Based on the preliminary findings in this feasibility study, the Mood Lifters program has the potential to address many of the barriers to accessing mental health care and is ready to be tested in a larger scale trial.

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Table 2.1***Demographic information for Study A***

	Study A (Completed Pre/Post)	Study A (All)
Age	54.40	53.57
Sex		
Male	2	2
Female	3	3
Race		
American Indian/Alaskan Native	0	1
White	5	7

Note. Participants were allowed to select more than one race, if it applied.

Table 2.2***Measures for Study A & B***

Measure	Citation
Drug Abuse Screening Test	Skinner, 1982
Michigan Alcoholism Screening Test	Selzer, 1971
Meaning in Life Questionnaire	Steger et al., 2006
Insomnia Severity Index	Bastien et al., 2011
Pittsburgh Sleep Quality Index	Buysse et al., 1989
Behavioral Activation for Depression Scale	Kanter et al., 2007
Beck Hopelessness Scale	Beck et al., 1974
Dysfunctional Attitudes Scale	Weissman & Beck, 1978
Automatic Thoughts Questionnaire	Hollon & Kendall, 1980
Mood and Anxiety Symptom Questionnaire	Watson & Clark, 1991
Patient Health Questionnaire-9	Kroenke et al., 2001
International Physical Activity Questionnaire	Craig et al., 2003
Emotion Regulation Questionnaire	Gross & John, 2003
Differential Emotion Scale-Modified	Fredrickson et al., 2003
Positive and Negative Affect Scale	Watson et al., 1988
Difficulty in Emotion Regulation Scale	Gratz & Roemer, 2004
Subscales of Ryff Scales of Psychological Wellbeing	Ryff, 1989
Social Well Being Scale	Sirgy, 2012
Generalized Anxiety Disorder Scale	Spitzer et al., 2006
Social Adjustment Scale	Weissman & Bothwell, 1976

Note. Only validated measures were included in this list.

Table 2.3***Demographic information for Study B***

	Overall	Professional	Peer
Age	60.75 (N=4)	58.7 (N=3)	67 (N=1)
Sex			
Male	2	1	1
Female	7	4	4
Race			
Black/African American	1	1	0
Asian	1	0	1
White	8	4	4

Note. Participants were allowed to select more than one race, if it applied, or leave it blank.

CHAPTER III: Testing the Efficacy of the Mood Lifters Program: a Semi-Randomized Control TRIAL

Introduction

There is a massive need in the United States (U.S.) for mental health care with almost half of the population likely to experience a mental disorder over the course of their lifetime (Kessler et al., 2005). Other individuals experiencing stress, grief, difficulties at work or at home may also benefit from mental health care without meeting criteria for a mental illness. However, research suggests that only 43% of those affected by mental illness sought care in the past year and 22% of those individuals dropped out of care prematurely (National Institute of Mental Health [NIMH], 2017; Olfson et al., 2009). This lack of mental health care suggests that people encounter barriers when trying to access the traditional mental health care system. Researchers in this area have identified two categories of barriers to care: attitudinal and structural; data suggests that attitudinal barriers are more commonly reported than structural barriers, although both prevent access to care, on their own and in combination (Andrade et al., 2014). This paper reviews current barriers and presents the testing of an alternative mental health care program, Mood Lifters, that increases accessibility by addressing these barriers to care.

Attitudinal Barriers

Attitudinal barriers, or barriers relating to attitudes and beliefs about mental health and seeking care, include beliefs that an individual should help themselves and stigma

Desire for Self-Improvement. Many studies report that the most commonly reported barrier to accessing mental health care is, “wanting to handle symptoms on my own” (Andrade et al., 2014; Walker et al., 2015; Sareen et al., 2007; Mojtabai et al., 2011). An overwhelming 73% of respondents in one nationally representative survey endorsed this barrier (Mojtabai et al., 2011).

Stigma. Another frequently endorsed attitudinal barrier is stigma (i.e., general negative attitudes/beliefs towards mental illness or help-seeking that can result in discrimination; Rüsçh et al., 2005; Corrigan et al., 2014). Despite increases in visibility of mental illness, especially in the public sphere, data suggests that stigmatizing beliefs continue to be widespread in the U.S. (Parcesepe & Cabassa, 2013). These persistent societal stigmatizing beliefs discourage individuals from seeking care. Stigma is the fourth most endorsed barrier to seeking mental health care with approximately 9% of respondents endorsing stigma as a barrier to seeking care (Clement et al., 2015; Mojtabai et al., 2011).

Summary. Taken together, desire for self-improvement and stigma, prevent a majority of individuals from seeking care. While it may seem that structural barriers, discussed below, are more prevalent than attitudinal barriers, research suggests that attitudinal barriers are most prevalent (Andrade et al., 2014). Thus, interventions developed to address current barriers to care should consider attitudinal barriers as they are critical to improving accessibility.

Structural Barriers

Structural barriers include financial barriers (e.g., cost and lack of insurance), lack of availability of providers and lack of evidence based care.

Cost/Financial Burden. One large study examining barriers to care in the U.S. found that 15% of people reported financial barriers in seeking care and 17% reported cost as a reason

for dropping out of care prematurely (Mojtabai et al., 2011). With the average cost of one “episode of care” at approximately \$340.05 for an average of seven sessions, this can be a significant financial burden especially for individuals who are already struggling (Crane & Payne, 2011). Unfortunately, even with increases in insurance coverage generally, and for mental health care in the U.S., research shows that many Americans still receive out-of-network mental health care, placing the financial burden on the individual despite health insurance coverage (Melek et al., 2017). The financial cost of care functions as either a barrier to care, a reason for drop out, or an additional burden on a struggling individual.

Availability. Despite the mental health care system being underutilized, there are still not enough available therapists for individuals who are seeking care. Researchers estimate that 13% of individuals report availability as a barrier to care (Mojtabai et al., 2011). Availability concerns impact rural and urban communities in the U.S. differently. Many rural communities do not have mental health care providers despite similar need for care in rural and urban communities (e.g., three fourths did not have a psychiatrist; Gamm et al., 2010). Availability of therapists is also a problem in urban communities where there is a greater need than the number of practicing providers. This often results in individuals being placed on a waitlist before receiving care; one patient-simulated study found that the average time before seeing a psychiatrist was approximately 25 days (Malowney et al., 2014). Regardless of location, lack of availability of mental health providers prevents individuals in need from receiving care.

Lack of Evidence-Based Care. If an individual seeking care is able to overcome attitudinal, and other structural barriers, there is little regulation determining the type of care they receive and whether it is empirically supported. The American Psychological Association (APA) has guidelines for evidence based care, but less than 25% of individuals in treatment receive care

consistent with these guidelines (González et al., 2010). Unfortunately, even these guidelines and standards may be out of date as it takes approximately 17 years for health care research to be translated into clinical care (Morris et al., 2011). And even more concerning, one third of therapists endorse non-empirically supported therapies as part of their theoretical orientation (Cook et al., 2010).

Summary. Structural barriers include cost/financial burden, availability and lack of evidence based care. While not as prevalent as attitudinal barriers, structural barriers continue to impact individuals seeking care. Further, even when individuals are able to overcome other barriers and access care, they are overwhelmingly not receiving evidence-based care.

Current Interventions Accounting for Accessibility

Tele-therapy/E-therapy. Tele-therapy typically refers to traditional psychotherapy interventions that are delivered via telephone or video call and E-therapy is internet based delivery of audio/video/chat functions with a psychologist. Both methods are included here, as they involve interacting with a psychologist/mental health care provider. These interventions appear to be at least equally as effective as in-person therapy for post-traumatic stress disorder, depression and anxiety, though efficacy varies slightly by delivery method, theoretical orientation and population (Barak et al., 2008; Olthuis et al., 2016; Osenbach et al., 2013; Haregu et al., 2015; Coughtrey & Pistrang, 2018). While these interventions are effective, they only fully address some barriers to care, such as difficulties with transportation, only partially address others, such as availability and cost, which may be slightly improved with these interventions, and introduce new barriers to care (e.g., needing access to telephone/internet; Brenes et al., 2011). Additionally, these interventions do not address the most frequently

endorsed barrier to care: wanting to improve on one's own, as these interventions involve direct interactions with mental health care professionals.

Self-Help Web Based Interventions. These interventions involve interacting with web-based services that do not involve direct interaction with a provider. These interventions appear to be equally as effective as e-therapy; however, some of the effects of web-based interventions appear to be enhanced if participants have some interaction with a provider, in addition to access to the web-based intervention (Barak et al., 2008). Web-based interventions do address more barriers to care than e-therapy/tele-therapy, such as cost and availability of providers, as mental health care professionals are not needed; however, it introduces an additional barrier to care: internet services, as only 82% of households in the U.S. have internet access (National Center for Education Statistics [NCES], 2016). Further, more research is needed to determine the full efficacy of stand-alone web-based interventions.

Mobile Applications. These interventions are delivered through smart-phone applications. There are many applications intended to improve mental health on the Android/iOS application stores; however, these are largely untested and there is no single application that would qualify as evidence-based (Lui et al., 2017; Price et al., 2014). Popular applications, such as Headspace, have some short-term evidence when being used regularly, but the effect sizes are small. Further, mobile applications have few long-term effects and have not been consistently tested against traditional psychotherapy or e-therapy/tele-therapy (Flett et al., 2019). Further, while these applications address some barriers to care, such as cost, availability and desire to improve on one's own, they introduce an additional barrier to care: access to a smartphone. Only 81% of American adults own a smartphone (Pew Research Center [PRC], 2019).

Wellness Programs. Wellness programs are usually brief interventions that typically occur in workplace settings or are offered by an individual's workplace. Research on these programs for mental health is lacking and the research that exists offers little support for these programs. For example, a recent review found that there is no evidence for programs focusing on stress management, relaxation, mindfulness or integrated programs (Ivandic et al., 2017; Osilla et al., 2012). Further, substance use and mental health programs are typically the least accessed workplace wellness programs, when they are offered at all (McCleary et al., 2017).

Summary. There have been many attempts to address barriers to mental health care and these novel interventions and delivery methods have improved access in important ways. However, their efficacy largely remains untested and unclear, particularly for mobile applications and workplace wellness programs addressing mental health. This indicates that there is still a need for unique accessible mental health solutions that can provide evidence-based care to more people.

Mood Lifters: A New Solution?

Unfortunately, it does not appear likely that the current mental health care system, or other novel interventions and delivery methods, have the ability to fully address barriers and increase access to care, in their current states. Other solutions that address these barriers are urgently needed. Therefore, clinical researchers developed a new program, Mood Lifters, a series of peer-led group meetings that teach skills from evidence-based psychotherapies and encourages at-home practice through a point system (Votta & Deldin, in preparation). Critical components of the program include the biopsychosocial model, evidence-based skills, accountability, weekly assessments and homework ("points"). Development decisions were made based on the most recent literature on these topics (Álvarez et al., 2012; Babalola et al.,

2017; Smith et al., 2013; Colla et al., 2015; Oussendik et al., 2017; Mohr et al., 2011; Beck, 2011; Hayes et al., 2012; Linehan, 2015; Cugelman, 2013; Brown et al., 2016; Kazantzis et al., 2016). See Votta & Deldin (in preparation) for a more in-depth analysis of the components of the program and its development. Mood Lifters addresses barriers to care in a variety of ways:

Desire for Self-Improvement. The program is designed to *meet people where they are*. Personal goals, measured through a point system, are set by the participant and integration into day-to-day life and at-home practice is the focus of each meeting. Peer leaders guide participants through the program at their own pace, empowering them to make their own changes and improvements.

Stigma. The use of peer leaders is expected to reduce stigma because they too have “been there,” and share their own triumphs as a result of Mood Lifters. This sharing can normalize struggle and provide hope in the face of mental illness for participants. The group setting reinforces this by exposing participants to others who are also looking to improve their lives.

Cost/Financial Burden. Mood Lifters addresses financial barriers by using peer leaders in a group setting. In contrast to individual appointments with professional psychotherapists, peer led group meetings can be offered at a reduced cost to the participant, as both group meetings and peer leaders reduce cost to run the program. Importantly, manualized based treatments implemented by peers are, at least, equally as effective as those treatments implemented by professional clinicians suggesting that the use of peer leaders could be a way to reduce cost without sacrificing effectiveness (Repper & Carter, 2011; Chinman et al., 2014).

Availability. Similar to financial barriers, peer led group meetings also address availability concerns. As peer leaders do not need the years of training required of professional therapists, it increases the availability of potential providers, in addition to reducing the cost of

service. Additionally, each peer leader is able to provide care for an entire group of individuals in one hour compared to an individual setting, where only one person receives care.

Lack of Evidence-Based Care. Mood Lifters meetings cover many systems that impact mental health including biology, cognition, mood, sleep, social and behavior. Each meeting was developed based on recent research and/or adapted from evidence-based treatments such as Dialectical Behavior Therapy, Cognitive Behavioral Therapy, Acceptance and Commitment Therapy, among others (Linehan, 2015; Beck, 2011; Hayes et al., 2012). The modular aspect of the program allows for the quick implementation of new evidence-based content into meetings shortly after it is published. Finally, research shows that homework completion seems to be related to participant improvement in some therapeutic interventions and this is an integral part of the Mood Lifters program (Kazantzis et al., 2016).

Development of and Early Support for the Mood Lifters Program

Dr. Patricia Deldin and her team developed the Mood Lifters program at the University of Michigan. The program was specifically developed to address the many barriers to care described above. The initial structure of the program was based on other peer-led health interventions and included a biopsychosocial approach to mental health, peer leaders, weekly meetings covering relevant topics/skills and a points-based homework system to foster accountability. See Votta & Deldin (in preparation) for a more detailed analysis of the literature and development of the Mood Lifters program. Early stages of development included in-depth literature reviews on skills/topics/interventions known to improve overall mental wellness and development/editing of participant and leader materials. Unique attention was paid to building the “point” system, important for accountability in the program and tracking homework completion over time, by researching relevant “dosage information” in the literature (e.g., 30

minutes of aerobic exercise five times a week) and determining that participants should complete homework across all areas (i.e., sleep, body, social, mind, mood and behavior; Bryne & Bryne, 1993). Finally, the entire team completed the program over eight weeks while rotating in as the leader. See Votta & Deldin (in preparation) for more specific information on the development of the program.

The team conducted two early feasibility studies to determine the feasibility and preliminary efficacy of the program (Votta & Deldin, in preparation). In Study A, participants responded well to the program and study structure. Despite the small sample, there were statistically significant changes in depression and trends towards improvements in emotional experience. Participants provided useful feedback for the program and study structure. In Study B, changes were made to the program to make it more accessible for participants and update materials based on more current research. Again, participants responded well to the program and study structure and provided helpful feedback to further improve the program and study. Outcome data from this study was not significant, but this may have been due to small sample size. Ultimately, the results of these early feasibility studies provided helpful feedback for larger trials and indicated that the program is palatable to participants.

While preliminary data from the feasibility study is promising (Votta & Deldin, in preparation), Mood Lifters had not yet been tested in a randomized control trial (RCT) with a waitlist comparison group. The following study is the semi-randomized control pilot trial for the Mood Lifters program as this type of study is a critical first step in establishing an intervention as evidence-based. Once Mood Lifters is established as an evidence-based intervention, it can be disseminated and improve accessibility to mental health care.

This study aims to examine the preliminary efficacy of the Mood Lifters program by comparing clinical and emotional well-being measures between participants in the Mood Lifters program and participants assigned to a waitlist control condition (Votta & Deldin, in preparation). We hypothesize that participants in the Mood Lifters program will improve on clinical and well-being measures compared to those on the waitlist. Additionally, we hypothesize that treatment effects will be enhanced by homework completion (i.e., “points” earned).

Methods

Participants

Participants were screened for symptoms of mania, psychosis and suicidality. If these were endorsed, participants were contacted by the study team and followed protocols to determine eligibility. Participants were included in these analyses if they attended at least seven meetings of the program in the treatment condition or completed pre-measures as a waitlist participant (i.e., at least half of the program, N = 77 in treatment condition and N = 24 in the waitlist condition). Note: Total sample includes 101 entries, as some participants in the waitlist condition completed a group after their time on the waitlist. The average age on the waitlist was 46.42 years (standard deviation = 15.15 years) compared to 47.04 years (standard deviation = 17.24 years) in the treatment condition. Approximately 83% percent of the waitlist condition identified as female and approximately 74% of the treatment condition identified as female. 75% percent of the waitlist condition identified as Caucasian/White and 82% percent of the treatment condition identified as Caucasian/White. 100% of both groups had at least a high school degree. There were no statistically significant differences in age, sex, race and education between participants in the waitlist and treatment conditions. Note: no demographic information was imputed. Demographic information is presented in Table 1.

Participants did not receive compensation for participating in the groups, but did receive compensation for completing follow up measures at one-month and six-month post group completion (\$20 and \$30 dollars, respectively). Waitlist participants did not complete one-month post group measures and were instead compensated for their initial measures (prior to the start of the waitlist group) and for completing six-month post group measures. 225 participants expressed interest in the study and 121 participants attended at least one meeting of the program. See Figure 1 for the Consort Flow Diagram for more specific recruitment and drop out information (Schulz et al., 2010). This study protocol was approved by a university institutional review board.

Mood Lifters Program & Meeting Structure

The program consists of in-person weekly, group meetings run by a leader who has completed the program as a participant and been trained in the Mood Lifters protocol. Meetings cover a variety of areas relevant to mental health (e.g., biology, cognition, mood/emotion, sleep, social and behavior) and were developed from multiple therapeutic interventions (e.g., Dialectical Behavior Therapy, Cognitive Behavioral Therapy, Acceptance and Commitment Therapy, etc.). The program consists of 15 hour long meetings held once a week. At each meeting, participants complete a brief questionnaire assessing their experiences and emotions from the past week. Additionally, at meetings 2-15, participants submit their “points,” or record of “homework” completed over the week. Participants are encouraged to earn points across a variety of categories as they progress throughout the program (e.g., body, mind, mood, sleep, social and behavior). Participants receive stickers and praise for homework completed. Then, the group leader reviews the topic for the day (e.g., sleep hygiene). The last portion of the meeting consists of a brief discussion of what counts as a “point” for that week’s meeting and planning

time to schedule activities. In the final meeting, participants are given feedback about their progress in the program (i.e., positive changes in individual data pre-to post program). To read more about the program and its development, see Votta & Deldin (in preparation).

Leaders

In this study, all leaders had previously completed the Mood Lifters program including the developers of the program. Leaders were either “peer” leaders, meaning no professional clinical/counseling psychology background or training, or “professional” leaders, meaning having formal psychotherapy training. The determination of “peer” or “professional” Mood Lifters group was made on the type of leader who led the meeting.

Peer leaders were recruited from previous studies of the program or were undergraduate research assistants. These leaders attended an eight-hour long training on clinical skills and Mood Lifters protocol held by a professor of clinical psychology. In total, there were three peer leaders, an undergraduate Psychology student, a stay-at-home mother and an engineer.

Professional leaders included a professor of clinical psychology and three graduate students with temporary limited licenses in psychology (TLLP). At each meeting, there were two trained leaders, although only one leader was responsible for leading the meeting, the other leader was designated as a “helper.” The helper assisted in the collection of weekly measures and answering questions. It is important to note that, in the case of clinical emergencies, there was a professional leader at every meeting, either leading the meeting, or in the case of a peer group, as the helper.

While leading a group, all leaders, professional or peer, were required to follow a “Leader Manual” which outlined how to cover each topic in the meeting, address each page of the “Participant Manual” and lead all participant activities. To ensure treatment fidelity, all

leaders and helpers were required to complete a treatment and leader fidelity checklist at the end of each meeting. The results of the treatment fidelity checklist are reported below.

During the study, leaders attended a one hour group supervision per week held by a professor of psychology. In this supervision, each leader reviewed the previous week's meeting with the other leaders and had the opportunity to troubleshoot any difficulties or struggles with participants. The supervisor also regularly reviewed clinical skills such as reflective listening, open-ended questions, etc.

Treatment/Leader Fidelity. At the end of each meeting, both leader and helper independently rated the meeting using a fidelity assessment created by the Mood Lifters team. The fidelity assessment evaluates both treatment fidelity and leader characteristics. Treatment fidelity was assessed based on the protocol for each meeting described in the "Leader Manual". For treatment fidelity, raters selected either 0, "Not covered", 1, "Reviewed topic as stated in Leader Manual", or 2, "Reviewed topic with participant discussion." Inter-rater reliability for all fidelity assessments for each leader/helper pair ranged from .378-.841, indicating that some leader pairs struggled to define and score participant discussion. For the sake of the analyses included in this dissertation, scores one and above were considered sufficient for establishing treatment protocol. It was not possible to calculate inter-rater reliability for this modified data set, as the majority of meetings included either a leader or helper whose scores were constant (e.g., selected "1" across all items for that meeting). Total score for each meeting was summed for each rater and a final score was computed by averaging the leader's and helper's ratings for that meeting. When data was missing (e.g., raters missed a question), the other rater's score was used to fill in missing data. If both ratings for an item were missing, they were both given a score of 0. These meeting fidelity scores were then averaged across all groups in the study for a final

percentage score. The range of average adherence to the treatment across the fifteen meetings was 97.51%-100.00%, indicating high treatment fidelity across the fifteen meetings. See Table 2 for average treatment fidelity scores for all fifteen meetings.

Both leaders and helpers also rated the leader's clinical characteristics at each meeting. This included engagement, pacing, openness and responsiveness to participant questions, and empathetic responding. These were rated on a 0, "Absent," or 1, "Sufficient," scale. Average leader fidelity scores were generated by averaging the two rater's scores for a meeting and then averaging these scores across groups in the study. The range of average leader fidelity scores was 90.77%-100.00%, indicating that leaders exemplified important clinical characteristics throughout the study. See Table 2 for average leader fidelity scores across the study. Note: The group that was closed was not included in treatment or leader fidelity scores.

Measures

Participants completed a series of questionnaires covering clinical symptoms, positive and negative affect, coping and emotion regulation skills, physical and social functioning, and drug and alcohol use. These measures took approximately one to two hours. The measures described below are those measures pertinent to this study, either as screening or outcome measures.

Altman Mania Scale (AMS). The AMS is a five-item screening questionnaire assessing for mania (Altman et al., 1997). The research study team contacted participants if they scored greater than five on the AMS. Researchers who developed this measure report an 85.5% sensitivity and 87.3% specificity at a cutoff of five for identifying active mania (Altman et al., 1997). The validation paper reports good internal reliability, reporting a Cronbach's α of .65-.79 (Altman et al., 1997).

Community Assessment of Psychic Experiences (CAPE). The CAPE is a 42-item screening measure that assesses a variety of psychotic symptoms (Mossaheb et al., 2012). The Mood Lifters team modified the CAPE to assess positive symptoms that may indicate a need for a higher level of care or that the participant may be disruptive to a group. Based on a participant's profile of responses, clinical staff made decisions about contacting participants in order to assess symptoms more clearly and gather more information about eligibility. Participants were immediately contacted if they endorsed any type of hallucination.

Patient Health Questionnaire-9 (PHQ-9). The PHQ-9 is a nine-question sub-measure from the Primary Care Evaluation of Mental Disorders (PRIME-MD) which was designed to evaluate clinical levels of depressive symptoms (Spitzer et al., 1999). This measure suggests cutoffs at 5, 10, 15, and 20, indicating mild, moderate, moderately severe and severe depression, respectively. This measure shows good internal reliability, with the validation paper reporting a Cronbach's α of .86-.89 (Kroenke et al., 2001). In the non-imputed data, the Cronbach α was .85 at Time 1 and .80 at Time 2. The ninth item on the PHQ-9 evaluates suicidal ideation. This item was a screening item for the study. If participants endorsed any level of suicidality, they were contacted by a study team member, who followed the team's suicide assessment protocol.

Generalized Anxiety Disorder-7 (GAD-7). The GAD-7 is a seven-question brief survey used to detect clinical levels of generalized anxiety symptoms (Spitzer et al., 2006). This measure has three "cut-off" points at 5, 10 and 15 indicating mild, moderate and severe anxiety, respectively. The GAD-7 shows great internal reliability; the validation paper reports a Chronbach's α of .92 (Spitzer et al., 2006). In the non-imputed sample, the Cronbach α was .87 at Time 1 and .91 at Time 2.

Perceived Stress Scale (PSS). The Perceived Stress Scale is a 10-item measure that examines a respondent's perception of their stress level (Cohen et al., 1983). Research suggests that increased perceived stress is related to physical and mental health difficulties. The PSS shows good internal reliability with the validation paper reporting a range of Chronbach's α of .84-.86 (Cohen et al., 1983). In the non-imputed data for this study, the Cronbach α was .89 at Time 1 and .88 at Time 2.

Study Design

Participants were recruited through online postings on Facebook, Craigslist and UM Health Research sites. Recruitment started after previous pilot studies in December 2017 and lasted through September 2018. Interested participants were instructed to email the study coordinator for more information and the link to a consent form, screening questionnaire and availability form. After participants consented, they were screened via online questionnaire for active suicidality, mania and psychosis. If participants endorsed any of these symptoms, a research assistant, trained in the screening protocol, would speak to the participant on the phone regarding these symptoms. If participants were endorsing active hallucinations, delusions or active manic symptoms, they were referred to other resources and excluded from the study. Participants who endorsed suicidal ideation were assessed for active risk. If participants were deemed an active risk, the principal investigator of the study was immediately notified and participants were referred appropriately and excluded from the study. If participants endorsed passive suicidal ideation or were not an active risk, they were given information and encouraged to seek other resources, but were included in the study. See Figure 1 for Consort Flow Diagram (Schulz et al., 2010).

Eligible participants were then sent baseline measures via Qualtrics. Upon completion of the measures, participants were randomly assigned to one of three conditions (i.e., Mood Lifters groups run by professionals, Mood Lifters groups run by peers and a waitlist control condition). If participants were available for only one group in their assigned condition, they were assigned to that group. If they were available for multiple groups in their assigned condition, they were randomly assigned to the available groups. If they were randomly assigned to one of the two treatment groups, and could not attend any of the groups within the condition (peer or professional) they were assigned, they were assigned to a group in the other active treatment condition (peer to professional = 19, professional to peer = 16). Randomization followed this process until groups were full. This process was replicated for newly recruited eligible participants for each of the three rounds of groups that were run for the study. At the end of the active treatment groups, the participants from the waitlist were randomly assigned to one of the two treatment conditions (i.e., peer or professional). Some waitlist participants did not respond to follow up and did not complete the groups (only 18 participants completed waitlist measures and went on to be part of the groups). See Consort Flow diagram for additional information on randomization (Schulz et al., 2010).

Participants attended 15 group “meetings” that covered a variety of topics known to improve mental health. Each meeting lasted approximately one hour and participants were encouraged to engage in homework activities outside of the meeting. Homework activities were tracked using Mood Lifter’s “points” (e.g., 30 minutes of aerobic exercise equals one “body” point). At the end of each meeting, both the leader and the helper completed fidelity assessments created by the Mood Lifters team to ensure treatment fidelity.

Participants completed the same measures after the 14th meeting and received feedback on these measures in their final meeting. Participants were contacted to complete follow-up measures at one month and six months post completion of the group and were compensated for time spent on these measures. Thus, participants each completed the measures four times (pre, post, one month, six month). Waitlist participants did not complete measures at one month post group, instead they were compensated for completing their initial measures (i.e., 20 dollars). They also completed the six months post group measures and were compensated 30 dollars, so that all participants received equal compensation for their participation (i.e., 50 dollars).

Data Analysis Plan

Preliminary analyses included reviewing averages of pre-and post-scores across treatment and waitlist conditions. Additionally, researchers examined the number of participants above clinical cutoffs for clinical measures at pre-and post-time points, the number of participants who changed clinical categories and the number of participants with either 25% or 50% symptom reduction. Change scores were also created for each measure by subtracting pre-from post scores.

Due to drop out from the groups, and subsequent loss to follow up, multiple imputation was used to address missing data in this study as data was not missing completely at random, and, therefore, complete case analysis may be biased (Royston, 2004; Schafer, 1999). Research suggests that multiple imputation is a sound way of addressing missingness in clinical trials with less than 40% missing data (Jakobsen et al., 2017). Missing change score data was imputed from independent variables (i.e., Time 1 data (T1), demographic information, group information). Variables contained less than 17.82% missing data (note: this was the maximum missing data for any one variable). Missing data was due to attrition. Following recommendations by Graham et

al. (2007), 20 data sets were imputed and simultaneously analyzed. Regression coefficients and standard errors were averaged across all models following standard procedures (Royston, 2004). The process converged after 34 iterations.

Multiple linear regressions were calculated to determine whether participation in the Mood Lifters program predicted change scores. Additional regressions were calculated to determine whether total points earned across the program (i.e., homework completed) also predicted change scores. All linear regression models included T1 score for the outcome measure, to control for their score at baseline.

Results

Completed Case Analyses

Means. For completed waitlist cases (N= 22), at Time 1, the average PHQ-9 and GAD-7 score was above the cutoff for “mild” depression and below the clinical cutoff for generalized anxiety, respectively. For completed cases in the treatment condition (N= 62), average score for both measures were above the “mild” clinical cutoff. At Time 2, for the waitlist condition, the average PHQ-9 scores continued to be in the mild range, while the GAD-7 average also raised above the “mild” clinical cutoff. For the treatment group, PHQ-9 average score remained in the “mild” depressive range, while GAD-7 average score was below the clinical cutoff for anxiety symptoms. These same patterns occurred for the multiply imputed means except for T1 GAD-7 score for the treatment condition, which was below the “mild” cutoff, and T2 GAD-7 score for the treatment condition, which also remained in the “mild” range. See Table 3 for means.

Clinical Improvements. Preliminary analyses included reviewing completed participant clinical data to examine how participants improved across groups. For anxiety symptoms, 41.94% of the treatment condition moved down at least one tier of severity compared to 4.55%

of the waitlist condition (e.g., moved from “moderate” to “mild” anxiety). This was a significant difference in a Chi-Square test ($p = .001$). Further, 27.42% of the treatment condition saw at least a 50% improvement in anxiety symptoms compared to 4.55% of the waitlist condition. A Chi-Square test also suggested that this was significant ($p = .025$). While a greater percentage of participants in the treatment condition moved down a tier in depression severity compared to the waitlist condition (e.g., moved from “moderate” to “mild” depression), this difference was not significant in a Chi-Square test ($p = .176$). Similar to the results for depression, a larger percentage of the treatment condition saw a 50% reduction in depression symptoms than the waitlist condition; however, this result was not significant in a Chi-Square test ($p = .335$). See Table 4 for counts.

Treatment Effects

A linear regression model, with treatment condition and GAD-7 T1 score predicting GAD-7 change scores was significant ($F(2, 79.8) = 11.90, p < .001, R^2 = .245$). There was a main effect of treatment condition, such that individuals in the treatment condition had a greater change in GAD-7 score than participants in the waitlist condition ($p = .002, R^2 = .129$). A second linear regression model, with treatment condition and PHQ-9 T1 score predicting PHQ-9 change scores was also significant ($F(2, 80.2) = 16.02, p < .001, R^2 = .302$). There was no significant effect of condition ($p = .196$). Finally, a linear regression model, with treatment group and PSS T1 score predicting change in PSS scores, was also significant ($F(2, 91.8) = 13.95, p < .001, R^2 = .245$). There was no significant effect of condition ($p = .174$). See Table 3 for means.

“Homework” Effects

In order to examine the effect of homework, through points, we completed similar regressions predicting change in GAD-7, PHQ-9 and PSS scores. First, when points earned in the

program and T1 GAD-7 scores were used to predict change in GAD-7 scores, the model was significant ($F(2, 87.8) = 13.14, p < .001, R^2 = .244$). Individuals who earned more points across the program had greater change in GAD-7 scores after the program; this was significant ($p = .001, R^2 = .139$). Another regression, with points earned across the program and T1 PHQ-9 scores predicting the change in PHQ-9 score, was also significant ($F(2, 86.1) = 17.77, p < .001, R^2 = .308$). Again, when participants earned more points, they saw a greater change in PHQ-9 scores; this effect trended towards significance ($p = .088, R^2 = .026$). Finally, a model with points earned across the program and T1 PSS scores predicting change in perceived stress scores, was also significant ($F(2, 94.8) = 16.01, p < .001, R^2 = .260$). Similarly, to both PHQ-9 and GAD-7 scores, participants who earned more points saw a greater change in perceived stress; this effect was significant ($p = .048, R^2 = .029$). See Table 3 for means.

Retrospective Power Analyses

While the findings for reduction of anxiety symptoms are strong, it may be the case that the study was underpowered for the program's impact on depressive symptoms and perceived stress. Thus, retrospective power analyses were conducted to assess the level of power in the study.

Treatment Effects. Based on the current sample statistics, the achieved power for Mood Lifter's effect on depressive symptoms was .42, suggesting that this study did not have sufficient power to assess the effect of the Mood Lifters program on depression symptoms. Further, the achieved power for Mood Lifter's effect on perceived stress was .37, again suggesting that the study did not have sufficient power to assess the effect of the Mood Lifters program on perceived stress.

“Homework” Effects. The achieved power for “homework”, or points earned across the program, effects on depressive symptoms was .38. This suggests that the study was again too underpowered to detect the effect of points earned across the program on depressive symptoms.

Discussion

Based on the results of this preliminary semi randomized control trial, Mood Lifters appears to make an impact on clinical symptoms and other measures related to emotional well-being despite not selecting for a clinical sample and/or screening for comorbidity or suicidality. First, compared to the waitlist condition, a greater percentage of Mood Lifters participants improved on anxiety measures and saw a 50% reduction in anxiety symptoms. Further, participating in the Mood Lifters program led to a statistically significant decrease in anxiety symptoms. However, there were no statistically significant changes in depressive symptoms or perceived stress based on group assignment. Finally, it appears that “homework” completion through the Mood Lifters point system is important for change over the course of the program as points completed leads to a statically significant change in anxiety symptoms. Notably, despite being underpowered, homework completed was significantly related to perceived stress change and trended towards significance for depressive symptoms. Taken together, these results suggest that attending a Mood Lifters group had an impact on anxiety symptoms, and that actively participating in the program, through homework, led to additional changes in perceived stress and depressive symptoms.

There are few other programs effectively addressing accessibility. Thus, it is most appropriate to compare Mood Lifters to other accessibility alternatives such as self-help based web interventions, mental health mobile applications and wellness programs, rather than traditional psychotherapy. Of these, self-help based web interventions seem to have the strongest

evidence in support of their effectiveness, compared to mobile apps, with limited research, and wellness programs, with limited supporting evidence. While there is significant existing literature on e-therapy/web based therapy, there is limited research on mental health mobile applications, with studies and reviews citing that more evidence is needed (Lui et al., 2017; Price et al., 2014). The most appropriate comparison is likely with workplace wellness programs, as these are the only accessibility options that include in-person interactions. Unfortunately, again, these programs have limited evidence to support them and more research is necessary (Ivandic et al., 2017). Overall, Mood Lifters adds to this accessibility literature with an in-person accessibility alternative that has impressive results for reduction in anxiety symptoms, even though more research is necessary to determine its effect on depressive symptoms and perceived stress.

While most clinical trials examine changes based on assignment to treatment condition, this study expanded the definition of participation by looking at participant engagement in the Mood Lifters program. Participants tracked completed homework, based on the mental-wellness topics covered in the weekly meeting, throughout the program using Mood Lifter's "points." By tracking these, investigators are able to examine how much behavioral change and skills use is occurring outside of the weekly meetings. This is important because studies show that, not only is attendance important for improvement, engagement outside of therapy sessions or meetings through "homework" also predicts treatment change and long-term improvements (Kazantzis et al., 2016; Kazantzis et al., 2000). Results from this study are similar to what is in the existing literature, specifically that there is a small effect of homework completion on treatment outcome (Mausbach et al., 2010). This suggests that it is not only treatment group that predicts change upon completion of the program, it is also "points," or engagement in the program. This is true

for anxiety and for perceived stress for the Mood Lifters program. Importantly, for perceived stress, treatment condition alone did not predict improvement, rather, improvement was predicted by engagement in the program. There was a trend to suggest that this may also be the case for depressive symptoms. This provides additional support that engagement outside of regular meetings is an important mechanism for change in therapeutic interventions.

One finding from this study, across both intervention and homework effects, is that Mood Lifters shows greater benefit for anxiety symptoms compared to depressive symptoms. Interestingly, other accessibility alternatives, such as web-based interventions and mobile applications, are more effective for anxiety compared to depressive symptoms, which mirrors the findings of this study (Barak et al., 2008). It may be the case that, similar to other interventions, Mood Lifters shows reduced effects for depressive compared to anxiety symptoms. However, it is important to note that analyses for depressive symptoms were underpowered, and, if the study was sufficiently powered, there may simply be a smaller effect for depression compared to anxiety.

While this study has many strengths, there are limitations. These limitations include a predominantly white and female sample, due to the location of the study and help-seeking populations. Future studies should examine the effects of the Mood Lifters intervention in more racially/ethnically diverse samples and in samples with more men. Additionally, participants in this trial had to be assigned to a different condition due to scheduling conflicts. A larger study with more concurrent groups could support a design that would allow for true randomization eliminating any possible effects of scheduling. Further, participants in our sample were not selected for any type of mental health difficulty or disorder. In fact, many participants who were included did not reach above the “mild” threshold for either generalized anxiety or depressive

symptoms. It is important to note that this was intentional, as Mood Lifters was not intended for a specific population or mental illness. However, this may have weakened the findings across the entire program, as people with lower scores may make less improvement overall. Additionally, it is not possible to complete an intent-to treat analysis as participants were lost to follow up and no additional data was collected after drop out.

The most pressing limitation of the study is the limited sample size. Researchers completed several “rounds” of groups during the duration of the study in order to reach a sufficient sample size. However, due to drop out and scheduling conflicts, the final sample size of the study was smaller than anticipated. Retrospective power analyses suggest that the study was underpowered for various questions (i.e., effect of treatment condition on perceived stress and depressive symptoms, and effect of homework on depressive symptoms,.37-.42), which is far below the recommended threshold of .80 (Cohen, 2013). An effort was made to correct this using statistical methods such as multiple imputation, but a larger study should explore the impact of Mood Lifters as this may have been a reason for the non-significant and marginally significant findings. A larger study would allow for a better analysis of the effects of the program for depressive symptoms and perceived stress. Additionally, a larger study could incorporate other suggestions (e.g., concurrent group times for different treatment conditions, over-sampling participants with high levels of depressive/anxiety symptoms).

Mood Lifters was designed to be a more accessible low-cost mental health intervention option. Thus, researchers found it imperative to implement this intervention in the public as soon as possible to increase accessibility to evidence-based mental health care. Based on the efficacy of the current trial, Mood Lifters is currently being offered in a variety of settings (e.g., organizations, direct to consumer). Future analyses of the current study will include a more in-

depth examination of the impact of points on clinical and emotional well-being measures as well as determining predictors of who succeeds in the program. Other analyses will address whether there is a difference in efficacy of the program for groups led by peer leaders compared to professional leaders. Additionally, the Mood Lifters team has begun to develop other iterations of the Mood Lifters program aimed at specific populations such as children, teenagers and seniors as well as specific clinical populations such as individuals with bipolar disorder and schizophrenia.

In conclusion, this study shows continued support for the feasibility, acceptability, and efficacy of the Mood Lifters program. It also offers a potential solution for many of the barriers to evidence-based mental health care by using peer leaders in a manualized group format. Finally, and of particular importance, it promotes autonomy and engagement by utilizing regular check-ins and a points system to help participants improve their own lives and get better on their own.

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Table 3.1***Demographic information for Mood Lifters semi-randomized control trial***

	Treatment	Waitlist
Age (SD)	47.04 (17.24)	46.42 (15.15)
Sex		
Male	20	4
Female	57	20
Race		
American Indian/Alaskan Native	0	0
Asian	7	3
Black/African American	3	0
Native Hawaiian/Pacific Islander	0	0
White	63	18
More than one race	3	2
Education		
Graduated High School	3	0
Some College (including Associate's Degree)	15	4
Bachelor's Degree	34	11
Graduate Degree	24	9

Note. One participant from the waitlist and one participant from the treatment condition declined to enter their race. One participant from the treatment condition declined to enter their education.

Table 3.2***Average treatment and leader fidelity scores per meeting***

	Treatment Fidelity	Leader Fidelity
M1	98.32%	92.31%
M2	99.18%	96.92%
M3	100.00%	100.00%
M4	99.18%	96.92%
M5	99.18%	100.00%
M6	99.29%	100.00%
M7	97.51%	90.77%
M8	99.55%	93.85%
M9	100.00%	99.23%
M10	98.08%	100.00%
M11	99.62%	100.00%
M12	98.46%	96.15%
M13	99.74%	97.69%
M14	99.52%	95.38%
M15	99.31%	100.00%

Note. The group that was closed was not included in treatment or leader fidelity score averages.

Table 3.3

Means and standard deviations for PHQ-9, GAD-7 and PSS scores for both complete cases and multiply imputed data sets

	Completed Cases			Multiple Imputation		
	PHQ-9	GAD-7	PSS	PHQ-9	GAD-7	PSS
	Treatment					
T1	7.683 (5.041)	5.714 (4.640)	17.556 (7.754)	7.416 (5.749)	4.680 (4.149)	17.809 (4.664)
T2	6.222 (4.794)	4.016 (4.018)	15.548 (7.528)	5.359 (4.089)	5.232 (4.098)	18.098 (7.942)
	Waitlist					
T1	6.727 (5.582)	4.591 (3.838)	17.091 (7.565)	5.266 (3.419)	3.219 (2.722)	13.094 (5.795)
T2	7.091 (4.242)	6.273 (5.767)	17.909 (5.673)	7.091 (4.242)	6.273 (5.767)	17.909 (5.673)

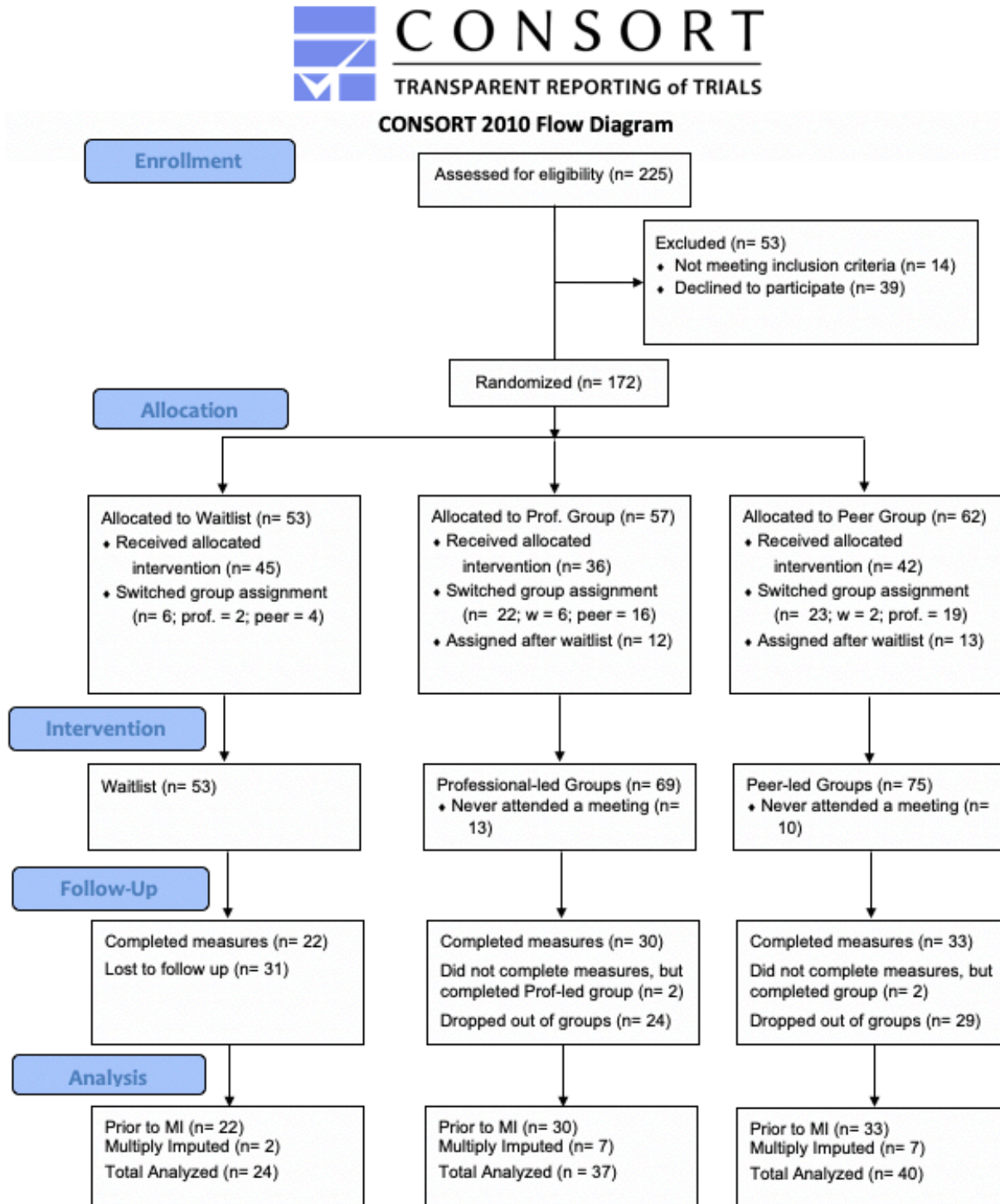
Table 3.4

Percentages for Chi-square tests comparing treatment conditions for 50% reduction in symptoms and moving down severity tiers for the GAD-7 and PHQ-9

	GAD-7		PHQ-9	
	Treatment	Waitlist	Treatment	Waitlist
50% Reduction in Symptoms	27.42%	4.55%	17.74%	9.09%
Moved Down At Least 1 Tier	41.94%	4.55%	38.71%	22.73%

Figure 3.1

Consort Flow Diagram of Recruitment



CHAPTER IV: Examining the Efficacy of Peer Leader in the Mood Lifters Program

Introduction

In 2016, the National Institute of Mental Health (NIMH) found that 44.7 million adults in the United States (U.S.) suffered from a mental illness (2017). They also found that since 1999, the suicide rate has increased by 28% (NIMH, 2018). Despite the need for mental health care that these statistics suggest, research has found that only 43% of individuals suffering from a mental illness received treatment in the last year (NIMH, 2017). This gap is likely due to barriers individuals experience when trying to seek care, like cost of service and availability of providers (Andrade et al., 2014; Mojtabai et al., 2011). One potential solution to some of these barriers is to develop group interventions and/or interventions delivered by paraprofessionals. However, determining whether paraprofessionals are as effective as trained psychotherapists is necessary prior to the implementation of such interventions.

The U.S. has the highest rates of endorsement for structural barriers, such as cost and availability, in comparison to other high-income countries (Andrade et al., 2014). In an American sample, 29% of those with serious mental illness and 9% of those with moderate or mild mental illness endorsed structural barriers to care; comparatively, the New Zealand sample, with the next highest endorsement of structural barriers out of the high-income countries, had only 16% of those with serious mental illness and 4% of those with moderate or mild mental illness reporting structural barriers. It is clear that structural barriers cause difficulty for a significant number of individuals seeking care in the U.S.

Cost

Financial barriers, a type of structural barrier, pose a significant concern for individuals seeking care in the U.S. with one study reporting that 15% of Americans endorsed financial barriers (Mojtabai et al., 2011). Mental health care in the U.S. is costly and the burden falls primarily on the individuals receiving care. Mental health care costs an average of 340 dollars for one “episode of care” in the U.S. (on average seven sessions; Crane & Payne, 2011). To reduce the burden, recent health insurance laws have required that mental health care coverage be included in health insurance plans. Unfortunately, despite attempts to increase coverage, data suggests that individuals still receive out-of-network mental health care at a higher rate than out-of-network physical health care (Melek et al., 2017). Taken together, even with health insurance improving coverage, mental health care is still too costly for many individuals and prevents them from accessing needed care.

Availability/Accessibility

Availability or accessibility of care, another structural barrier, also impacts access in the U.S. with one study reporting that 13% of Americans endorse this as a barrier (Mojtabai et al., 2011). Population level research in this area notes that nearly 20% of the counties in the U.S. lack adequate services by non-prescribing clinicians (e.g., social worker, psychologist); further, almost all the counties in the U.S. lack adequate services by prescribing clinicians (e.g., psychiatrists, 96%; Thomas et al., 2009). While availability/accessibility impacts the entire country, this problem impacts rural and urban areas differentially. Unfortunately, the majority of “small rural counties” do not have a psychiatrist and only half have a master’s or doctoral level psychologist (Gamm et al., 2010). This is not due to a decreased need for care as need is similar in both rural and urban communities. Further, rural communities actually have an increased

suicide rate compared to their urban counterparts (Gamm et al., 2010). Availability/accessibility is also problematic in urban communities where there are more providers, but also increased need due to population size. In these communities, there may not be appointments available and individuals seeking care may be more likely to be put on a waitlist. One patient-simulated study found that the average wait list time for a psychiatrist appointment was 25 days (Malowney et al., 2014). Based on these findings, it is clear that availability/accessibility of care is a significant problem across the U.S.

What Do We Do?

Reducing these structural barriers to mental health care would increase access to care substantially within the United States. One way of reducing both of these barriers is by utilizing trained peers/peer support, or as defined by Solomon (2004, p. 393): “social emotional support, frequently coupled with instrumental support, that is mutually offered or provided by persons having a mental health condition to others sharing a similar mental health condition to bring about a desired social or personal change.” Many wellness programs have successfully used peer support to promote and guide behavioral change. For example, Weight Watchers uses former members to lead current members in their weight loss journey. Outside of the realm of physical health, peer support has also been used successfully in a number of mental health care support groups (e.g., Alcoholic Anonymous, Depression Bipolar Support Alliance). The use of peer leaders instead of professional leaders reduces cost and increases availability as peer leaders are hired at a lower salary and do not require the years of training involved in becoming a mental health professional.

Empirical research suggests that individuals working with peers gain additional benefits compared to individuals working with traditional care providers. In a review of the empirical

literature on the benefits of peer support, Repper & Carter (2011) found that individuals receiving peer support reported increased empowerment, self-esteem and self-confidence across program and population types, including veterans and individuals with severe mental illness. They also found that many studies reported that individuals in care with peer helpers had increased empathy, feelings of acceptance and validation. And in direct comparison with treatment as usual, by professional psychotherapists, Sells et al. (2006) reported that individuals receiving care delivered by peers had more feelings of being understood, accepted and liked than individuals receiving care delivered by professionals. Additionally, individuals receiving care delivered by peers often report increased social support, social functioning and hope (an important protective factor for suicide risk) and reduced negative attitudes towards individuals with mental illness (i.e., stigma; Repper & Carter, 2011; Kovacs et al., 1975). Both theoretically and empirically, peer helpers seem to confer benefits to their clients that go beyond what is provided by traditional psychotherapists.

However, this leaves an important question: do individuals receiving mental health care from peer helpers see improvements in clinical symptoms and impairment? Do they improve as much or more than individuals receiving care from traditional therapists? Reviews on peer delivered mental health care suggest that studies report mixed results (Repper & Carter, 2011; Chinman et al., 2014). Mixed findings from these reviews appear to be a result of inconsistent definitions of peer support/intervention, differences in experimental conditions and sample differences. For example, several studies continued care as usual and the conditions under study were individuals receiving traditional care who had adjunct peer connection and those without a peer connection. Other studies included treatment as usual with lodging run by peers.

Despite differences in the studies examining peer support, there is tentative evidence for the efficacy of peer support groups and interventions. Broadly, no studies found any significant differences in efficacy between conditions facilitated by peers and professionals (Clarke et al., 2000; Solomon & Draine, 1995a; Solomon & Draine, 1995b; Pfieffer et al., 2011). Further, when narrowing the sample to depression, it appears that peer support groups are more effective than usual care and equally as effective as CBT group interventions (Pfieffer et al., 2011). Overall, reviewed studies suggested that individuals in peer care saw improved symptomatology, reduced in-patient hospital stays and improved functioning. However, very few studies addressed identical interventions delivered by peers compared to professionals.

Importantly, for the context of this study, in studies of “peers delivering curricula,” findings were consistent in showing that peer-led curricula programs were more effective than treatment as usual (i.e., Wellness Recovery Action Plans, Building Recovery of Individual Dreams and Goals, Health and Recovery Peer; Chinman et al., 2014). Unfortunately, the investigators in each randomized control trial of these programs were unable to distinguish the efficacy of the program from the efficacy of the peer-leaders as the program was not tested with other leader types (e.g., trained mental health professionals). Ultimately, both reviews determined that peer delivered mental health services (across type of service) are at least as effective as non-peer delivered services; although, both advocated for more research on peer delivered interventions (Repper & Carter, 2011; Chinman et al., 2014).

Mood Lifters, a peer-based low-cost mental health intervention, was developed in order to reduce barriers to mental health care and improve accessibility to efficacious evidence-based care. Mood Lifters utilizes effective components of psychological and behavioral health interventions including a biopsychological model, evidence-based skills, homework (through a

“points” system), weekly assessments, and accountability to create a holistic personalizable and accessible mental health intervention (Álvarez et al., 2012; Babalola et al., 2017; Smith et al., 2013; Colla et al., 2015; Oussendik et al., 2017; Mohr et al., 2011; Beck, 2011; Hayes et al., 2012; Linehan, 2015; Cugelman, 2013; Brown et al., 2016; Kazantzis et al., 2016). See Votta & Deldin (in preparation) for a more detailed analysis of the literature and more information on the development of the program. In prior studies, researchers found that the Mood Lifters program was feasibly implemented and improved participants’ symptoms when compared to a waitlist control group (Votta & Deldin, in preparation; Votta et al., in preparation). In the RCT for the program, groups were led by either clinically trained leaders (i.e., licensed graduate students in a clinical psychology program or a psychologist) or peer trained leaders (i.e., individuals who had previously been through the program, improved their symptoms and been trained in the Mood Lifters Protocol). However, researchers have not yet examined the difference in participant symptom improvement between the peer and professional conditions. The following study will examine the differences between the three types of leader assignment (i.e., peer, professional and waitlist conditions) and examine post-hoc comparisons between conditions to determine if peer-leaders are equally as or more effective than professional leaders. Based on the literature of other peer-based programs, we expect that participants in the peer led groups will improve as much or more than participants in professionally led groups and that both groups will improve compared to the waitlist condition.

Methods

Participants

Participants were recruited using online postings on Facebook, Craigslist and UMHealthResearch. Recruitment flyers were also posted in the community. 225 participants

expressed interest in the study and 121 participants attended the first meeting of the program. Participant loss was due to non-response after initial interest emails and screening out due to ineligibility. Participants were screened out after phone interview with a team member, who called if screening items assessing mania, psychosis or suicidality were endorsed (more information below). This analysis includes individuals who attended at least seven meetings or more (i.e., more than half of the program). 37 participants were in “professional” groups, 40 participants were in “peer” groups and 24 participants served as the waitlist control condition. These waitlist participants were randomized into a treatment condition upon completing their waitlist period. There were no statistically significant differences in demographics between conditions. Demographic information is presented in Table 1. See Figure 1 for the Consort Flow Diagram and more information on recruitment and drop out (Schulz et al., 2010). Participants were not compensated for participating in each weekly Mood Lifter meeting. However, they were compensated for completing online measures at one month and six months post group (\$20 and \$30, respectively). Participants were also reimbursed for weekly parking for the meetings. Note: one group closed during the entire study; this group was led by a “professional” leader. The study protocol was approved by the University of Michigan Institutional Review Board.

Mood Lifters Program

The Mood Lifters program is a 15-week low-cost evidence-based mental health program as described in Votta & Deldin (in preparation). Participants attend one-hour weekly meetings on a variety of topics found to improve mental health. They are encouraged to earn “points” between meetings to practice what they learn throughout the program. At each meeting in the program, participants complete a brief online “check-in” measure to assess their mood in the past week. In all meetings after the first meeting, participants also submit a record of their completed

“points” for the week, or homework they completed between meetings. Participants earn points across a variety of categories as the program continues and more information is presented in the meetings (i.e., body, mind, mood, sleep, social and behavior). Participants are rewarded for completing homework in different categories by receiving stickers and praise from leaders. Then, the meeting leader reviews the psychoeducation content for the meeting and engages participants in any related activities. Finally, participants are encouraged to schedule homework activities for the week. Before the final meeting, participants complete the post-measures for the group, and, in the final meeting, participants are given feedback on their progress throughout the program. To read more about Mood Lifters, see Votta & Deldin (in preparation) and/or Votta et al. (in preparation). Note: In this study, groups were run by a leader who was either clinically trained or a paraprofessional peer trained in the Mood Lifters protocol (i.e., “professional” versus “peer”).

Leaders

Mood Lifters “peer” leaders were previous members of the pre-pilot Mood Lifters group as described in Study A of Votta & Deldin (in preparation) or undergraduate research assistants. After reducing their symptoms and successfully completing the program, they were asked if they would be interested in being peer leaders for the program moving forward. No “peer” leaders had formal clinical psychology training. The peer leaders included a stay at home mother, an undergraduate psychology student and an engineer. Mood Lifters “professional” leaders were the developers of the program, including a professor of clinical psychology and graduate students in a clinical psychology program. All “professional” leaders had some formal clinical psychology training.

In addition to completing the program, all leaders, both “professional” and “peer” completed an 8-hour long training that included presentations and activities on basic clinical

skills, skills on how to manage groups and a thorough suicide and risk assessment and training. The training was developed and led by a professor of clinical psychology who is also the director of clinical training. In addition to the day-long training, leaders and helpers were provided with a “Leader Manual” that they were to follow for every meeting. This manual included a chapter for every meeting in the 15-week program. It included three main points to convey to participants for that meeting, frequently asked questions with evidence-based answers, a word for word script of a sample meeting, and a bullet point review with screen shots of the participant materials to use as they were leading the meeting. Leaders were also instructed to consider the references included in the manual and ask for additional readings provided by the developers of the program, if necessary.

Each meeting included two trained leaders; however, only one leader was responsible for leading the meeting. The other leader was a “helper” who assisted in setting up the meeting, collecting participant materials, and answering participant questions, etc. The helper was also there to assist in the case of any clinical emergencies. The determination of a “peer” or “professional” Mood Lifters group was made based on the type of leader who was responsible for leading the group.

During the study, leaders attended a weekly supervision meeting led by a professor of clinical psychology. This supervision provided leaders with an opportunity to review clinical skills, ask questions and troubleshoot difficulties. During the meetings, leaders were required to follow along a “Leader Manual” which addresses how exactly the meetings should be led and how participants should be guided through content and activities. At the end of each meeting, leaders and helpers completed a fidelity assessment to evaluate treatment and leader fidelity. Specifics on leader fidelity will be discussed and examined below.

Leader Fidelity. Each leader and helper rated each meeting using a fidelity assessment specific to the Mood Lifters protocol and program. This assessment evaluated both treatment fidelity and leader characteristics. Treatment fidelity was assessed through self-report of the leader and helper on whether target activities/discussions in the leader manual occurred during the meeting as outlined in the manual. Leader fidelity questions briefly assessed important clinical characteristics of the leader (e.g., warmth, openness to questions). Inter-rater reliability for all fidelity assessments for each leader/helper pair ranged from .378-.841. This that some pairs had difficulty identifying additional participant discussion or the definition was poor. For the sake of the analyses included in this paper, scores one and above were considered sufficient for establishing treatment protocol. Unfortunately, we were unable to estimate inter-rater reliability for the modified data set, since many meetings included either a respondent whose scores were constant (e.g., selected “1” across all items). The range of average adherence to the treatment across all meetings and groups was 97.51%-100.00%. This indicates high treatment fidelity. The range of adherence to important leader characteristics was 90.77%-100.00% across the study indicating sufficient adherence to clinical characteristics for all leaders. See Table 2 for average treatment and leader fidelity scores for each meeting. Note: the closed group was not included in the calculation of these scores.

Measures

As described above, participants completed several questionnaires at the beginning and end of the program covering clinical symptoms, affect, emotion regulation and coping skills, physical health and other measures. Measures also included screening items. Participants completed these measures in about one to two hours.

Altman Mania Scale (AMS). The AMS includes five items for assessing manic symptoms and can reliably be used as a screening measure (Altman et al., 1997). Previous research indicates an 85.5% sensitivity and 87.3% specificity at a cutoff of five. Research team members contacted participants who scored greater than five and followed protocol to assess for eligibility. The validation paper reports that the AMS shows adequate internal reliability, with a Cronbach's α of .65-.79 (Altman et al., 1997).

Community Assessment of Psychic Experiences (CAPE). The CAPE is a 42-item screening measure that assesses a range of psychotic symptoms (Mossaheb et al., 2012). This study used a modified CAPE that was shortened and focused on positive symptoms that might indicate a need for a higher level of care. Based on the profile of the participant's responses, clinical staff made decisions about contacting participants and further assessing any psychotic symptoms.

Patient Health Questionnaire-9 (PHQ-9). The PHQ-9 is a nine-question measure from the Primary Care Evaluation of Mental Disorders. This evaluation was created to assess for a variety of mental illnesses including depression (Spitzer et al., 1999). Based on previous research, this measure shows adequate internal reliability; the validation paper reports Cronbach's α of .86-.89 (Kroenke et al., 2001). In the non-imputed sample for this study, the Cronbach α was .847 at Time 1 and .803 at Time 2. This measure includes an item assessing suicidality. This item was used as a screening question. If participants endorsed suicidality on this measure, a study team member contacted them and followed the suicide assessment protocol.

Generalized Anxiety Disorder-7 (GAD-7). The GAD-7 is a brief seven item measure that assesses for generalized anxiety symptoms (Spitzer et al., 2006). The validation paper

suggests good internal reliability with a Chronbach's α of .92 (Spitzer et al., 2006). In the non-imputed sample for this study, the Cronbach α was .871 at Time 1 and .910 at Time 2.

Perceived Stress Scale (PSS). The perceived stress scale is a 10-item questionnaire evaluating levels of participant's perceived stress (Cohen et al., 1983). Perceived stress is associated with greater psychological stress, daily hassles and physical health problems. The validation paper reports a Cronbach's α of .84-.86 across three samples. In the non-imputed sample for this study, the Cronbach α was .887 at Time 1 and .881 at Time 2.

Study Design

Participants were recruited through Facebook, Craigslist and UM Health Research beginning in December 2017 and ending in September 2018. After consenting to participate, participants completed a screening questionnaire and availability form. Participants were screened for active mania, psychosis and suicidality. If participants endorsed any of these symptoms, they were contacted by research staff who assessed their status and determined their fit for the program. If participants were deemed unfit for the program, they were given other resources and excluded from the study. See Figure 1 for Consort Flow diagram of recruitment (Schulz et al., 2010).

Once eligible, participants completed a series of randomized questionnaires on the online survey platform, Qualtrics ("pre" measures). Participants were randomized to a Mood Lifters group led by a "peer," a Mood Lifters group led by a "professional" or the waitlist condition. If participants were assigned to a treatment group (e.g., "peer"), but they were not available for those group times, they were switched to the other active treatment condition (e.g., "professional"). At the end of the first round of groups, waitlist participants were randomly assigned to either a "peer" or "professional" Mood Lifters group. There were three "rounds" of

consecutive groups (i.e., February 2018 start date, June 2018 start date, September 2018 start date) with a total of 14 groups run (seven “peer” and seven “professional”).

Participants attended weekly Mood Lifters meetings for 15 weeks (as described in Votta & Deldin, in preparation). At every meeting, participants completed a check in form asking about their mood and experiences in the past week using a visual analog scale (VAS; i.e., positive/negative emotions, relationships, thoughts, activity level). This form also included the Patient Health Questionnaire-4 (PHQ-4) to assess for symptoms of anxiety and depression. Prior to the last meeting, participants were asked to complete the same series of randomized questionnaires on Qualtrics. Similar data was collected at one-month and six-month post completion of the groups.

Data Analysis Plan

First, treatment and leader fidelity scores were examined to find any differences in treatment delivery or quality between peer and professional leaders. T-tests for independent samples were completed to determine if these differences were statistically significant. Additionally, for cases that had meetings attended and total points not imputed, t-tests for independent samples were conducted to determine if there were differences between peer and professional conditions for total number of meetings attended and for points earned across the program.

Due to drop out from the study, multiple imputation was used to address missing data (Royston, 2004; Schafer 1999). Research on missing data in clinical trials has found that multiple imputation is appropriate for this setting (Jackobsen et al., 2017). Change scores for relevant outcome measures were computed prior to multiple imputation by subtracting pre- from post scores. Missing change score data was imputed from independent variables (e.g., Time 1 data,

sex, race, age). Imputed variables had less than 17.82% missing data which was due to drop out. Following recommendation by Graham et al. (2007), 20 data sets were imputed and simultaneously analyzed. Regression coefficients and standard errors were averaged across all data sets following standard procedures (Royston, 2004). The process converged after 34 iterations.

Linear regression models were analyzed to determine whether group assignment in the program predicted outcome measure change scores (i.e., professional group, peer group and waitlist). All linear regression models controlled for T1 outcome score at baseline. It is important to note that a $p > .05$ does not indicate support for the null hypothesis (i.e., peer groups are equivalent to professional groups), instead this indicates that we cannot accept the alternate hypothesis that there is no difference between groups. However, Gerwandter et al. (2017) suggests that a confidence interval can be interpreted as support for the null hypothesis, if the upper bound of the confidence interval is below a determined clinically significant number (i.e., acceptable difference between groups that would not be clinically significant). For the purpose of this study, we set the “clinically significant” bound at two meetings (for attendance), at 66 “points” (i.e., the number of points that would be earned for two missed meetings, for homework), and at one point on the PHQ-9, GAD-7 and PSS. Thus, if the upper bound of the confidence interval is below two for attendance, 66 points for homework and two points on any of the above measures, this can be interpreted as support for equivalence between peer and professional groups.

Results

Treatment & Leader Fidelity

The range of average adherence to the treatment protocol across all meetings for the professional leaders was 97.6%-100.0%. For peer leaders, the range of average adherence to the treatment protocol was 96.4%-100.0%. There were no statistically significant differences in treatment fidelity between peer and professional leaders for any meeting ($p > .05$ for all meetings). The range of average adherence to leader characteristics (e.g., warmth) was 93.3%-100.0% for professional leaders and 87.1%-100.0% for peer leaders, across the study. There were also no statistically significant differences in leader fidelity between peer and professional leaders for any meeting ($p > .05$ for all meetings).

Participation Measures

For completed cases, the average number of meetings attended by participants in groups led by peers was 12.51 (SD = 1.48), compared to 13.00 (SD = 1.97) for groups led by professionals. There was no statistically significant difference between conditions for meeting attendance ($p = .277$, 95% CI [-.868, 1.104]). For completed cases, the average number of points earned across the program by participants in groups led by peers was 303.15 (SD = 102.64), compared to 340.53 (SD = 72.51) for professional led groups. This difference was not significant ($p = .098$, 95% CI [-23.400, 64.018]).

Outcome Measures

A linear regression model, with leader assignment and GAD-7 score predicting GAD-7 change scores was significant ($F(2, 79.0) = 10.89$, $p = .001$, $R^2 = .231$). There was a significant main effect of leader type ($p = .005$). Post-hoc comparisons show that there was no statistically significant difference between peer and professional groups ($p = .550$, 95% CI [-2.307, 1.239]). However, there were significant differences between peer and professional groups and the waitlist condition ($p = .003$ and $p = .009$, respectively). See Table 3 for means.

A second linear regression model, with leader condition and PSS T1 score predicting PSS change scores was significant ($F(2, 91.6) = 15.08, p < .001, R^2 = .261$). There was a trend towards significant effect of leader assignment ($p = .062$). Post-hoc comparisons show that there was no statistically significant difference between peer and professional leaders ($p = .194, 95\% \text{ CI } [-5.319, 1.102]$). However, there was a trend towards a significant difference in PSS change score between participants in groups led by peers and individuals on the waitlist ($p = .072$). See Table 3 for means.

A final linear regression model, with leader assignment and PHQ-9 T1 score predicting PHQ-9 change scores was significant ($F(2, 79.5) = 15.68, p < .001, R^2 = .299$). There was no main effect of leader assignment, such that individuals across all groups did not differ in PHQ-9 score change. A post-hoc comparison suggested that there was no difference between peer or professional groups in PHQ-9 change score ($p = .842, 95\% \text{ CI } [-2.162, 1.767]$). See Table 3 for means.

Discussion

The results of Votta et al. (in preparation) showed that, in a semi-randomized control trial, participants who engaged in Mood Lifters groups improved on several clinical measures despite having limited exclusion criteria. This study expanded on those analyses and built further support for the Mood Lifters program by examining differences in outcome measures based on group leader type (i.e., peer or professional leaders). First, there were no differences in treatment or leader fidelity between peer-led groups and professional-led groups. This means that, both professional and peer leaders were equally able to adhere to the treatment protocol and exhibit important clinical skills (e.g., “common factors”). Second, there were no differences between leader conditions for meeting attendance or points earned across the program. Lastly, group

assignment was related to a statistically significant change in anxiety and trend towards significant change in perceived stress. However, post-hoc comparisons showed that there was no statistically significant difference between peer and professional groups for either measure. While there was no statistically significant support for differences in outcome between peer and professional, a *p*-value of greater than .05 does not indicate support for no differences between groups. Upon examining the confidence intervals, as recommended by Gerwandter et al. (2017), the upper bound of the confidence intervals did not exceed the clinically significant bound of two meetings for attendance, 66 “points” for homework and two points for any of the clinical measures. This offers support that there is no difference between peer and professional groups for attendance, homework (i.e., “points” earned) or clinical outcomes. In fact, the change in perceived stress score trended toward significant between waitlist condition and participants in peer-led groups; however, there was no difference between waitlist condition and participants in professionally-led groups. This indicates that there may be some additional benefit to being in peer-led groups compared to professionally-led groups. Taken together, there appears to be no meaningful differences between peer-led and professionally-led Mood Lifters groups. This supports the efforts towards a lower cost mental health alternative by using peer leaders instead of professional leaders as there is no discernable advantage to having professionally trained leaders.

To date, there are few, if any studies, that directly compare peer leaders and traditional mental health professionals delivering the same program (Repper & Carter, 2011; Chinman et al., 2014; Pfeiffer et al., 2011). Further, previous research on peer interventions has largely included only specific populations (e.g., depression, substance use; Pfeiffer et al., 2011; Brooks & Penn, 2003). This study examined the same program delivered by peer and professional

leaders in a mixed sample (i.e., no requirements for mental health disorders, individuals across the spectrum of mental illness). Importantly, this study found that there were no statistically significant differences between peer and professional leaders for treatment and leader fidelity, indicating that, based on self-report, there were no differences in execution of the same treatment between leader types. Further, there were no differences in attendance or points earned across the program between leader types. This completes the picture on similar delivery of the intervention as participation (defined by attendance and points earned) was similar across leader type. Taken together, this adds to the literature on peer led interventions indicating that peer leaders, with adequate training, are as able to deliver an intervention as professional leaders.

To expand beyond simple delivery of an intervention, this study also compared the efficacy, defined by clinical improvement, between peer and professional leaders. There was no statistically significant difference between peer or professional conditions for change in generalized anxiety symptoms, perceived stress or depressive symptoms. This is consistent with the literature that peer leaders are at least as equally effective as professional leaders (Repper & Carter, 2011; Chinman et al., 2014; Pfeiffer et al., 2011). This expands on the current literature base as it may be one of the earliest examinations of the same program delivered by peers and professionals for a mixed group sample.

It is important to note that there are several limitations to this study. First, the sample size for this semi-randomized control trial is small. While many attempts were made to increase the size of sample (e.g., completing several “rounds” of groups), the final sample size may not have been large enough to detect smaller effects on all measures. While multiple imputation was used to address this limitation, further studies should examine the impact of the Mood Lifters program in a larger sample. Another limitation was the uneven number of groups and timing of groups

between peer-led and professionally-led groups. Again, all efforts were made to provide an equal number of groups in each condition and similar timing. Further, there were no differences in demographics or pre-scores between groups. However, scheduling proved difficult and one group was closed over the course of the study. Further studies on the Mood Lifters program should offer an equal number of peer/professional groups and similarly timed groups per condition. Not only would this address differences in peer/professional led groups, but would also allow for true randomization between conditions that is unaffected by scheduling difficulties. Finally, the sample in this study is predominantly Caucasian and female due to the location of the study and the makeup of traditional help-seeking populations. Future studies would benefit from examining the program in more racially/ethnically/gender diverse samples. Overall, a larger randomized control trial would address many of these concerns and provide further evidence for the program.

Importantly, Mood Lifters was developed to address many of the barriers individuals experience when trying to access mental health care in the U.S. This study supports the program's use of peer leaders as there appear to be no differential outcomes between participants in peer-led versus professionally-led Mood Lifters groups. This allows the program to be offered at a lower price, yet maintains high quality evidence based care. The Mood Lifters program is currently being offered commercially in a variety of settings including by employers for employees, community centers (e.g., YMCA) and a low-income clinic and housing neighborhood. The peer-led aspect of the program also allows for employment of individuals who may have otherwise not held a position due to their mental illness.

Future analyses of the data for this study will include a deeper examination of peer-led and professionally-led groups to determine if there are any individual or group characteristics

that predict change in the Mood Lifters program. Additionally, future analyses will look at mechanisms of change in the program including developing new emotion regulation strategies, increases in physical activity or improvement in social relationships. Finally, the Mood Lifters team has and continues to develop other versions of the program that target specific populations, such as children/teenagers, seniors and parents of children in palliative care in order to continue expanding access to evidence-based care.

In conclusion, this paper shows support for Mood Lifters' use of peer led leaders, as there was no advantage, in terms of participant outcomes or treatment fidelity, for participants in professionally-led Mood Lifters groups. This then allows Mood Lifters to offer more affordable and available evidence based care and increases accessibility for more individuals who have not yet been able to access care.

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Testing the efficacy of the Mood Lifters Program: A semi-randomized control trial.

Table 4.1***Demographic information for Mood Lifters semi-randomized control trial***

	Professional	Peer	Waitlist
Age (SD)	43.19 (16.02)	50.60 (17.76)	46.90 (17.18)
Sex			
Male	9	11	4
Female	28	29	20
Race			
American Indian/Alaskan Native	0	0	0
Asian	4	3	3
Black/African American	2	1	0
Native Hawaiian/Pacific Islander	0	0	0
White	31	32	18
More than one race	0	3	2
Education			
Graduated High School	0	3	0
Some College (including Associate's Degree)	7	8	4
Bachelor's Degree	18	16	11
Graduate Degree	12	12	9

Note. One participant from the waitlist and one participant from the treatment condition declined to enter their race. One participant from the peer condition declined to enter their education.

Table 4.2*Average treatment and leader fidelity scores per meeting by condition*

	Professional (n = 6)		Peer (n = 7)		Overall (N = 13)	
	Treatment Fidelity	Leader Fidelity	Treatment Fidelity	Leader Fidelity	Treatment Fidelity	Leader Fidelity
M1	98.96%	98.33%	97.77%	87.14%	98.32%	92.31%
M2	100.00%	96.67%	98.47%	97.14%	99.18%	96.92%
M3	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%
M4	98.81%	100.00%	99.49%	94.29%	99.18%	96.92%
M5	100.00%	100.00%	98.47%	100.00%	99.18%	100.00%
M6	99.48%	100.00%	99.11%	100.00%	99.29%	100.00%
M7	97.55%	93.33%	97.48%	88.57%	97.51%	90.77%
M8	100.00%	93.33%	99.16%	94.29%	99.55%	93.85%
M9	100.00%	100.00%	100.00%	98.57%	100.00%	99.23%
M10	100.00%	100.00%	96.43%	100.00%	98.08%	100.00%
M11	100.00%	100.00%	99.29%	100.00%	99.62%	100.00%
M12	99.44%	95.00%	97.62%	97.14%	98.46%	96.15%
M13	99.44%	100.00%	100.00%	95.71%	99.74%	97.69%
M14	99.48%	100.00%	99.55%	91.43%	99.52%	95.38%
M15	98.61%	100.00%	100.00%	100.00%	99.31%	100.00%

Note. The group that was closed was not included in treatment or leader fidelity score averages.

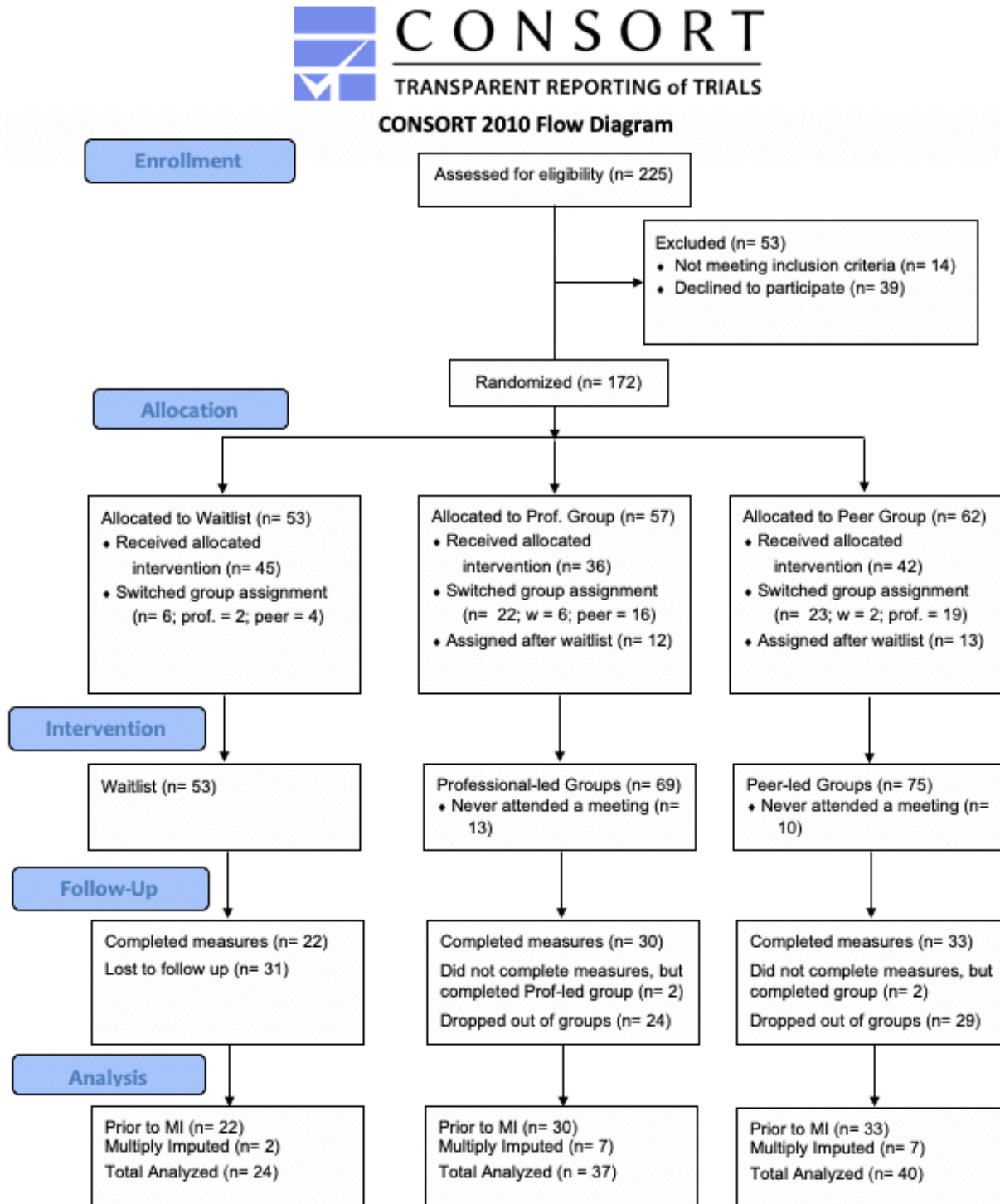
Table 4.3

Means and standard deviations for PHQ-9, GAD-7 and PSS change scores for both complete cases and multiply imputed data sets

	Completed Cases			Multiple Imputation		
	Professional	Peer	Waitlist	Professional	Peer	Waitlist
GAD-7	-1.138	2.182	1.682	-1.303	-.440	2.485
Change	(.691)	(.551)	(.815)	(4.327)	(4.214)	(3.603)
PSS	-.310	-3.333	.818	1.218 (8.270)	-1.783	2.747
Change	(1.356)	(1.280)	(1.033)		(8.159)	(5.633)
PHQ-9	-1.467	-1.455	.364	-1.374	-1.264	1.820
Change	(.951)	(.766)	(.794)	(6.029)	(5.607)	(3.969)

Figure 4.1

Consort Flow Diagram of Recruitment



CHAPTER V: Summary and Conclusions

Almost every American will be impacted by mental illness, either their own or that of a loved one, over the course of their lifetime (Kessler et al., 2005). Unfortunately, research suggests that only about 43% of individuals experiencing mental illness received care in the last year (NIMH, 2017). Further, a recent meta-analysis suggest about one in five individuals in care will drop out early (Swift & Greenberg, 2012). Based on the numbers, it is clear that there is a massive, mostly unmet need for mental health care in the United States (U.S.) and that the mental health care system that is in place is inefficient and underutilized.

Researchers have begun to identify why individuals struggle to connect with the system and get help they could benefit from. They separate these barriers into two categories: attitudinal barriers, those associated with beliefs or ideas about mental health and the system, and structural barriers, those associated with the mental health care system itself. Attitudinal barriers are reported far more frequently with 97% of individuals who were interested in seeking care, but did not, endorsing them, compared to structural barriers, which were endorsed by 22% of the same sample (Mojtabai et al., 2011). Attitudinal barriers include desire to resolve one's own symptoms and stigma; structural barriers include cost, insufficient availability of providers, and lack of evidence based care. While they are endorsed to varying degrees, both attitudinal and structural barriers collectively prevent many individuals from seeking the care they need.

There has been some movement towards introducing more accessible alternatives to traditional mental health care. Recent research has examined the effectiveness of tele-therapy/e-

therapy, self-help web based interventions, mobile applications and workplace wellness programs (Barak et al., 2008; Olthuis et al., 2016; Osenbach et al., 2013; Haregu et al., 2015; Coughtrey & Pistrang, 2018; Lui et al., 2017; Price et al., 2014; Ivandic et al., 2017; Osilla et al., 2012). Tele-therapy and self-help web based interventions appear to be as effective as traditional care, but they introduce additional barriers to care, such as needing access to internet services, and don't fully address other barriers to care, such as cost of provider, in the case of tele-therapy and e-therapy (Barak et al., 2008; Olthuis et al., 2016; Osenbach et al., 2013; Haregu et al., 2015; Coughtrey & Pistrang, 2018; Brenes et al., 2011). Further, while mobile applications are becoming more popular, there is no single application that would be considered sufficiently evidence-based (Lui et al., 2017; Price et al., 2014). Current studies show some support, but no programs have been tested against traditional psychotherapy or e-therapy/tele-therapy (Flett et al., 2019). Finally, workplace wellness programs have shown very little evidence for efficacy and mental health wellness programs are the least used workplace wellness program (Ivandic et al., 2017; Osilla et al., 2012; McCleary et al., 2017). Overall, the research on accessible alternatives to traditional mental health care shows some preliminary evidence in support of more accessible alternatives, but there is still a need to develop and test additional alternatives.

Due the unmet need for care, underutilization of the current system and limited reach of other more accessible alternatives, new solutions are needed. In response, our team at the University of Michigan, led by Dr. Patricia Deldin, developed a novel mental wellness program, Mood Lifters, that addresses many of these barriers to care. First, the program uses peer leaders, or individuals who have already completed the program themselves, rather than traditionally trained mental health professionals. Previous research suggests that peer leaders are equally as effective as professional psychotherapists for manualized treatments. Further, employing peer

leaders addresses some of the barriers to care mentioned above including cost, availability of providers and decreased stigma around mental illness (Repper & Carter, 2011; Chinman et al., 2014). The previous research on peers suggests that they may be a more accessible alternative to traditionally trained clinicians. Second, Mood Lifters utilizes group meetings, which allows for more individuals to receive care at the same time, thereby increasing availability and decreasing cost. Research generally supports group therapy as a more accessible evidence-based alternative to individual psychotherapy (McDermut et al., 2001; Burlingame et al., 2003). Third, Mood Lifters takes an eclectic and integrative approach and develops all meetings from the most recent research in psychotherapy and mental health, providing an evidence based alternative, as many individuals currently receiving care are not receiving evidence based care (González et al., 2010). Finally, Mood Lifters focuses on self-improvement and homework completion, fully acknowledging and applauding the role of the individual in improving their own mental health which addresses the most prevalent barrier to mental health care: wanting to improve on one's own (Mojtabai et al., 2011). Taken together, the development of the program was based on the available evidence base in psychotherapy research with the goal of developing the most accessible program possible.

The papers included in this dissertation provide initial evidence for this novel program whose focus is mood improvement and accessibility. In the first paper of this dissertation, we designed a series of small pilot studies to test the feasibility of the Mood Lifters program and study protocol. In Study A, participants were given the first iteration of the Mood Lifters program with leaders who had formal clinical training and who had developed the program. Findings from this small pilot study show that participants were able to engage with the program, both earning points and regularly attending meetings. While the study was too small to draw

conclusions about efficacy, subjective reports from participants and preliminary analyses suggest that participants gained some mood improvement from the program. Further, participants offered important feedback, such as outcome measures taking too long to complete and that they would prefer all measures, both weekly and pre/post, to be online, rather than on paper. Further feedback was given about the program itself with participants stating that they would benefit from weekly, rather than bi-weekly meetings, and, therefore, extending the overall length of the program. Finally, despite the small sample, participants showed improvement in depressive symptoms, showing limited and early support for the efficacy of the program. This study provided preliminary evidence that the Mood Lifters program was accessible and acceptable as a research study, with some improvements needed.

In Study B, we expanded the pilot to two additional groups and sought to examine the feasibility of using peer leaders, with no formal clinical training. Results suggested that there did not appear to be any qualitative differences between “peer” and “professional” leaders and participants were equally engaged in the program regardless of leader type, for this small sample. Participants gave similar feedback to Study A, suggesting shorter and online measures. Additionally, while active participants appreciated the weekly meeting format, there was greater drop-out than in Study A, though it was unclear if this is uniquely due to the change in schedule. Overall, between the two studies, researchers found that participants were able to consistently engage in the program (i.e., regularly earn points and attend meetings) and the study (i.e., complete measures). Initial preliminary analyses indicated that Mood Lifters participants gained some benefit by being in the program, based on measures and subjective report. Again, this study showed preliminary evidence for the efficacy of the Mood Lifters program and study, and importantly, showed that peers could deliver it. Based on the results from both studies, we

decided to proceed with a larger semi-randomized control trial to establish further evidence for the program.

In the second and third papers of this dissertation, we reviewed data from the semi-randomized control trial of the Mood Lifter's program. In this trial, participants were randomly assigned to one of three conditions, waitlist, Mood Lifters groups led by peer leaders or Mood Lifters groups led by professional leaders. Participants on the waitlist were randomized to either peer or professional groups after their waitlist period. Participants also completed outcome measures prior to the start and at the end of the program. These measures assessed several areas of the Mood Lifters program that are important for mental and physical health (i.e., body, mind, mood, social, behavior, sleep). Due to unexpected attrition in the study, multiple imputation was used to account for missing data; recent research supports the use of multiple imputation in clinical trials (Jakobsen et al., 2017).

The primary aim of the second paper was to determine the efficacy of the Mood Lifters program compared to the waitlist control group. To test this, we completed analyses on change scores for anxiety, depression and perceived stress. Regression models showed that participants in the Mood Lifters groups experienced statistically significant reductions in anxiety. This showed that participation, through attendance, in the Mood Lifters groups benefited participants more than receiving no treatment at all. Further, through the tracking portion of the program (i.e., "points"), we were also able to examine whether or not change over the course of the program was related to "points" earned, or homework completed. These additional analyses showed that earning more "points," or completing more homework, across the course of the program contributed to statistically significant reductions in anxiety and perceived stress and trends towards significant reductions in depressive symptoms. Thus, Mood Lifters produces benefits to

mental health, not through simply attending the program, but through work completed outside the weekly group meetings, in the form of “points.” Thus, analyses in the second paper of this dissertation suggest that the Mood Lifters program produces mental health benefits for participants, particularly for participants who engaged with points outside of the program.

From a broader perspective, this paper adds to the literature on more accessible alternatives to mental health care. It indicated that, through a non-traditional in-person care program that is more accessible, participants still saw improvements on clinical measures. Additionally, this study illuminated the role of “points,” or homework completion, within the program, suggesting that participants who are more engaged see greater improvements. These results lend further support to previous studies that suggest that homework completion is an important mechanism for change in psychotherapy and that benefiting from an intervention requires more than just physical attendance (Kazantzis et al., 2016).

In the final paper of this dissertation, we examined the efficacy of “peer” leaders compared to “professional” leaders and the waitlist control condition. Within the trial, leaders and helpers were required to complete treatment, gauging adherence to treatment protocol, and leader, evaluating important clinical characteristics, fidelity assessments after each meeting. Analyses of treatment and fidelity assessments showed that there were no statistically significant differences in either assessment between groups led by peers and groups led by professionals. This suggests that peer leaders were equally able to follow the treatment protocol and exhibit important clinical characteristics as professional leaders. Further, there were no differences in attendance or points earned across the program between participants in peer and professional led groups. Additional analyses were conducted to examine whether participants in peer and professional groups experienced similar mental health benefits across the program. Models were

analyzed using group assignment (i.e., waitlist, peer leader or professional leader) to predict change scores for depression, anxiety and perceived stress. Group assignment was related to statistically significant change in anxiety symptoms and marginally significant change in perceived stress. Further, post-hoc comparisons showed that there was no significant difference between peer-led and professional-led groups; rather, that these findings were attributable to differences between the waitlist and active treatment conditions. This data suggests that there were no differences in improvements in mental health between peer and professionally led groups. Taken together, analyses in the final paper of this dissertation showed that there were no differences between peer and professional leaders, showing support for the use of peer leaders as a way to address barriers to mental health care in the Mood Lifters program.

This paper adds support to the existing literature on peer-led interventions that have previously shown peer leaders to be equally as effective as professional leaders and more effective than waitlist conditions (Repper & Carter, 2011; Chinman et al., 2014; Pfeiffer et al., 2011). Further, this data contributes beyond effectiveness, and suggests that there are no differences in attendance, homework completion, delivery or clinical characteristics between peer-led and professionally led groups, although this was based on self-report. This also contributes new information to the peer led intervention literature as it directly compared leader types within the same intervention, allowing for direct comparisons of peer-led versus professionally-led groups. Importantly, this has implications for clinical training as a whole. Leaders who had engaged in the program themselves and who attended a day long clinical training were equally as effective as leaders with professional clinical psychology training for this manualized based treatment. This has larger implications for the field and accessibility as

peer leaders, in this program in particular, are able to effectively contribute to mood improvement for participants.

In summary, the studies included in the first paper of this dissertation found that the Mood Lifter's program and study structure was feasible. It also provided important feedback to improve the study and the program itself. The semi-randomized control trial of the Mood Lifters program, examined in the second and third papers of this dissertation, showed preliminary evidence for the efficacy of the Mood Lifters program including significant reductions in anxiety and perceived stress, particularly for those individuals who completed more "points" across the program. Finally, these analyses also showed that there was no significant difference between "peer" and "professional" leaders delivering the Mood Lifters program, increasing support for the use of leaders that increase accessibility in a variety of ways (e.g., reduced cost and availability). Collectively, this dissertation effectively introduces the Mood Lifters program by showing evidence of feasibility and efficacy for this novel mental wellness program designed to increase accessibility to evidence-based mental health care.

While these studies show ample evidence for the program, there are several limitations to the studies included in this dissertation. First, all samples were predominantly Caucasian and female due to the sampling location and the traditional make-up of mental health care seeking populations. Second, the sample size across all three studies was small. This impacted the first study to a lesser extent than the semi-randomized control trial. The semi-randomized control trial was particularly small due to attrition. Efforts were made to compensate for the small size during the analysis (i.e., multiple imputation; Jakobsen, 2017). Further research on the program should include larger sample sizes with a more ethnically/racially/gender diverse sample to build further evidence for the Mood Lifters program. It would also be of benefit to have many groups running

concurrently or groups being run at a variety of times to increase accessibility for participants regardless of when they are unavailable for group times.

The Mood Lifters program development and research is ongoing and has many exciting avenues as access to mental health care is an evolving and ongoing struggle. First, there are continued analyses on the studies described in this dissertation. These papers examine whether individual characteristics predict engagement and improvement in the Mood Lifters program, the role of learning new emotion regulation strategies as a mechanism of change and more specific examinations of improvements in the variety of areas that Mood Lifters covers (i.e., body, mind, mood, sleep, social and behavior). Additional analyses will be completed on the weekly data that was collected over the course of the trial. Time series analyses will be completed in order to determine when change occurs, in a variety of areas, over the course of the Mood Lifters program. For example, does improvement in physical health occur after the meetings addressing these issues? Finally, there are many current and upcoming research studies on the original Mood Lifters program and adaptations of the program for specific populations including for children, teens, seniors, graduate students and parents of children in palliative care. Additionally, there are plans to complete a randomized control trial of a novel delivery system, remote online delivery, which has shown success in small pilot studies and is ready to be taken to trial. All of these adaptations increase the accessibility of the program to new populations in new ways.

In addition to ongoing research, Mood Lifters became a for-profit company in early 2019. Over the first year of the company, over two hundred participants participated in the program and access is continuing to expand. The program has been offered direct to consumer, for employees of various companies (e.g., University of Michigan and Sasche construction), by health clinics and in low-income housing communities. We are hopeful and excited to continue

increasing accessibility to mental health care beyond the traditional mental health care system. Beyond increasing accessibility, the company has also been able to provide jobs for individuals with mental health difficulties who improved in the program. This includes peer leaders in low income communities, who bring the program into their communities, and whose communities also benefit from having a leader of their own.

In summary, the Mood Lifters program addresses important barriers to evidence-based mental health care including structural and attitudinal barriers, like cost, availability, and desire to improve on one's own. It does this by offering skills based weekly meetings developed from the most recent evidence-based mental health intervention. These meetings are held by peer leaders in a group setting which decreases cost and increases availability. This dissertation provided support for the feasibility and efficacy of the Mood Lifters program suggesting that it had a meaningful and significant impact on important aspects of mental health (e.g., anxiety, depression and stress).

While the findings described above are an important contribution of this dissertation, these studies speak to mental health intervention research in a broader sense. First, it is not clear that individuals suffering from mental illness or general stress need to attend individual therapy if they can gain skills and relief through a more accessible program. This is not to say that there is no role for individual therapy or inpatient psychiatry, as more severe populations were not considered in the context of these studies. However, non-traditional mental health care programs, such as Mood Lifters, may provide accessibility and relief for people who are currently unable or unwilling to access the traditional care system. Second, findings from Chapter 4 of this dissertation and previous research on peer-led programs offer support for the idea that individuals who provide mental health care do not necessarily need years of training and

advanced degrees. It is clear that our current system has not been providing sufficient care for people who need it and we suggest that a paradigm shift may be needed in order to maximize care and change the trajectories of worsening mental health in the U.S. Those solutions may lie in programs, such as Mood Lifters, where intervention developers consider barriers to care in the development of the program and think outside the lines of traditional psychotherapy.

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