

Feasibility and Acceptability of a Values-Based Telehealth Intervention to Promote Adherence
in Cardiopulmonary Rehabilitation Patients

By

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Background: Current research indicates an ongoing need to identify interventions to promote Cardiopulmonary Rehabilitation (CVPR) participation, as participation in CVPR remains low despite positive effects on health outcomes. Values-based interventions, such as Behavioral Activation and Acceptance & Commitment Therapy (ACT), have been shown to be effective for improving the quality of life of patients with a variety of chronic illnesses including cardiovascular disease. We hypothesized that a values-based intervention may be helpful to promote CVPR participation through reduced avoidance and exploration of intrinsically motivating factors that improve patients' willingness to engage in potentially unpleasant activities (e.g., physical activity) that are important for managing their diagnoses. The COVID-19 pandemic also provided the opportunity for more widespread implementation of telehealth interventions to increase access to psychosocial support, especially for marginalized patient populations who experience a high number of attendance barriers.

Purpose: The purpose of this study was to assess the feasibility and acceptability of a novel telehealth intervention that is informed by ACT principles and focused on improving adherence to CVPR.

Methods: Participants in this single-armed study could choose to participate in a 5-session ACT-informed telehealth intervention via live virtual meetings (at home) or self-guided pre-recorded videos (at home or onsite) featuring the same content. Feasibility was assessed by the number of participants enrolled (goal of 50), sessions attended, Ecological Momentary Assessment (EMA) response rates (measuring mood, experiential avoidance, values congruence), and rates of post-completion assessment. Acceptability was assessed through a qualitative interview following the five-week intervention period.

Results: Feasibility of the study was hindered by low participation. Forty-four participants were consented and 21 did post-completion questionnaires. Only 8 participants attended \geq of the 5 live sessions. Twenty participants requested pre-recorded videos, and though exact numbers of views could not be determined due to our distribution method, only 6 reported watching \geq 1 videos.

Participants often reported difficulty with the virtual meetings and EMA technology, despite staff demonstrating its use and a prior study's success with the same EMA program. Also, participants anecdotally reported exhaustion with virtual meetings across multiple settings.

Fourteen participants dropped out of the study due to illness/hospitalization or time conflicts.

Five participants completed the qualitative follow-up interview. Qualitative responses generally indicated a high acceptability of the intervention, though this small group included mostly those with high engagement; those who dropped out may feel differently.

Discussion: Overall, our results indicate that major changes are needed to increase feasibility and better measure acceptability of this intervention. Participants provided helpful feedback

regarding their preferences, challenges encountered, and suggestions for improvement that will be helpful for future repetitions of this research. The results especially highlight the potential benefits of developing a self-guided version that is modified to improve accessibility to the technology required to participate in the intervention.

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Chapter 1: Literature Review

Introduction

Cardiovascular diseases (CVDs) and chronic respiratory diseases (CRDs) are among the leading causes of death and disability in the United States (Virani et al., 2020). Cardiopulmonary rehabilitation (CVPR) is an outpatient secondary prevention care model designed to mitigate this burden by improving health outcomes through comprehensive delivery of secondary prevention strategies, including health education, nutritional counseling, risk factor management, stress management, and supervised physical activity training (Balady et al., 2007). To date, there is much research confirming the beneficial effects of CVPR programming on health outcomes of patients with CADs and CRDs, including reduced mortality and hospital readmissions (Halewijn et al., 2017; Lan et al., 2014; Anderson et al., 2016). Furthermore, CVPR has been linked to improved functional capacity and reduced disability, as well as improvements in mood, illness-related fatigue, and health-related quality of life (QOL; Suna et al., 2015; Heerema-Pelman et al., 2013; Lacasse et al., 1996).

Cardiac rehabilitation (CR) and pulmonary rehabilitation (PR) programs are often discussed separately, although the overall exercise recommendations are similar. Additionally, CR and PR programs are often co-located within the same facilities. CVD is an umbrella term that includes all cardiac and circulatory diseases, such as angina, coronary heart disease (CAD), myocardial infarction (MI), congenital heart disease, hypertension (HTN), heart valve disease, cardiomyopathy, heart rate and rhythm irregularities (e.g., atrial fibrillation), stroke, and vascular dementia. This term includes everything from cardiovascular conditions that are congenital (i.e., diagnosed at birth), or genetically inherited, to cardiovascular conditions that develop over time. Several health conditions in combination with lifestyle factors can increase one's risk for

developing CVD, including high blood pressure, high cholesterol, and smoking, and nearly half of Americans (47%) have at least one of these three key risk factors (Fryar, Chen, & Li, 2019). Other lifestyle factors such as inactivity or sedentariness (i.e., defined as no physical activity or fewer than three times per week and/or less than 20 minutes per session of physical activity; CDC, 2019), eating an unhealthy diet (i.e., eating a diet high in saturated fats, trans fat, cholesterol, and sodium; CDC, 2019), as well as overweight (BMI 25.0 to <30) and obesity (BMI 30.0 or higher; CDC, 2021) place people at greater risk for developing CVD (Hubert, Feinleib, McNamara, & Castelli, 1983; Oldridge, 2008).

Given the critical role that lifestyle factors play in the development of CADs, CR was initially developed in the 1950s in response to increased awareness and understanding of behavioral risk factors as well as the importance of multidisciplinary approaches aimed at preventing and containing cardiovascular mortality, morbidity, and disability in patients with CVDs. Like patients with CVDs, it is often recommended that patients with CRDs, including those with progressive diseases such as chronic obstructive pulmonary disease (COPD), pulmonary fibrosis, and pulmonary hypertension, participate in comprehensive exercise-based pulmonary rehabilitation (PR) programs. CRDs are known to cause severe functional impairment in life areas such as physical, occupational, and social functioning (Vestho et al., 2013). Risk factors such as genetic predisposition and prolonged exposure to irritants that damage the lungs and airways (e.g., exposure to air pollution, smoking, as well as working with chemicals, dust, and fumes) increase one's risk for developing CRDs such as COPD (American Lung Association, 2021). Tobacco smoke is the leading risk factor for COPD, with approximately 85-90% of COPD cases being caused by smoking or secondhand smoke (American Lung Association, 2021). Participation in a PR program has been shown to improve exercise tolerance,

depression and anxiety, illness-related fatigue, and health-related QOL in patients with CRDs (Coventry & Hind, 2007; Lacasse, Martin, Lasserson, & Goldstein, 2007; Vogelmeir et al., 2017).

Although much research supports the effectiveness of CVPR in improving health outcomes and health-related QOL in patients with CADs and CRDs, participation in these rehabilitation programs remain low, with completion ranging from 21% to 75% (Johnston & Grimmer-Somers, 2010; De Vos et al., 2013). Many studies have examined factors that may contribute to CVPR non-adherence, including physical barriers (e.g., physical pain with exercise, fatigue) and disease severity (Grace et al., 2010), health system barriers (e.g., lack of referral, cost, negative experiences with health system; Resurreccion et al., 2017), logistical barriers (e.g., geographical distance, transportation, availability of resources; Resurreccion et al., 2017), intrapersonal barriers (e.g., health beliefs, motivation, perceived control; Resurreccion et al., 2017; Reges et al., 2013), and interpersonal barriers (e.g., social support, work conflicts; Resurreccion et al., 2017; Meillier, Nielson, Larsen, & Larsen, 2012). Depressed mood is often considered a barrier to CVPR enrollment and has been reported to predict low attendance (Busch et al., 2015). However, little is known about how moment-to-moment or contextual shifts in psychological factors such as depression may affect CVPR participation. Additionally, the potential impact of behavioral symptoms of depression, such as avoidance behaviors, on CVPR adherence is also poorly understood. Ecological momentary assessment (EMA) methodology can provide real-time sampling of psychological and behavioral factors such as depression and experiential avoidance to better understand how these factors may influence CVPR participation over time on a moment-to-moment basis.

The abundance of studies examining barriers to CVPR and suboptimal rates of adherence suggest the need for additional research to identify intervention targets for improving CVPR attendance and completion. Behavioral Activation Treatment of Depression (BATD) and Acceptance and Commitment Therapy- (ACT) are context-oriented approaches that seek to reduce patterns of avoidance (e.g., avoidance of negative thoughts and feelings, avoidance of potentially unpleasant experiences) that are maintaining depression (Lejuez, Hopko, Acierno, Daughters, & Pagoto, 2011). Through exploration of personal values, the characteristics, and behaviors that an individual finds intrinsically motivating in guiding their decisions and goals can be utilized to achieve long-lasting behavioral changes. Previous studies suggest that values-based interventions, can be helpful in improving the QOL of patients across a wide variety of chronic health conditions (e.g., CADs, cancer, chronic pain, HIV, and epilepsy; Spatola et al., 2014; Gregg, Callaghan, Hayes, & Glenn-Lawson, 2007; Lundgren, Dahl, Yardi, & Melin, 2008; Dahl, Wilson, & Nilson, 2004; Moitra, Herbert, & Forman, 2011). Values-based interventions may assist CVPR patients in exploring intrinsically motivating factors that may improve motivation to attend CVPR and throughout their journey of making the necessary health behavior changes to manage their conditions. The goal of the proposed study is to assess the feasibility and acceptability of a novel values-based intervention aimed toward improving CVPR participation, and to use mobile EMA to examine contextual changes in mood and experiential avoidance that may affect CVPR participation.

Cardiopulmonary Rehabilitation (CVPR)

Cardiopulmonary rehabilitation (CVPR) is an evidence-based secondary prevention intervention that offers supervised physical activity, health education, and risk reduction strategies to improve health outcomes, functional capacity, and quality of life (QOL) of patients

who have experienced a recent cardiac event, such as myocardial infarction (MI), have undergone cardiac surgery (e.g., coronary artery bypass surgery, angioplasty and stent placements, heart transplant, heart valve repair or replacement), or have been diagnosed with a chronic cardiovascular condition (e.g., heart failure, coronary artery disease, valve disease, arrhythmia). CVPR programming also aims to benefit those who have been diagnosed with chronic respiratory diseases (CRDs) such as chronic obstructive pulmonary disease (COPD), emphysema, pulmonary fibrosis, or other lung conditions using a similar approach to secondary prevention strategies.

CVPR programming utilizes a multifaceted and multidisciplinary approach to address health complications and symptoms associated with the CADs and CRDs, including exercise intolerance and dyspnea (Balady et al., 2007). To accomplish this goal, the American Heart Association (AHA) and the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR) have identified six core components that are essential to reduce cardiopulmonary risk, enhance emotional wellbeing, reduce disability, and maximize functioning, as well as to promote long-term health behavior change (e.g., healthy diet, active lifestyle) for patients with CADs and CRDs (Balady et al., 2007). These six core components include: 1.) baseline patient assessment, 2.) nutritional counseling and education, 3.) risk factor modification and individualized behavioral intervention (e.g., weight management, diabetes management, blood pressure management, and tobacco cessation), 4.) psychosocial assessment and intervention as it relates to engagement in CVPR programming, 5.) physical activity counseling, and 6.) physician-prescribed, supervised aerobic exercise and resistance training. Finally, it is recommended that each patient have an individual treatment plan that is reviewed every 30 days upon enrollment in CVPR programming (CMS, 2010).

Home-based CVPR (HBCVPR) incorporates a very similar structure described above in a manner that can be performed at a patient's home through virtual methods. Several randomized controlled trials have demonstrated equivalence in health outcomes among patients receiving HBCVPR when compared to center based CVPR (CBCVPR), suggesting that telerehabilitation is a viable approach for patients with CADs and CRDs. Additionally, the Covid-19 pandemic reinforces the need of delivering CVPR outside of the hospital or clinic-based setting and is evidenced by the fact that many programs closed operations for a period of time to reduce risk of contracting SARS-CoV-2, the virus responsible for the Covid-19 pandemic. To improve patient access and engagement in CVPR, telehealth psychoeducational interventions has been proposed as an option to address specific barriers to attendance and improve patient motivation to remain engaged in making health behavior changes to reduce their risk and improve functional health outcomes. However, there has been little research on whether telehealth-based psychoeducational interventions are helpful in improving outcomes in CVPR patients.

CVPR Outcomes for Cardiac Patients

There is a large body of research supporting the effectiveness of cardiac rehabilitation (CR) for improving health outcomes across a wide spectrum of patient populations with a variety of disease states, including those with cardiac conditions, comorbid diabetes mellitus, overweight or obese patients, those with high or low baseline exercise capacity, and elderly patients (Williams et al., 2002; Vonder Muhll, Daub, Black, Warburton, & Haykowsky, 2002; Lavie & Milani, 2000). Overall, participation in comprehensive, exercise-based CR programs results in improvements in exercise capacity, body mass index, lipid profiles, measures of psychosocial factors (e.g., depression, anxiety, stress) and QOL, as well as all-cause mortality and cardiac-specific mortality and morbidity (Anderson et al., 2016; Listerman, Bittner, Sanderson, &

Brown, 2012). Furthermore, recent reviews have demonstrated the effectiveness of CR in optimizing physical functioning and reducing disability, as well as risk of future cardiac-related complications (e.g., sudden cardiac arrest, recurrent myocardial reinfarction; Anderson et al., 2016; Halewijn et al., 2017). However, health outcomes may differ across various disease states. For post-MI patients, CR has been shown to reduce cardiovascular and all-cause mortality by about 20-25%, and hospital readmissions by 18% (O'Connor et al., 1989; Oldridge, Guyatt, Fisher, & Rimm, 1988). Similar findings have been seen in a large sample of patients following percutaneous coronary intervention (PCI) such that CR participation was associated with significant reductions in all-cause mortality and decreased cardiac-specific mortality; however, there was no effect observed for myocardial reinfarction or revascularization (e.g., coronary artery bypass grafting, percutaneous coronary intervention; Goel et al., 2011). Furthermore, recent systematic reviews of heart failure (HF) patients have shown that those who participate in CR have a lower risk for HF-related hospitalizations; however, all-cause mortality is not reduced (Davies et al., 2010).

It is well-established that reduction in cardiovascular mortality, hospital readmissions, and recurrent cardiac-related complications can be attributed to the positive influences of exercise-based CR on physical fitness and exercise tolerance. The American Heart Association (AHA) recommends that CR patients consistently receive 30-60-minutes of moderate-intensity physical activity each day and reduce sedentary behavior to reduce cardiovascular and all-cause mortality (American Heart Association, 2010). Recent meta-analyses have found that CR patients can expect marked improvements in exercise tolerance by about 1.5 metabolic equivalents (METs) following >36 sessions of exercise-based CR (Sandercock, Hurtado, & Cardoso, 2013), and these changes are often sustained in the long-term (e.g., comparable

physical activity at 6-12 months following CR; Meiring, Tanimukai, & Bradnam, 2020). Such improvements in exercise tolerance have been found to be associated with significant reductions in cardiovascular mortality in both general populations and cardiac patients (Kavanagh et al., 2003; Sandercock, Hurtado, & Cardoso, 2013; Meiring, Tanimukai, & Bradnam, 2020).

There are also several other important outcomes beyond improvements in physical fitness and reduced risk for mortality or future hospitalizations, including improvements in QOL. A recent meta-analysis by Anderson and colleagues (2016) found that 14 of 20 published studies demonstrated marked improvements in health-related QOL when compared with a control group (i.e., no exercise-based CR group). Such increases in health-related QOL and exercise tolerance have also been observed across a range of cardiac disease states, including HR patients enrolled in exercise-based CR (Davies et al., 2010). Notably, improvements in exercise tolerance and health-related QOL are highest among patients receiving ≥ 36 sessions, suggesting that improvements in outcomes following CR are dose-related (Sandercock et al., 2013). A strong dose-response relationship was also demonstrated in a national sample of Medicare beneficiaries who attended at least one CR session (Hammill, Curtis, Schulman, Whellan, 2010). After adjusting for demographic characteristics, comorbid conditions, and subsequent hospitalization, patients who attended 36 sessions had a 14% lower risk of death and a 12% lower risk of death and 12% lower risk of MI, compared to those who attended 24 sessions. Furthermore, those who attended 24 sessions had a 22% lower risk of death and 23% lower risk of MI, compared to those who attended 12 sessions (Hammill et al., 2010). Overall, these studies demonstrate the importance of regular attendance and completion of CR programming, as well as the importance of identifying and understanding factors that may interfere with adherence to CR programming.

Several randomized controlled trials have investigated outcomes in home-based CR (HBCR) in relation to center-based CR (CBCR) and demonstrated greater adherence and equivalent improvements in cardiorespiratory fitness, quality of life, risk factor modification, and mortality following 12-weeks of HBCR in comparison to CBCR (Choxi et al., 2021). The results of randomized controlled trials investigating the differences in outcomes between HBCR and CBCR suggest that telerehabilitation is an equivocally effective care model that can be utilized to address specific barriers to adherence.

CVPR Outcomes for Pulmonary Patients

Among patients with chronic respiratory diseases (CRDs), pulmonary rehabilitation (PR) is considered an effective secondary prevention strategy for reducing disability and improving health related QOL (Lacasse, Goldstein, Lasserson, & Martin, 2006; Coventry & Hind, 2007); however, PR outcomes remains understudied in comparison to CR outcomes. According to a recent systematic review, there have been two randomized controlled trials examining the effects of PR on mortality in patients with COPD (Hakany, Bolton, & McKeever, 2017). One RCT examining survival rates of 62 COPD patients found no statistically significant differences in 3-year survival rates when compared non-PR controls (Ries, Kaplan, Limberg, & Prewit, 1995). The second RCT showed that participation in PR led to significant improvements in 1-year survival rates of patients with COPD ($N=92$) when compared to non-PR controls; however, this difference was not statistically significant (Griffiths et al., 2000).

Several studies have demonstrated that PR relieves dyspnea and fatigue, improves psychosocial functioning (e.g., reduced anxiety and depression), and enhances the sense of control that PR patients have over their condition (McCarthy et al., 2015). Furthermore, a meta-analysis of 14 RCTs found that 4-weeks of PR led to improvements in health-related QOL, as

well as exercise capacity, as measured by the 6-minute-walk-test, among patients with COPD (Lacasse et al., 1996). Similarly, a recent systematic review and meta-analysis found several studies demonstrating that participation in >36 PR sessions could significantly decrease dyspnea and fatigue, increase health related QOL, and reduce hospital readmissions and healthcare costs for patients with idiopathic pulmonary fibrosis and interstitial lung disease (Cheng et al., 2018; McCarthy et al., 2015; Maltais et al., 2005; Dowman, Hill, & Holland, 2014). Overall, results from systematic reviews suggest that PR programming is an important component in the management of CRDs and is beneficial for improving health related QOL and exercise capacity, although there is little evidence supporting the effectiveness of PR in improving mortality.

Referral, Attendance, and Completion Rates

Despite proven benefits and improvements in health outcomes for patients with cardiovascular diseases (CADs) and chronic respiratory diseases (CRDs), cardiopulmonary rehabilitation (CVPR) remains considerably underutilized, with only an estimated 20% of eligible patients enrolling and completing CVPR programming (Mampuya, 2012). Many factors contribute to suboptimal participation rates, including low rates of referrals, barriers to enrollment, and difficulty retaining patients who are enrolled in the program. There are many instances in which healthcare providers fail to provide a referral to CVPR. For example, a systematic review by Brown and colleagues (2009) found that only 56% of patients hospitalized for a recent myocardial infarction (MI), percutaneous coronary intervention (PCI), or coronary artery bypass graft (CABG) procedure were referred to CR at discharge. Referrals to PR tend to be even lower, with only an estimated 3-16% of eligible patients with COPD being referred for PR programming (Milner, Boruff, Beaurepaire, Ahmed, & Janaudis-Ferreira, 2018; Azarisman et al., 2008; Bourbeau et al., 2008; Lange et al., 2007; Yawn & Wollan, 2008).

It is estimated that fewer than 30% of eligible patients utilize CVPR services following a referral, with the lowest participation rates occurring in rural areas of the Southeast region of the United States (Thomas et al., 2019; Hayton et al., 2013; Suaya et al., 2007). Given the low rates of referral enrollment, it is unsurprising that many patients who do enroll in CVPR programming do not complete the recommended course of 36 one-hour sessions. A recent review of Medicare data demonstrated these challenges with retention, with approximately 24% of Medicare-eligible MI patients attending at least one CR session, and 27% completing the recommended full-course of 36 sessions (Ritchey et al., 2021). Furthermore, one recent meta-analysis of 14 studies examining CR enrollment and adherence revealed that enrolled cardiac patients ($N = 8176$) attended approximately 37-85% of prescribed CR sessions (i.e., minimum eight weeks duration of programming, one to three CR sessions prescribed per week; Oosenbrug et al., 2016). Another study of discharged cardiac patients ($N = 526$) found that 63% of non-completers discontinued due to non-medical reasons, including patients being “not interested” or “too busy”, or believing they “can do it at home” (Sanderson, Phillips, Gerald, DiLillo, & Bittner, 2003).

Like CR patients, adherence among PR patients is also suboptimal. One retrospective analysis of COPD patients ($N=711$) found that 157 (31.8%) patients failed to attend a single session of PR after being referred (Hayton et al., 2013). Furthermore, among those who enrolled in PR, only 393 (70.9%) of patients attended at least 63% of prescribed sessions (i.e., 23 of 36 sessions; Hayton et al., 2013). Overall, these results highlight that rates of referral, enrollment, and adherence to CVPR programming are low, and have demonstrated little improvement in recent years. Further research is needed to better understand possible predictors for low adherence to CVPR, as well as to identify ways in which various patient-level, provider-level,

and system-level barriers to attendance can be addressed throughout the course of treatment to increase rates of attendance and completion.

Barriers to CVPR Attendance and Completion

The extent to which patients can receive optimal benefits from CVPR programming largely depend on patient-level factors including willingness, motivation, or ability to attend the 36 prescribed CVPR sessions, as well as the ability to adhere to the recommended health behaviors that are necessary to achieve the desired outcomes (e.g., prescribed physical activity and dietary recommendations; Sanderson et al., 2003). Given the low participation rates, several large-scale studies have examined barriers to CVPR programming, including specific barriers to referral, attendance, and completion. Barriers to referral include gaps in healthcare provider awareness of which patients might benefit from CVPR programming, inconsistency in referral patterns (i.e., non-systematic approach to referring eligible patients), lack of automated referral systems, and lack of knowledge about available local CVPR programs (Balady et al., 2007). While the problem of low referral rates occurs across patient populations, women, as well as people belonging to minority and marginalized groups, and those with low socioeconomic status are even less likely to be given a referral to CVPR (Shanshan et al., 2018).

While targeted referral strategies (e.g., automated referral systems) have been shown to increase patient enrollment in CVPR programming on the front end, there are other healthcare system-level or logistical barriers to participation that must also be considered. Patients often face significant barriers that make participation in CVPR programming difficult or unattractive. For instance, some eligible patients do not understand the important potential benefits of exercise-based rehabilitation programs to their immediate and long-term health. Furthermore, eligible patients may be interested in enrolling in CVPR but face practical or logistical barriers,

such as inconvenient hours of operation or scheduling conflicts (Ades et al., 2017). Additionally, patients living in rural areas are about 30% less likely to participate in CVPR programming due to barriers related to geographical distance (e.g., limited access to programs, long travel distances to CVPR locations) as well as transportation difficulties (Ressurreccion et al., 2017; Suaya et al., 2007; Fan et al., 2008). Suaya and colleagues (2007) used cardiac patients' residential zip codes to calculate the geographical distance to the closest CR center, and found that those with a mean distance of 31.8 miles (the group furthest from the CR center) were 71% less likely to participate in CR. Furthermore, geographical distance has also been demonstrated as an important predictor for PR participation, with driving distances greater than 36 miles being a risk factor for non-adherence for PR patients (Fan et al., 2008). Results from these studies demonstrate the need for accessible interventions to help address barriers to attending CVPR, including opportunities to receive telehealth services and interventions.

The cost of participating in CVPR is also an important barrier for some eligible patients, particularly for patients who have received less education or are otherwise socioeconomically disadvantaged. Although Medicare and most private insurers cover the bulk of the cost of CVPR services for eligible individuals, patients are typically faced with out-of-pocket costs, including deductibles and copayments, in addition to travel costs and time spent off work to participate (Balady et al., 2007). Furthermore, eligible patients with lower incomes are significantly less likely to participate in CVPR due to barriers related to cost (Ades et al., 2017; Gaaleema et al., 2014). A recent meta-analysis of 21 studies examining socioeconomic factors related to CR attendance found that post-high school education as well as full- or part-time employment is associated with increased likelihood of participating in CR programming (Sun et al., 2017). Furthermore, CR patients with a gross annual income of \$27,000 or greater in addition to having

health insurance coverage are significantly more likely to participate in CR programming (Shanshan et al., 2018). While fewer studies have examined socioeconomic factors related to adherence in PR patients, these services tend to be significantly underutilized by patients of older age (>70 years) and those who are unemployed or have received less education (Hayton et al., 2013).

In addition to practical or logistical barriers, many previous studies have examined patient-level barriers to participation including medical and non-medical reasons. One study found that while many patients are not able to attend due to medical reasons (e.g., multiple medical comorbidities, disability status), eligible patients are more likely to drop out due to non-medical reasons, including reasons related to psychosocial factors (e.g., anxiety, depression, stress, low social support; Ressurreccion et al., 2017; Sanderson et al., 2003). Previous studies have also reported that disease severity, as well as how a patient experiences and mentally frames living with a disease (i.e., illness perception; Weinman & Petrie, 1997), can affect enrollment and adherence to CVPR. These factors have also been shown to negatively affect exercise tolerance, such that patients with more severe symptomology and/or poorer illness perception tend to be less adherent to physical activity recommendations due to greater functional impairment (Heerema-Poelman, Stuive, & Wempe, 2013). Furthermore, low perceived control in one's ability to improve their own health has also been shown to be associated with low levels of CVPR adherence (Vos et al., 2013).

Brief Interventions and Retention Strategies for CVPR

Although multiple factors contribute to low participation rates in CVPR, many effective strategies have been developed to address the challenges at each stage of participation – referral, enrollment, and retention. The first step in improving participation in CVPR is ensuring that

eligible patients receive a timely referral. One successful strategy for increasing the rate of referrals is the implementation of automated referrals, with which a referral is automatically generated based on qualifying patients' electronic medical records (Grace et al., 2010). Many eligible patients fail to enroll because they lack the information needed to enroll, or do not fully understand the health benefits of exercise-based CVPR programming (Balady et al., 2007). Therefore, it is ideal for automated referrals to be accompanied by meaningful discussions between healthcare providers or care coordinators and eligible patients about the benefits of CVPR. Research suggests that the combination of patient education with automated referrals can increase rates of CVPR referrals from 30% to 86%, and enrollment from 20% to 74% (Ades et al., 2017). Other effective strategies to improve enrollment to CVPR include addressing financial barriers through implementation of payment plans, or by developing motivational videos and educational materials to encourage patient enrollment (Wall, Stolp, Lucindo, & Graff, 2018), and by notifying referring healthcare providers when patients fail to enroll (Ades et al., 2017).

The barriers to participation in CVPR are multifaceted and some may be addressed through alternative service delivery strategies. For this reason, several strategies and alternative models of service delivery have been developed over the years to promote CVPR patient enrollment and participation, including flexible program hours (e.g., open gym model; Whited et al., 2019), rewarding patients for regular attendance, using automated appointment reminders, connecting patients to program ambassadors or support groups, providing progress reports to referring physicians, and providing services outside of working areas to more convenient locations (e.g., home-based or virtual option; Ades et al., 2017). Overall, these results suggest that barriers to enrollment can be addressed by educating patients about the benefits of CVPR

and ensuring that patients are able to enroll in the program by inquiring about potential barriers (e.g., financial barriers, transportation difficulties, family- or work-related responsibilities).

Additional barriers to participating in CVPR programming include transportation difficulties and geographical distance to the CVPR site, which may be addressed through telehealth-based services. Recent literature has also demonstrated that telephone-based interventions have been successful in overcoming obstacles such as diminishing barriers to enrollment and improving perceived benefits from CVPR participation, increasing self-control, and enhancing the perception of controllability. One recent randomized controlled trial by LaValley and colleagues (2019) demonstrated that a brief, education, and motivational interviewing-based telephone intervention delivered shortly after enrollment significantly reduced early dropout rates when compared to standard care in cardiac rehabilitation patients. Another randomized controlled trial was conducted by Cossette and colleagues (2012), who evaluated the effect of an intervention based on Leventhal's self-regulation theory, focusing on the modification of the perceptions of illness (i.e., improving perceived control and encouraging a positive attitude toward rehabilitation), which resulted in greater initial enrollment in cardiac rehabilitation. These results suggest that telehealth interventions are a viable and effective strategy for improving adherence to CVPR. However, while telehealth-based interventions may be an effective strategy for addressing barriers to CVPR adherence, there have been no online retention interventions to date.

Once patients enroll in a CVPR program, it is important that they complete the recommended ≥ 36 sessions to ensure they receive optimal health benefits. However, despite the known health benefits of participating in CVPR, approximately half of patients who enroll in CVPR programming discontinue within the first two weeks of enrollment (Casey et al., 2008).

Furthermore, levels of physical activity have been reported to steadily decline following completion of CVPR programming, with up to 80% of CVPR patients failing to maintain regular physical activity during the first year of following CVPR completion (Bock, Carmona-Barros, Esler, & Tilkemeier, 2003). These trends of underutilization and low adherence highlight the need for targeted interventions to address modifiable factors that may be contributing to low adherence in order to help patients receive optimal benefits from CVPR programming.

Studies have been implemented to identify predictors of dropout, which vary widely. Most relevant to this study are depression and anxiety, as well as perceived illness severity and patient's confidence in the ability to manage their chronic health conditions independently. Low self-efficacy, poorer illness perception, depression, and anxiety are highly correlated with CVPR non-adherence, particularly for patients aged 65-years and older (Vos et al., 2013). Based on existing literature, an intervention program which decreases the number of patients who drop out or increases the number of CVPR sessions completed would likely improve health outcomes in this population. Several interventions have been developed to improve rates of referral and enrollment; however, there have been fewer interventions aimed to improve retention for CVPR patients (e.g., increasing total number of sessions completed, reducing the dropout rate). Considering the persistently low retention rates in CVPR, it is important to develop interventions that address patient-level factors (e.g., mood, self-efficacy, illness perception) that are common barriers to attending CVPR.

Lynggard and colleagues (2017) conducted a randomized controlled trial ($N = 825$) of an education-based intervention, 'Learning and Coping Strategies' (LC-REHAB), which was designed to improve cardiac rehabilitation enrollment and utilization by addressing patients' illness perceptions through the structured use of narratives (i.e., sharing brief examples of similar

patients' successes in changing a habit or solving a problem), motivational interviewing (i.e., exploring patients' reasons for changing their behavior toward a healthier lifestyle), as well as action-planning and goal-setting techniques (Lynggard et al., 2017). Results from this study showed that participation in the LC-REHAB intervention improved CR adherence both in terms of exercise training (i.e., 80% attended at least 75% of the exercise sessions versus 73% in the control group) and education classes (i.e., 79% attended at least 75% of education sessions versus 70% in the control group). Furthermore, CVPR patients with lower levels of education and household income appeared to benefit more from participating in the LC-REHAB intervention as evidenced by even greater improvements in adherence and health outcomes (Lynggard et al., 2017). These results suggest that intervention such as these may be particularly helpful for improving adherence among patients who experience greater barriers to adherence and are more at-risk for early dropout (Lynggard et al., 2017).

McGrady and colleagues (2014) designed an intervention using brief motivational interviewing and stress management techniques to improve patients' ability to manage stress in the context of participating in cardiac rehabilitation (CR). Patients who participated in the intervention completed an average of 30 CR sessions, which was significantly greater than the standard care control group (i.e., the average number of sessions attended by the CR-only group was 6 sessions; McGrady et al., 2014). Predictors of drop out remained the same across both the intervention and standard care control groups such that patients with greater anxiety and depression symptoms were significantly less likely to complete CR (McGrady et al., 2014). These results demonstrate the need for targeted interventions that use behavioral strategies and therapeutic techniques to address these common psychosocial barriers to CVPR adherence and completion.

Stress management techniques, including structured relaxation and cognitive reframing techniques, have long been recognized as effective strategies for managing anxiety and depression symptoms that often interfere with patients' motivation to engage in rehabilitation, as well as their perceived ability to make health behavior changes. Furthermore, stress management techniques have been implemented in numerous interventions for CR patients and has been associated with reductions in hypertension and overall improvements in cardiovascular health in this population (McGrady, Burkes, & Badenhop, 2014; Lear et al., 2003). Borg and colleagues (2020) conducted a randomized controlled trial to investigate adherence to and the effects of an intervention consisting of goal-setting and self-monitoring strategies and found that those who participated in the stress management intervention were more adherent to CVPR programming when compared to patients who received standard care. Health outcomes were similar across both the intervention and standard care groups; however, there were greater improvements in psychological health outcomes (e.g., anxiety and depression symptoms) for the intervention group (Borg et al., 2020).

The adoption of healthy lifestyle behaviors (e.g., eating healthy, increasing physical activity) and maintenance of these behavior changes is often accompanied by distressing physical sensations and negative thoughts that can negatively affect one's mood. Patients with low distress tolerance may be less motivated to adopt and maintain health behavior changes that are necessary for effectively managing chronic health conditions, such as cardiovascular and pulmonary diseases. For example, adopting a healthy diet can require patients to compromise on portion-size and taste of the food (e.g., smaller portion sizes and reduced sodium intake; Falk, Bisogni, & Sobal, 2000; Forman, Butryn, Hoffman, & Herbert, 2009). Furthermore, increasing physical activity can often lead to physical discomfort (e.g., shortness of breath, increased heart

rate) and associated increases in health-related anxiety or hopelessness (e.g., fear of causing exacerbations in chronic health conditions, ruminating thoughts that one's health will never improve despite their efforts; Butryn Forman, Hoffman, Shaw, & Juarascio, 2011). Additionally, smoking cessation is an important health behavior change for reducing risk for many adverse health effects; however, it can be very difficult for patients to stop smoking due to nicotine dependence, changes in habitual behaviors, and psychological cravings (Gifford et al., 2004; Brown Lejuez, Kahler, Strong, & Zvolensky, 2005). Furthermore, greater psychological distress and limited coping skills is often associated with poorer medication adherence across several patient populations, including HIV-positive patients as well as patients with breast cancer (Vervoort et al., 2009). These results further support the need for targeted interventions to help patients cope with the psychological distress that often limits one's motivation to adhere to medical recommendations and health behavior changes that are necessary for chronic disease management.

The connection between patients' core personal values and their motivation to make health behavior changes is important to consider. From a behavioral standpoint, personal values are defined as "freely chosen", verbally constructed consequences of ongoing, dynamic, evolving patterns of behavior, which establish predominant reinforcers for specific activities that align with what an individual considers important or meaningful to them (Wilson & Dufrene, 2009; Hayes, Strosahl, & Wilson, 2012). In other words, personal values come from an individual's life experiences and help to establish the types of activities that will feel more intrinsically rewarding and reinforcing to the individual. When someone perceives little connection between their personal values and a specific activity or behavior (e.g., engaging in physical activity, eating healthy foods), that individual may sacrifice long-term behavioral goals (e.g., adopting and

maintaining a healthy lifestyle, adhering to medical recommendations for chronic disease management) in service of their short-term goals (e.g., reducing the psychological distress or physical discomfort they are experiencing at that moment). Avoidance of potentially distress or uncomfortable experiences, also known as experiential avoidance, is a common technique that is used (most often unintentionally and without the individual's awareness) to reduce distress in the present moment. Experiential avoidance may also explain the difficulty many patients experience when making health behavior changes, despite them being informed or educated on the medical risks associated with failing to make these lifestyle changes (Spatola et al., 2014). Exploration of personal values is a clinical technique used in collaboration between patients and providers to empower patients to recognize their own motivations for engaging in a specific behavior or activity for engaging. Additionally, values exploration is a helpful therapeutic technique for identifying meaningful and personally relevant behavioral goals. Values-based interventions have been recently implemented in numerous patient populations and for a variety of health behavior changes, including chronic pain management (Veehof, Trompetter, Bohlmeijer, & Schreurs, 2016; Saracutu, Edwards, Davies, & Rance, 2018), behavioral weight management (Forman & Butryn, 2015), and smoking cessation (Jones et al., 2015). These results have shown promise for using values exploration as a therapeutic technique for helping individuals make difficult health behavior changes, such as increasing physical activity and healthy eating for CVPR patients.

According to self-determination theory (SDT), motivation to engage in a behavior exists on a continuum ranging from controlled to autonomous motivation, in which more autonomous or intrinsic forms of motivation result in more sustained behavior changes (Ryan & Deci, 2000). Previous studies suggest that SDT may be a useful framework for examining cardiac patients'

motivation to make health behavior changes. For example, Russel and colleagues (2010) found that patients' engagement in values-consistent or intrinsically motivating forms of physical activity is associated with greater engagement and maintenance of physical activity outside of rehabilitation. Therefore, an SDT may be a useful framework to consider when developing interventions to support adherence and health behavior changes for CVPR patients. Many SDT-based interventions, including Behavioral Activation Treatment for Depression (BATD) and Acceptance and Commitment Therapy (ACT), promote strategies for values exploration and values-based behavior change as one of the key components in the interventions. BATD and ACT are also context-oriented interventions that seek to reduce maladaptive patterns of behavior, including experiential avoidance (e.g., avoidance of potentially distressing or unpleasant experiences) that maintain symptoms of anxiety and depression and pose as barriers to making health behavior changes necessary for chronic disease management (Hayes, Strosahl, & Wilson, 2012). The activities and behaviors that an individual finds intrinsically meaningful and motivating can be identified through values exploration to help guide CVPR patients in making long-lasting health behavior changes that are personally relevant and rewarding.

Several values-based interventions have been used to increase CVPR enrollment; however, none have been developed to address low adherence and completion of CVPR. Butrn and colleagues (2011) developed a brief, two-session intervention to assist behavioral weight management patients in exploring their personal values and identifying values-consistent forms of physical activity to improve long-term adherence to medical recommendations. This intervention also utilized therapeutic techniques based on the core principles of ACT, including mindfulness, defusion from distressing thoughts, and committed action. The results from this study did not support the idea that a values-based intervention can lead to long-term maintenance

of physical activity in a behavioral weight management patient population. However, it is encouraging that results from this study revealed that a brief values-based intervention was associated with greater adherence to physical activity recommendations in the short-term. These results provide promising evidence that a values-based intervention may be useful for improving adherence and completion inpatients referred for CVPR, which is a patient population that is frequently asked to make similar health behavior changes as behavioral weight loss patients.

Brief values-based interventions have demonstrated an ability to address core theoretical processes that can contribute to sustained health behavior changes. Therefore, more research is warranted to explore the feasibility and acceptability in using values-exploration and other principles of ACT to improve adherence to health behavior changes that are often difficult but necessary for managing chronic disease. It is especially important to explore the utility of a values-based intervention to improve adherence to medical recommendations for patient populations who experience a high level of psychological barriers to care, including CVPR patients. Depression and anxiety have consistently been implicated as common barriers to CVPR adherence. It is important to consider how patterns of behavior, including avoidance of potentially unpleasant experience, may be associated with CVPR adherence.

Implications for CVPR During the COVID-19 Pandemic

The impact of telehealth during the Covid-19 pandemic has been significant, particularly in preventing morbidity and direct person-to-person exposure to pathogens in settings such as hospitals and clinics. Prior to the Covid-19 pandemic (January 2020), approximately less than 10% of the U.S. population had utilized telehealth services for a medical encounter, and only 18% of healthcare providers had provided telehealth services (Koma, Cubanski, & Neuman, 2021). However, the slow rate of adoption of telehealth prior to the Covid-19 pandemic was not

due to lack of empirical support. In particular, the delivery of psychological and behavioral health services via telehealth platforms, known as telemental health or teletherapy, has a robust evidence base. Numerous studies have demonstrated its effectiveness in addressing psychological concerns, including anxiety, depression, and other psychosocial factors, across a broad range of technological modalities including webchat, video conferencing, and telephone calls (Tuerk, Keller, & Aciemo, 2018).

The American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR), American Heart Association (AHA), and American College of Cardiology (ACC) examined the evidence for using home-based CVPR (HBCVPR) programs to improve health outcomes among cardiac patients prior to the Covid-19 pandemic. Overall, these organizations released a statement concluding that HBCVPR may be a reasonable option for low- to moderate-risk patients who otherwise cannot attend a traditional in-person, or center-based CVPR (CBCVPR) program. According to the Centers for Disease Control and Prevention (CDC), older adults (aged 65 and older) and adults (aged 18 and older) diagnosed with chronic health conditions such as CADs and CRDs are at increased risk for developing severe illness from Covid-19 (CDC, 2021). Therefore, there has been a movement toward increasing access to telehealth-based medical care, including telerehabilitation services, to comply with public health guidance on social distancing and reduce risk of exposure to Covid-19. Telerehabilitation, including home-based CVPR (HBCVPR), offers an opportunity for patients to participate in routine rehabilitation services safely and remotely. Past research has also demonstrated that HBCVPR produces similar health outcomes to center-based CVPR (CBCVPR) while also addressing common barriers to CVPR adherence, including geographical distance, transportation difficulties, busy work schedule, caregiver responsibilities (Choxi et al., 2021).

Expert consensus has suggested the utilization of technologies (e.g., smartphones, online platforms, video conferencing) to deliver telerehabilitation services is a viable option for CVPR patients with limited access to in-person services. CVPR centers have recently started to innovate and expand access to telerehabilitation services, implementing strategies such as remote monitoring tracking, mobile apps, online coaching, and virtual interviewing to optimize health outcomes (Choxi et al., 2021). Remote monitoring allows both healthcare providers and patients to track daily physical activity, nutrition information, and vital sign parameters (e.g., blood pressure, heart rate) in a way that has the potential to empower patients to make informed decisions regarding their health and promote self-regulatory health behavior changes. Remote monitoring can also provide healthcare providers and staff with meaningful insight to tailor treatment plans to fit the needs of a specific patient based on context and situation. However, although there are many advantages to telehealth services, digital inequity is an important barrier that must be considered, including limited access to technology (e.g., high-speed internet, smartphones, web cameras), limited familiarity with using technology, and barriers to technology faced by people with disabilities (e.g., vision and hearing impairment). Older adults (aged 65 and older) often experience greater barriers to technology including limited experience in using technologies and higher rates of disabilities that may impact their ability to access technology required to participate in telehealth services. Importantly, the CVPR population tends to be age 65 and older, on average, and participation in telehealth services requires access and familiarity in using smartphones, internet capabilities, and video conferencing that may not be available for some individuals due to financial constraints and digital inequality (Moulson et al., 2020; Choxi et al., 2021). Therefore, it is important to consider strategies to expand technology access, such as patient education on telehealth services and technology support, when developing

interventions for this patient population. This is especially important for patients who experience greater barriers to CVPR in general, as these individuals would likely benefit the most from targeted intervention to address psychosocial barriers to CVPR adherence.

Recent studies have demonstrated that nationwide rates of depression, anxiety, and loneliness has increased exponentially in the wake of the Covid-19 pandemic. Furthermore, older adults (age 65 and older) who are homebound may be at further increased risk for rapid decline in psychological wellbeing, increased sedentariness, limited social interaction, and poorer illness perception (Choxi et al., 2021). These results further support the importance of developing brief, accessible telehealth interventions aimed toward addressing common psychosocial barriers to adherence in the CVPR patient population.

Technology Tools and Ecological Momentary Assessment

Technology has long held promise for expanding access to healthcare services and psychosocial interventions. For example, research suggests that older patients, especially those with lower income and those living in rural areas, can benefit greatly from telehealth services because technology can reduce common barriers related to transportation, scheduling challenges, and geographic distance (Koma, Cubanski, & Neuman, 2021). Therefore, the integration of mobile technology in the delivery of CVPR services is currently being explored and implemented to expand access to rehabilitation services by increasing opportunities for patients to utilize these services virtually when they otherwise could attend these sessions in-person. In addition, the potential for technology to support public health efforts has also been demonstrated. For example, the use of technology tools to collect real-time data can inform individualized treatment plans and can be used as an education tool to support self-regulation of health behavior changes.

Historically, psychological research has primarily relied on cross-sectional or retrospective self-reports as a means to gather information about research participants. However, there is strong evidence suggesting that retrospective self-reports are subject to recall biases that challenge both reliability and validity of the data (Trull & Ebner-Priemer, 2009). Furthermore, there are often discrepancies between real-time and retrospective assessments of psychological factors and specific health behaviors across a wide range of patient populations with chronic diseases and comorbid anxiety and depression (Trull & Ebner-Primer, 2009). In recent years, EMA has received increased attention as a methodological approach to data collection that is capable of sampling specific behaviors and experiences in real-time and within their everyday environment, thus capturing the temporal and contextual nature of target variables in psychological research (Shiffman, Stone, & Hufford, 2008; Kim, Marcusson-Clavertz, Yoshiuchi, & Smyth, 2019).

There are numerous data collection tools have been developed to record participant experiences at varying time intervals including written diaries, electronic diaries, physiological sensors (e.g., actigraphy), and mobile applications. EMA in psychological research is less influenced by recall biases and highly sensitive to day-to-day or moment-to-moment changes in variables of interest (Shiffman, Stone, & Hufford, 2008). Through use of these tools and the strategic selection of times of data collection, researchers can collect data that can highlight how specific behaviors and emotional experiences can vary across time and contexts. For instance, previous daily diary studies have demonstrated that individuals with higher depressive symptoms at baseline tended to engage in experiential avoidance on a day-by-day basis (Shahar & Herr, 2011). Similarly, Machell and colleagues (2015) conducted a daily diary study and found that

daily avoidance behaviors strategies predicted higher negative mood, lower positive mood, less enjoyment in daily activities, and less perceived meaning in life.

Given the variability in daily mood and experiences, EMA appears to be an ideal approach for approach for assessing fluctuating avoidance and other coping behaviors to regulate negative mood as it arises in-the-moment. Most recently, Wenze and colleagues (2018) used mobile EMA methodology to examine the relationship between mood, experiential avoidance, and perceived stress in college students. Overall, their findings demonstrated that experiential avoidance could serve as both a trigger for and consequence of negative mood and anxiety (Wenze, Gaugle, Sheets, & Decicco, 2018). Furthermore, they found that higher levels of experiential avoidance were associated with lower positive mood and fewer positive thoughts, suggesting that when participants were feeling good or thinking positively, they were less likely to avoid specific experiences (Wenze et al., 2018). Taken together, these findings support the idea that mood and experiential avoidance are bidirectional, context-specific processes that can be measured on a within-person, within-day basis (Wenze, Gaugle, Sheets, & DeCicco, 2018).

Information gathered using an EMA approach can be helpful for examining the fluid, dynamic association between mood, ways of coping with aversive experiences, and the likelihood of engaging in certain behaviors. For example, EMA has been used in in college student samples to examine how daily ratings of depression and anxiety fluctuate and influences the likelihood of engaging in specific behaviors for weight management (e.g., daily engagement in physical activity; Shahar & Herr, 2011, Machell, Goodman, & Kashdan, 2015). However, EMA studies have predominantly used college student samples to establish the feasibility and utility of using EMA methodology.

Few studies have implemented an EMA approach to data collection in specific populations of patients with chronic health conditions. Given the dynamic nature of living with a chronic medical condition, it is important to utilize real-time measurements to better understand how psychological factors may impact adherence to medical recommendations, and the sustainability of health behavior changes on a momentary basis. Given that depression and anxiety symptoms are common barriers to CVPR adherence, it is important to gain a better understanding of contextual shifts in mood and avoidance of specific health behaviors that may influence CVPR adherence. Taken together, this momentary data could potentially highlight important processes, intervention targets, and outcomes for examining the effectiveness of novel interventions aimed toward improving CVPR adherence.

The goal of the present study is to assess the feasibility and acceptability of a brief values-based intervention with the goal of improving CVPR adherence through promotion of values-consistent health behaviors. Furthermore, the secondary goal of the present study was to utilize ecological momentary assessment (EMA) to examine preliminary outcomes of the brief intervention as well as contextual changes in depression, anxiety, and experiential avoidance that may also affect CVPR adherence.

Aims and Hypotheses

The **first aim** for the study included assessing the feasibility and acceptability of a novel values-based telehealth intervention for improving adherence to CVPR. Feasibility was assessed by examining the number of participants enrolled in the present study, number of intervention sessions attended by participants, response rates for EMA prompts, and follow-up rates for post-completion sessions. Acceptability was assessed through a semi-structured qualitative interview that was conducted following the five-week intervention period, as well as informal feedback

provided by participants throughout the five-week study period. For the present study, acceptability was assessed using questions pertaining to comfort with using technology tools, barriers to participating in the intervention, experiences of taking part in the intervention, and specific feedback for improvement of the intervention.

The **second aim** for the study was to use EMA methods to investigate indirect effects of the telehealth adherence intervention on CVPR adherence by observing week-to-week variations in attendance. This secondary aim was to assess preliminary outcomes of the adherence intervention. This study originally aimed to examine the potential association between intervention adherence (i.e., participation in the live sessions and self-guided, pre-recorded version) and overall CVPR adherence (i.e., number of CVPR sessions attended, CVPR completion status). Based on previous research conducted in behavioral weight management populations, we hypothesized that:

- a. Within-person variations in weekly CVPR attendance would be observed across the five-weeks of study participation, and weekly CVPR attendance would be positively correlated with weekly adherence intervention attendance.
- b. The number of adherence intervention sessions attended over time would be positively correlated with CVPR completion status.

The **third aim** of the study also involved examining preliminary outcomes of the intervention for exploratory purposes, using EMA methodology. The tertiary aim was to contrast baseline mood state and experiential avoidance with day-to-day assessment of these variables. Additionally, we aimed to examine whether momentary mood state and experiential avoidance was associated with overall adherence to the live intervention sessions and daily CVPR attendance. We hypothesized that:

- a. Negative mood (i.e., higher ratings of depression and anxiety) and higher experiential avoidance on a day-to-day basis would be negatively associated with CVPR attendance for the same day.
- b. Attendance to the live intervention sessions would be positively associated with increased positive mood, lower experiential avoidance, and greater congruence between CVPR attendance and personal values following the five-week study period.

Chapter 2: Methods

Study Design

This is a mixed-methods study focusing on determining the feasibility and acceptability of a novel values-based telehealth intervention aimed to promote CVPR adherence. The main outcomes of this study include the feasibility of the recruitment process and measurement tools, and the acceptability of the intervention based on adherence and participant feedback.

Quantitative data was collected at baseline and post-completion including measurements of depression and anxiety symptoms, congruence between personal values and CVPR participation, and perceived barriers to CVPR adherence.

It was originally planned that ecological momentary assessment (EMA) would be used to collect quantitative data regarding secondary outcomes for exploratory purposes, including daily mood ratings and experiential avoidance, in order to monitor changes in these outcomes over time as it relates to CVPR adherence and intervention participation. However, we were unfortunately unable to conduct these analyses due to technological difficulties which are further discussed later on. Following the five-week intervention period, a post-completion session will be held in order to repeat self-report measures from the beginning of the study and to invite participants to participate in a post-completion interview. This semi-structured qualitative interview was conducted with interested participants to provide insight into their experiences of taking part in the intervention and suggestions for improvement.

Participants and Recruitment

Participants were recruited from the current patient population at ECU Health's Cardiovascular and Pulmonary Rehabilitation (CVPR) program and included both cardiac and

pulmonary patients. The recruitment process was developed through collaboration between the research team and CVPR staff. Recruitment was carried out in partnership with CVPR staff and was performed in two stages as indicated in Table 1. All incoming patients were provided relevant information about the study and invited to participate in the intervention either through conversations with CVPR staff or members of the research team. Furthermore, announcements were made during regularly scheduled CVPR sessions in order to provide information about the intervention study.

Members of the research team worked in conjunction with CVPR staff to identify recently enrolled patients. It was originally planned that the intervention study would only include patients within their first two-weeks of enrollment at CVPR, as this is the period in which patients are most susceptible to dropping out of CVPR. However, this was later expanded to include patients within their first two months (1-8 sessions) of CVPR enrollment in order to increase study enrollment. Eligible patients were provided with informational handouts regarding the intervention study and asked about their potential interest in participating. There was no specific exclusion criteria for age, gender, or race/ethnicity; however, the ability to read, write, and speak English was required to participate in the study (see Table 1).

Patients were not excluded based on limited access or familiarity with technology but rather were offered multiple options for participating in the intervention study including self-guided/prerecorded videos of the intervention sessions and live virtual group meetings. This decision was made by the researchers to address barriers to participating in the present study so these patients could also provide feedback on the intervention. Regarding momentary data collection, patients were not excluded based on whether they owned a smartphone but were

provided with paper versions of the daily diary forms and asked to set alarms to prompt them to complete these forms on the same schedule as those using their smartphone device.

Stages of Recruitment	
First Stage	Second Stage
<ol style="list-style-type: none"> Members of the research team and CVPR staff identified eligible patients within their first two months of CVPR enrollment. Members of the research team applied the inclusion criteria: patients who are able to read, write, and speak English; patients able and willing to commit to five consecutive weekly group meetings, to be interviewed about taking part in the study, and to complete mobile EMA monitoring three times per week. 	<ol style="list-style-type: none"> Members of the research team reiterated the nature of the telehealth intervention (there will be a total of five virtual group meetings or viewing of five pre-recorded videos, remote monitoring three times per week, and followed by completion of post-intervention measures, and an invitation to participate in a qualitative interview at the end of the study period). Patients were provided the opportunity to ask questions regarding the intervention and technology prior to consenting to participate in the study.

Table 1: Description of recruitment stages.

According to the National Center for Complementary and Integrative Health (NCCIH), the goal of assessing feasibility and acceptability studies is not necessarily to test specific hypotheses but to gain valuable insight into participants’ experiences of taking part in the study (Kraemer, Mintz, Noda, Tinklenberg, & Yesavage, 2006). As such, past research suggests that it was not necessary to provide power analyses for the planned sample size of the present study. Based on the patient flow at ECU Health’s CVPR Center (i.e., average of 8 new patients per week, totaling 40 new patients over the five-week study period), it was determined that it would be reasonable to recruit at least 50 participants to evaluate the feasibility and acceptability of the intervention. This goal of recruiting 50 participants for the purposes of the proposed study was further supported by previous power analysis and multilevel linear regression findings using

EMA methodology (Midgette, Ellis, & Whited, 2021). A power analysis for a previous study using EMA in the current patient population was conducted using MLPowSim software (Brown, Lahi, & Parker, 2009), and it was determined that 50 participants completing approximately 21 prompts would achieve 89% power.

Measures

Baseline depressive symptoms. Symptoms of depression were assessed using the Patient Health Questionnaire – 9 (PHQ-9). The PHQ-9 is a brief, self-report measure that is commonly used to assess the severity of depressive symptoms for patients in both clinical and research settings (Kroenke, Spitzer, & Williams, 2003). The PHQ-9 assesses the degree to which an individual has experienced each of the nine DSM-V diagnostic criteria for depression over the past two weeks, scoring each as 0 (“not at all”) to 3 (“nearly every day”). These scores are then totaled, with higher scores reflecting greater depression severity. Total PHQ-9 scores of ≥ 10 indicate mild depression, scores of ≥ 15 indicating moderate depression, and scores of ≥ 20 indicating severe depression. The PHQ-9 has demonstrated good reliability and validity for use in clinical and research settings and a variety of patient populations (Kroenke, Spitzer, & Williams, 2003).

Baseline anxiety symptoms. Symptoms of anxiety were assessed using the Generalized Anxiety Disorder Questionnaire – 7 (GAD-7). The GAD-7 is a 7-item questionnaire developed to identify individuals with probable symptoms of Generalized Anxiety Disorder (GAD), using the seven most prominent diagnostic features of GAD (Spitzer, Kroenke, Williams, & Lowe, 2006). The GAD-7 asks participants to rate how often they have been bothered by each of the seven core symptoms of GAD over the past two weeks on a 4-point Likert scale, scoring each as 0 (“not at all”) to 3 (“nearly every day”). Spitzer et al. (2006) reported acceptable sensitivity and

specificity for this measure in screening symptoms of GAD using a cutoff score of 10 or higher (sensitivity = 89% and specificity = 82%). Furthermore, the GAD-7 has demonstrated good internal consistency, test-retest reliability, as well as convergent, construct, criterion and factorial validity for both primary care patients and the general population (Spitzer et al., 2006).

Momentary mood ratings. Three times per week, participants were asked to indicate the extent to which they were feeling depressed (e.g., sad, lonely), anxious (e.g., jittery, nervous), angry (e.g., hostile), happy, and excited in that current moment using a Likert scale ranging from 1 (“not at all”) to 6 (“a lot”). Previous EMA studies have shown that momentary ratings for depressed, anxious, and angry moods can be averaged to obtain a total score to reflect overall negative mood (Wenze et al., 2018). Similarly, scores on the two positive mood items (i.e., happy, excited) can be averaged to yield an overall measure of positive mood. These EMA items were drawn from the Positive and Negative Affect Schedule – Expanded Form (PANAS-X; Watson & Clark, 1994) and have been successfully used in several EMA studies examining the bi-directional associations between day-to-day variations in mood and experiential avoidance (Wenze et al., 2018; Wenze, Gunthert, & Forand, 2007; Wenze, Gunthert, & German, 2012). A list of the EMA items used for this study is listed in Appendix A.

Momentary experiential avoidance. Momentary experiential avoidance was measured three times per week with five statements reflecting various aspects of experiential avoidance (see Appendix B). These items were developed based on the subscales of the Multidimensional Experiential Avoidance Scale (MEAQ; Gamez et al., 2011) and have been successfully used in previous research using EMA. Each of the five items represents subscales of the MEAQ (i.e., Behavioral Avoidance, Distress Aversion, Procrastination, Distraction & Suppression, Repression & Denial; Gamez et al., 2011). However, the Distress Endurance subscale was

excluded to minimize patient burden as this item has performed poorly across several studies (Gamez et al., 2011; Rochefort et al., 2018; Wenze et al., 2018). When responding to items on this measure, participants are asked to rate the extent to which they agree with statements reflecting multiple aspects of experiential avoidance on a Likert scale ranging from 1 (“strongly disagree”) to 6 (“strongly agree”).

Values congruence with CVPR attendance. Three times per week, participants were asked the following question: “How well do you think your goal to attend Cardiopulmonary Rehab is consistent, or in line with, your values (or what’s important to you) today?” on a 6-point Likert scale. This question was developed for use in this study to assess the level of congruence between CVPR attendance and personal values as there is no existing, validated measure for this construct in the literature.

Perceived barriers to CVPR attendance. The presence of barriers to attendance at CVPR will be assessed using 12 items from the Cardiac Rehabilitation Barriers Scale (CRBS). The CRBS is a 21-item self-report questionnaire, which asks patients to indicate the extent to which each item reflects a personal barrier to participating in cardiac rehabilitation (Shanmugasagaram et al., 2012). Items on the CRBS were intended for use in a cardiac patient population regardless of whether they were referred to or enrolled in cardiac rehabilitation. Therefore, CRBS items were selected for the present study based on the most relevant subscales (i.e., logistical factors, work/time conflicts, comorbidities/functional status) to be applicable to patients enrolled in both cardiac and pulmonary rehabilitation. Items were rated on a 6-point Likert scale ranging from 1 (“strongly disagree”) to 6 (“strongly agree”). Participants completed this measure during the post-completion session following the five-week study period to further assess potential barriers to participating in the intervention (see Appendix C).

Feasibility and Acceptability. The primary aim of the present study was to assess the feasibility and acceptability of a novel values-based telehealth intervention to promote CVPR adherence. Feasibility was assessed using quantitative data from the recruitment process (e.g., the number of participants referred), intervention attendance, and the measurement tools (e.g., response rate for EMA questions, participation in post-completion sessions). To assess acceptability, participants were invited to participate in a semi-structured qualitative interview based on the Multi-Construct Theoretical Framework of Acceptability of Healthcare Interventions (Sekhon, Cartwright, & Francis, 2017), to enhance our understanding of participants' experiences of taking part in the study, their overall understanding of the intervention, factors that may have influenced their willingness to engage with the intervention, and suggestions for improvement.

Acceptability will be divided into seven categories including: 1.) Self-Efficacy (the participant's confidence that they can perform the behaviors required to participate in the intervention), 2.) Perceived Burden (the perceived amount of effort that is required to participate in the intervention), 3.) Opportunity Costs (the extent to which benefits or values must be given up to engage in the intervention), 4.) Intervention Coherence (the extent to which a participant understands the intervention and how it works), 5.) Perceived Effectiveness (the extent to which the intervention is perceived as likely to achieve its purpose), 6.) Affective Attitude (how an individual feels about the intervention), and 7.) Suggestions for Improvement (Sekhon, Cartwright, & Francis, 2017).

The post-completion interview questions included the following: 1.) How comfortable did you feel using the technology required for the present study? (i.e., EMA Mobile Application, Cisco WebEx, YouTube; if applicable); Did you encounter any difficulties using the technology?

(Self-Efficacy); 2.) What are some reasons you did (or did not) participate in the program? (Perceived Burden & Opportunity Costs); 3.) In your own words, what do you think was the overall purpose or aim of the program? (Intervention Coherence); 4.) What did you learn from the program? Were there aspects of the program that you found helpful? Were there aspects of the program you did *not* find helpful? (Intervention Coherence & Perceived Effectiveness); 5.) What aspects of the program did you like the most? What was your favorite activity or session? (Intervention Coherence & Affective Attitude); 6.) Can you tell us more about your experience of taking part in the program? Have your perspectives of cardiopulmonary rehab changed as a result of taking part in the program? If the answer is ‘Yes’, what changed? (Affective Attitude & Perceived Effectiveness); 7.) What do you think could be improved about the program? (Suggestions for Improvement); 8.) Would you recommend the program to someone you care about if they were starting cardiopulmonary rehab? Why or why not? (Affective Attitude); 9.) On a scale from 1-10 (1 ‘no effort at all’, 10 ‘extreme effort’), how much effort do you think it took for you to participate in the program? Why did you give this rating? (Perceived Burden); 10.) How well do you think the program helped you in reaching your goal of attending cardiopulmonary rehab? (Perceived Effectiveness). See Appendix D.

All participants, regardless of whether they dropped out of CVPR or participated in the intervention, were contacted following the five-week intervention period to invite them to participate in the qualitative interview. Participants were informed that they were welcome to opt out of this interview if they preferred not to participate or otherwise wanted to discontinue the intervention study. Participants who indicated that they had stopped participating in the intervention study (e.g., ceased attending intervention sessions or watching pre-recorded videos, and/or stopped responding to EMA prompts) were asked if they would be interested in

participating in a brief interview pertaining to their experiences of taking part in the intervention study, as well as reasons for discontinuing their participation in the intervention. The questions for the participants who discontinued the intervention included: 1.) What are some reasons why you decided to discontinue the program (Perceived Burden & Self-Efficacy)? 2.) Is there anything that would have made it easier for you to participate in the program (Perceived burden & Self-Efficacy)? An outline of the qualitative interview questions used to assess acceptability of the intervention are listed in Appendix D.

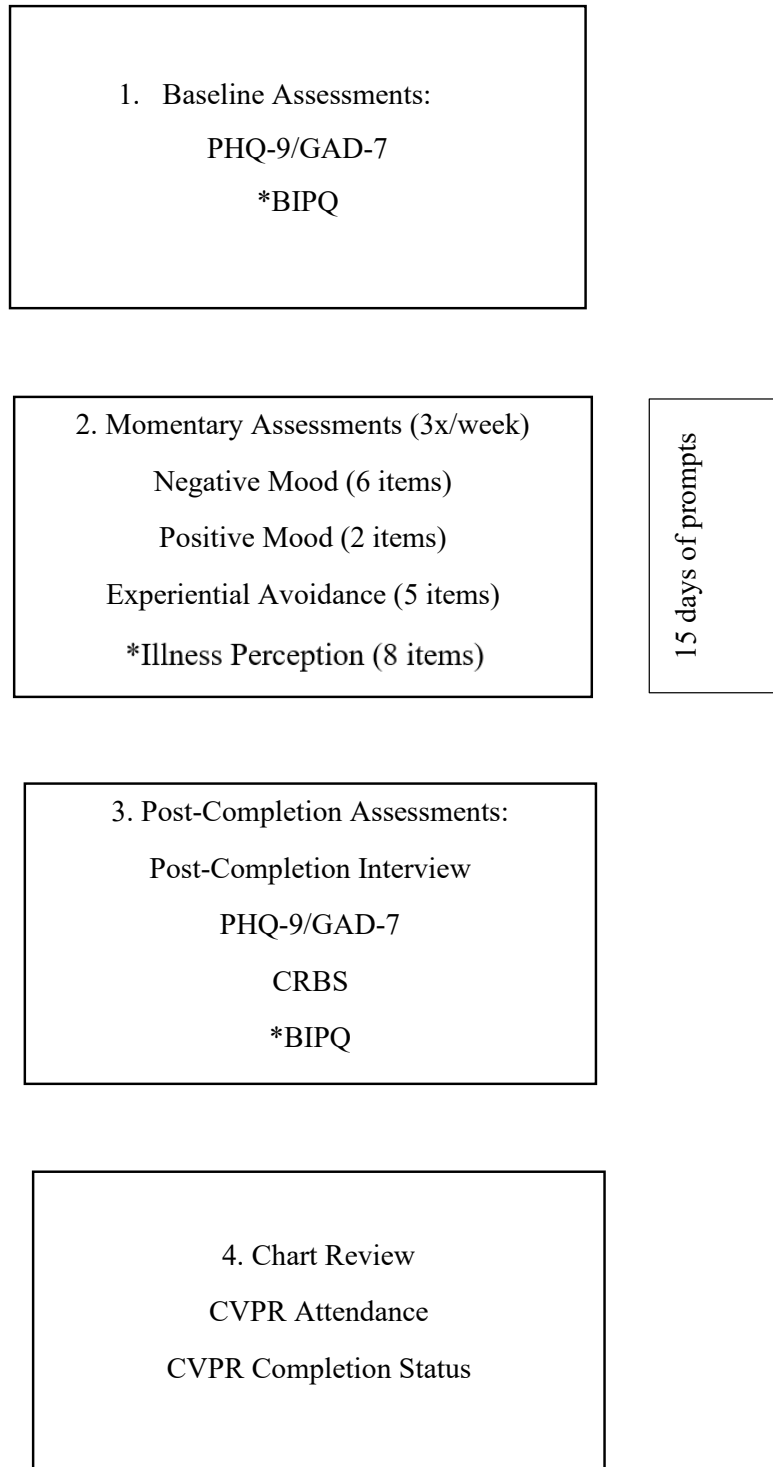


Figure 1: Outline of baseline measures, EMA assessments, post-completion measures, and outcomes. Measures listed with an asterisk are relevant to a joint study. EMA = Ecological Momentary Assessment. CVPR = Cardiopulmonary Rehabilitation. PHQ-9 = Patient Health Questionnaire Depression Screener. GAD-7 = Generalized Anxiety Disorder Screener. CRBS = Cardiac Rehabilitation Barriers Questionnaire. BIPQ = Brief Illness Perception Questionnaire.

Procedure

The study was conducted at the Cardiovascular and Pulmonary Rehabilitation (CVPR) program at ECU Health. Handouts with general information were posted around the CVPR facility and announcements were made to provide information regarding the study. Patients who were within their first two months (6-8 sessions) of CVPR were approached by members of the research team and CVPR staff to ask if they might be interested in participating in the intervention study. Patients who expressed interest were invited to participate in a baseline session with a member of the research team to provide additional information regarding the intervention study. This baseline session lasted approximately 20-25 minutes and participants were provided with informed consent and invited to ask questions regarding the study. Interested participants who did not own a smartphone device or otherwise unable to use the mobile app were given the opportunity to complete paper versions of the EMA prompts.

After providing informed consent, participants were monetarily compensated for their agreement to participate in the study by being provided with a Walmart gift card with a ten dollar value. Participants were then asked to complete baseline measures of anxiety and depression symptoms and congruence between personal values and CVPR adherence. Participants were also given the opportunity to ask questions regarding the study procedures and educated by research staff on how to use the technology required for the study. As needed, brief follow-up visits were conducted either on-site at CVPR or virtually to provide additional guidance on using the technology required for the study. As part of a joint research study, participants were also asked to complete a modified, eight-item version of the Brief Illness Perception Questionnaire. Following this, participants were introduced to the EMA mobile app (Personalized Analytics Companion) and were instructed on the procedures for responding to daily prompts. The

Personalized Analytics Companion (PACO) is an open-source data collection platform that was designed for ecological momentary assessment. Participants were then asked to complete an initial EMA survey to orient them to the app and provide the opportunity to ask questions.

Participants were then introduced to Cisco WebEx, a free online video-conferencing platform that was utilized for the present study for participation in the live group meetings. Participants were instructed on the procedures for downloading the app on their preferred device (e.g., smartphone, laptop, tablet). Participants who wished to attend the live group meetings using their smartphone or tablet were assisted in downloading the mobile app (Cisco WebEx) and instructed on how to create an account. During this time, participants were asked to practice joining a virtual session to orient them to the video platform and were given the opportunity to ask questions. Participants who wished to attend the live group meetings using their personal computer or laptop device were provided instructions on how to download the desktop app for Cisco WebEx and were asked to schedule a time to follow-up with a research team member within the first week of study enrollment. The purpose of this brief follow-up meeting (10-15 minutes) was to ensure they had downloaded Cisco WebEx on their preferred device and were able to access the virtual group meetings.

Intervention. The values-based intervention of the present study is a brief telehealth program composed of weekly 45-minute-long sessions, taking place over five consecutive weeks. Each of the five sessions were developed based on principles of Acceptance and Commitment Therapy (ACT) and designed to specifically focus on adopting adaptive coping strategies to deal with emotional distress in CVPR and promote values-consistent health behavior changes. In particular, each of the five intervention sessions emphasized the importance of identifying personal values to inform health behavior goals and reduce unhelpful avoidance

behaviors in the context of CVPR participation (e.g., avoidance of physical activity). The structure of each session consisted of an introduction to each topic followed by reflection on the ways in which session material can be used to make meaningful and sustainable health behavior changes during and after CVPR participation.

At the beginning of each session, participants were introduced to one another, and the research team members introduced themselves. The research team member then provided a brief overview of the purpose of the program, including an explanation of basic tenets of ACT as it relates to the nature of managing chronic disease (i.e., increasing values-driven behavior, getting caught in the moment-to-moment struggle, accepting where you are, your role in self-care). A brief overview and the objectives for the session were presented, and participants were invited to ask questions about specific content as the session proceeds. A summary of session-by-session content is listed in Table 3. The review of session content included an invitation for participants to ask questions and reflect on the content, practice learned strategies, and an introduction to practice exercises. Each session ended with a reminder for participants to complete mobile monitoring using the EMA mobile app, as well as an invitation for participants to ask questions regarding the technology and/or data collection tools.

Sessions	Content
Acceptance & Values	<ul style="list-style-type: none"> • Acceptance as opposed to avoidance. • What are personal values and why are they important? • Values clarification exercise. • Pleasant activity scheduling sheet.
Cognitive Defusion & Values Clarification	<ul style="list-style-type: none"> • What defusion is and how to distance self from thoughts. • The ‘Passengers on the bus’ metaphor.

	<ul style="list-style-type: none"> • Getting caught in the struggle and brief reflection on personal values. • Embedding mindfulness into daily activities (e.g., eating, walking, communication, acts of kindness, and other valued activities).
Committed Action & Goal Setting	<ul style="list-style-type: none"> • Brief reflection on personal values. • Committed action toward a rich, meaningful life. • The ‘Two sides of the same coin’ metaphor (pain and values). • The impact of chronic disease on daily living and activity pacing. • Creating an action plan exercise.
Problem-Solving & Values Clarification	<ul style="list-style-type: none"> • Brief reflection on personal values. • Problem analysis exercise. • Integrating personal values into problem-solving. • ‘Getting unstuck’ and coping with difficult dilemmas.
Self-Compassion & Self-Care	<ul style="list-style-type: none"> • What is self-compassion? • Treating yourself as you’d treat a good friend. • Examples of self-compassionate and self-care activities. • The ‘Bull’s-eye’ exercise. • How to take self-compassion breaks.

Table 2. Overview of the values-based telehealth intervention.

Each participant received a workbook that was developed by the research team and contained handouts, worksheets, and practice exercises based on each of the five intervention topics. Participants were able to retain the workbook following the five-week intervention period. The research team encouraged participants to practice learned strategies, read the workbook, and complete practice exercises based on each week’s topic. There were no specific criteria for how many intervention sessions participants must complete to remain active in the study given that the present study was focused on assessing the feasibility and acceptability of the intervention. Therefore, it was up to each participant to decide the degree to which they engaged with the session content and practice exercises in the intervention.

The intervention topics rotated and repeated on a fixed schedule. The virtual sessions were offered twice per week and were scheduled for afternoon and evening times to minimize time constraints (e.g., conflicting work schedule, medical appointments) that are common barriers to participating in intervention studies. Reminders to attend the live group meetings or video the pre-recorded videos were sent via email the day before each virtual intervention session. As previously mentioned, participants who were unable to meet during the live group meeting were offered the opportunity to participate in the study by viewing pre-recorded videos of the intervention focusing on the same five topics and practice exercises.

Participants were asked to attend the live group meetings or view the pre-recorded videos of these sessions over the course of the five-week study period. Each live meeting or pre-recorded video lasted between 30-45-minutes. The virtual intervention sessions were delivered by the primary researchers with the additional support of graduate-level research assistants. The research assistants were provided with training in facilitating the intervention sessions by the primary researchers and a clinical supervisor who was available to provide additional support to research staff.

Momentary Assessments. Once per day, participants were to respond to an initial question asking if they have a scheduled CVPR session that day, regardless of whether they plan to attend this scheduled session or not. For participants who respond ‘Yes’ to this question, they were prompted to respond to momentary ratings. Participants were asked to respond to momentary ratings of mood, experiential avoidance, and level of congruence between their personal values and CVPR attendance approximately three times per week over the course of the study (i.e., 15 prompts over 5 weeks). Following five weeks of EMA monitoring, each participant was asked to delete the mobile EMA app (PACO) from their personal smartphone device, return their loaned

smartphone device, or return their completed paper daily diary forms during the post-completion session.

Post-Completion Session. As previously mentioned, the primary aim of the study was to assess the feasibility and acceptability of the values-based intervention, recruitment process, and measurement tools. Following the five-week intervention period, participants were asked to meet (5-10 minutes) with a member of the research team to complete post-completion outcomes measures (i.e., PHQ-9, GAD-7, CRBS, BIPQ). Participants who completed post-completion measures were provided with an additional Walmart gift card for their participation.

During the post-completion session, participants were also invited to schedule a time (20-25 minutes) to participate in the post-completion qualitative interview with a research team member. Participants were given the option to schedule this post-completion session either in-person or virtually using Cisco WebEx or by calling the participant. Participants who discontinued or otherwise dropped out of the intervention were also contacted by phone to invite them to respond to questions regarding their experience of participating in the intervention, barriers, and reasons for discontinuing the intervention, and suggestions for improvement. A graphic depiction of the study design and flow of participation is shown in Table 4.

CVPR Attendance and Completion. Patients are regularly monitored as they progress through the CVPR program at ECU Health. Once patients completed the CVPR program or otherwise dropped out, outcomes data is added to their medical chart as part of standard care. Following the five-week intervention period, these data was reviewed by research team members including the total number of CVPR sessions attended, the number of no-showed or cancelled sessions, and whether the patient successfully completed CVPR. Rates of completion are determined by whether the patient met their treatment goals set by the patient, CVPR staff, and

medical providers. It was originally planned that participants' CVPR attendance and completion data would be matched to their EMA data and then deidentified by deleting identifying information not deemed pertinent to the study (e.g., first and last names, dates of birth, email addresses) to protect the confidentiality of participants. However, the EMA data collected for this study was deemed uninterpretable due to the substantial technological difficulties that limited participants' ability to respond to prompts using the mobile app for EMA. The technological difficulties encountered throughout the study are later discussed in subsequent sections throughout this document.

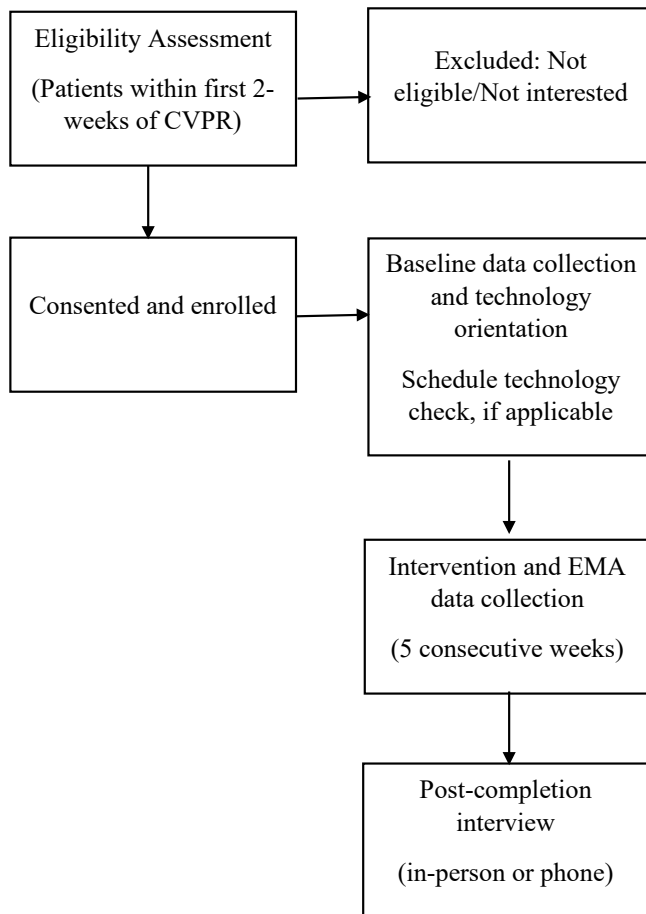


Figure 2: Flow diagram of the study designed to assess the feasibility and acceptability of a values-based telehealth intervention to promote CVPR adherence.

Planned Data Analyses

The goal of the present study was to assess the acceptability and feasibility of a novel values-based intervention. Therefore, the primary analyses were intended to focus on the key parameters necessary for conducting a future trial. As mentioned previously, feasibility was determined by assessing the recruitment process (i.e., the number of participants enrolled in the intervention study), the measurement tools (i.e., response rates for EMA measures, rates of participation in the post-completion sessions), and the intervention itself (i.e., the number of participants attending minimum session requirements). Acceptability was assessed through qualitative interviews and included questions pertaining to participants' experiences of taking part, including their perceptions of the intervention, barriers to participation, overall satisfaction with the intervention, and suggestions for further improvement. These data collected through qualitative interviews was recorded and responses were documented using an interview outline (see Appendix D). Factors pertaining to engagement in the intervention were qualitatively investigated, including acceptability (e.g., experienced cognitive and emotional responses to the intervention), receipt of the session content (i.e., comprehension of the content, barriers to participation), and the use of learned skills especially as it relates to CVPR adherence and maintenance of health behavior changes.

A thematic framework was utilized to identify, analyze, and report patterns within the interview transcripts (Braun & Clarke, 2006). Given the limited participation in the post-completion qualitative interviews in the present study, we were unable to conduct thematic analysis using NVivo, Version 10 as initially planned. Therefore, qualitative data was analyzed by the primary researcher to comment on the general feedback of participants on the intervention. Major themes were organized and are discussed later on using the Multi-Construct

Theoretical Framework of Acceptability of Healthcare Interventions (Sekhon, Cartwright, & Francis, 2017).

The secondary aim of this study was to examine the preliminary and indirect effects of the intervention on CVPR adherence through observation of daily and weekly variations in intervention attendance and overall CVPR completion status. It was planned that negative-binomial regression would be employed to examine the within-person associations between intervention attendance and CVPR adherence. To explore these within-person associations, it was planned that weekly intervention attendance (level 1) would be nested within individuals (level 2), thus allowing for the examination of the unique association between weekly intervention and CVPR attendance for each participant. Overall completion status (level 1) was planned to be dichotomized into categories (i.e., completed versus not completed) and then nested within individuals (level 2) to examine if weekly intervention attendance was associated with CVPR adherence.

The tertiary aim of the study was to examine the potential role of daily mood and experiential avoidance in predicting CVPR attendance for exploratory purposes. It was planned that the within-person associations between daily mood and experiential avoidance with CVPR attendance would be examined using multiple linear regression. The variables of interest (level 1) were nested within individuals (level 2) to examine whether these variables were negatively associated with same-day CVPR and intervention attendance.

Anticipated Methodological Limitations

There were several potential methodological limitations that were considered with the proposed methodological approach. Firstly, we anticipated that some eligible patients would

express disinterest, discomfort, or uncertainties related to using the technology required to participate in the intervention. In particular, it was anticipated that some CVPR patients would have limited exposure to or familiarity in using mobile technology, given the older age and rurality of the majority of the current CVPR patient population at ECU Health. On the other hand, it was expected that increased exposure and access to telehealth-based services since the onset of the Covid-19 pandemic would help to reduce discomfort in using the technology required for the present study. Furthermore, a previous study utilizing EMA methodology at this particular CVPR facility yielded a 78% response rate across two weeks of data collection, suggesting relatively high levels of familiarity and comfort with using the mobile app for EMA (Midgette, Ellis, & Whited, 2021).

The present study offered participants the opportunity to watch prerecorded videos of the five sessions to address barriers to participating in the intervention, including scheduling conflicts. These prerecorded videos were also available for participants to view using a laptop that was stationed in the education room that could be accessed before and after participants' regularly scheduled CVPR sessions. Over the five weeks of the intervention, participants were encouraged to discuss any technological difficulties with a member of the research team either by phone or in-person during their scheduled CVPR sessions. To further address barriers to participation in the intervention study, we provided paper versions of the EMA questions to enrolled participants who were unable to use the mobile app. Participants were invited to ask questions regarding the technology required in study during the baseline session, and participants were also walked through the process of completing EMA data collection and participating in the intervention. Participants who planned to participate in the live group meetings were provided

written instructions on how to download and access the required software to attend the live group meetings.

Due to the nature of this feasibility and acceptability study, it was not possible to randomize participants to intervention and control groups. Therefore, it was anticipated that the conclusions of the present study would be limited due to a lack of a control group. Nevertheless, it was expected that the results of feasibility and acceptability would provide valuable information that could be used to carry out a full-scale clinical trial in the future, as well as to conduct a process evaluation to better understand the process of change across participation in the intervention. Assessing feasibility and acceptability is a crucial step in examining potential issues related to recruitment and enrollment, intervention retention, the facilitation of intervention sessions, barriers to participating in the study, and satisfaction with the intervention. One additional limitation arises from the fact that this study includes a combined sample of cardiac and pulmonary rehabilitation patients. As such, it is important to highlight that cardiac and pulmonary patient populations are inequivalent across diagnoses, prognoses, and level of functional impairment. Despite this, however, it was expected that this study would potentially highlight specific group differences in the acceptability and feasibility of the intervention, which is an important consideration for future full-scale clinical trials.

The secondary and tertiary aims of the present study were exploratory and aimed toward examining whether CVPR adherence was associated with participation in the telehealth intervention as well as other variables of interest (i.e., mood, experiential avoidance) at the momentary level. However, it is possible that patients who expressed interest in participating in the present study were more likely to be regular attendees. As such, it would be difficult to determine whether participation in the intervention would influence CVPR adherence or daily

variations in mood and experiential avoidance. However, we planned to address this issue by recruiting participants who were within their first two months of CVPR enrollment, when they are more susceptible to poor attendance and dropout (Casey et al., 2008). Lastly, we expected that participants who experienced more difficulties with attendance would be less likely to attend the intervention session or respond to EMA prompts. However, the present study aimed to collect qualitative data from participants who dropped out of the intervention to reflect on barriers to participation and changes to the study that could have addressed these barriers. Overall, despite these anticipated limitations, these methodological considerations also provided valuable insight regarding the feasibility and acceptability of the intervention study for future clinical trials and outcomes monitoring in the CVPR patient population.

Chapter 3: Results

Demographics and Retention

Figure 3 outlines the demographics, outcomes measures, and other elements of participation of all participants who enrolled and completed the study (i.e., attended the post-completion session). The sample for the present study consisted of forty-four enrolled participants. Of these participants, twenty-one (47.7%) completed all study procedures including the post-completion interview, and five (23.8%) provided additional feedback in the optional qualitative interview at the end of the five-week study period. For the present study, participants were considered to have completed all study procedures if they participated in the post-completion session following the five-week study period. These participants were considered to have completed the study regardless of whether they attended any live intervention sessions, watched any pre-recorded videos, or participated in the optional post-completion qualitative interview. This is due to the nature of the present study which focused on assessing the feasibility and acceptability of the intervention. Participants were not required to attend a minimum number of intervention sessions or to view a minimum number of pre-recorded videos as the present study aimed to establish participants' willingness to engage in the intervention and factors that may have positively or negatively influenced their participation in various elements of the intervention throughout the study.

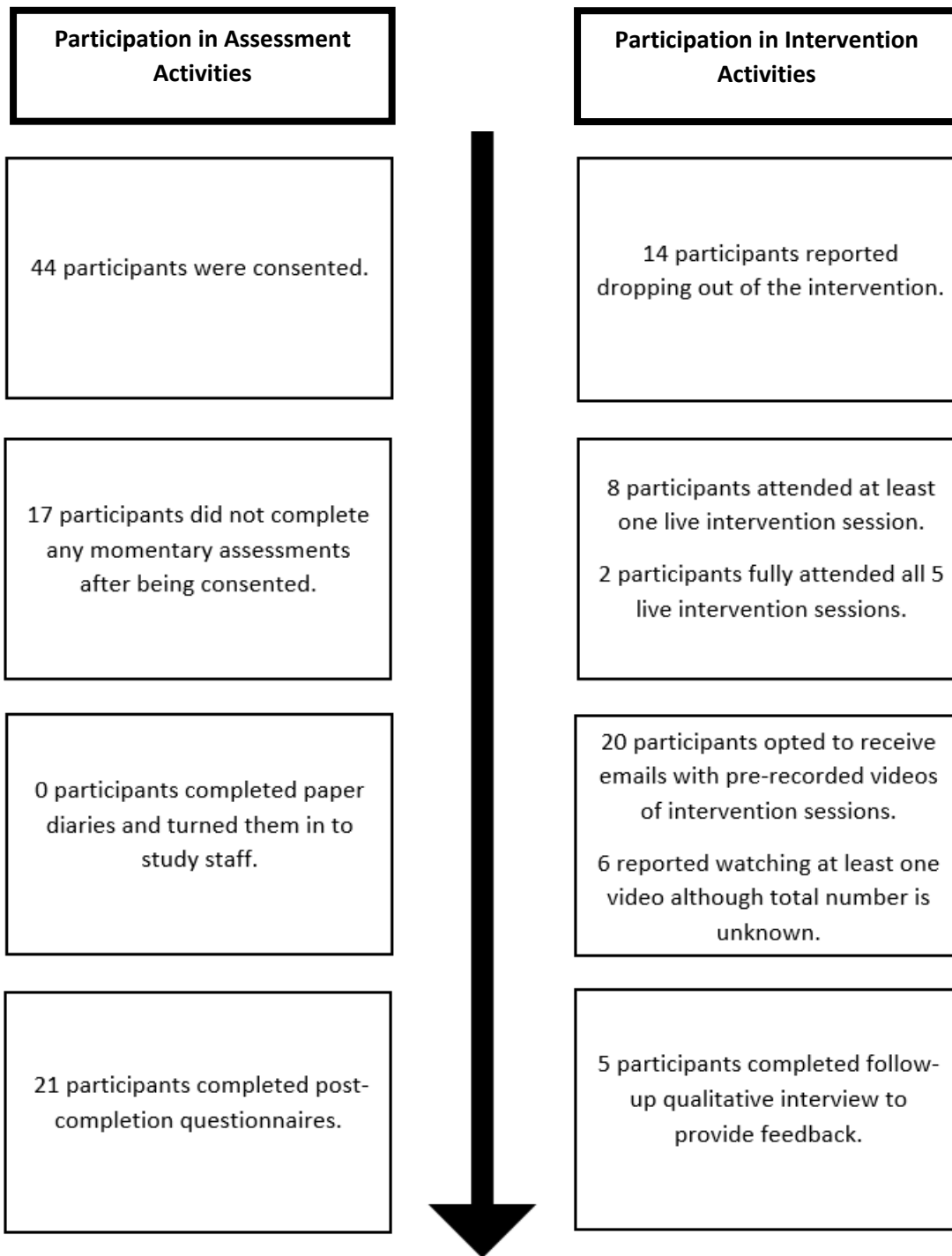


Figure 3: Diagram of Study Participation

Many participants indicated they preferred watching the pre-recorded videos over attending the live group meetings. Of the twenty-two participants who initially opted to participate in the live sessions, six (27.3%) later decided to switch to viewing the pre-recorded videos partway through the study due to barriers including scheduling conflicts, lack of familiarity and trouble accessing the required technology, and general technological difficulties. During the study, fourteen of the enrolled participants (9.1%, $N= 44$) informed research study staff that they had dropped out of the intervention due to barriers including illness and/or hospitalization and their busy work schedules. Participants who dropped out of the study ($N= 14$) were also invited to provide feedback on the intervention and study procedures including reasons why they chose to discontinue the study, as well as suggestions for improvement (Appendix D). Demographic information and participant characteristics for all enrolled participants are reported below in Table 5.

Table 3: Demographic Information and Participant Characteristics

Characteristic	Enrolled ($n = 44$)	Completed ($n = 21$)
Age, years	64.72 ± .483	65.60 ± 9.9
Sex		
Male	22 (45.0%)	9 (42.9%)
Female	18 (55.0%)	12 (57.1%)
Did Not Report	4 (9.1%)	--
Race/Ethnicity		
White	24 (54.5%)	15 (71.4%)
Black/African American	13 (29.5%)	6 (28.6%)
Hispanic/Latinx	2 (4.5%)	--
Did Not Report	5 (11.4%)	--
Education		
High School Graduate	11 (25.0%)	7 (33.3%)
Some College or University	5 (11.4%)	3 (14.3%)
College or University Graduate	14 (31.8%)	8 (38.1%)
Post Graduate School	6 (13.6%)	3 (14.3%)
Did Not Report	8 (18.2%)	--

CVPR Program	Cardiac	28 (63.6%)	13 (61.9%)
	Pulmonary	16 (36.4%)	7 (33.3%)
Attendance	CVPR Non-Completers	13 (29.5%)	8 (38.1%)
	CVPR Completers	31 (70.5%)	13 (61.9%)
	# CVPR Sessions (Mean)	20.8 ± 9.9	15.7 ± 8.6
	# CVPR Absences (Mean)	11.1 ± 8.0	13.1 ± 10.6
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Intervention Modality			
	WebEx	23 (52.3%)	10 (47.6%)
	Pre-Recorded Videos	21 (47.7)	11 (52.4%)
Assessment Modality			
	Paper Forms	35 (18.5%)	5 (23.8.2%)
	Mobile App	9 (20.5%)	16 (76.2%)
<hr/>			
Outcomes			
	Pre PHQ-9 (Mean; n =)	8.09 ± 5.4	8.95 ± 9.0
	Post PHQ-9 (Mean; n =)	6.61 ± 4.9	7.29 ± 6.0
	Pre GAD-7 (n = 21)	4.95 ± 3.1	5.76 ± 3.9
	Post GAD-7 (n = 7)	3.05 ± 4.4	3.86 ± 3.5
	Pre-Values Congruence (Mean)	5.45 ± .97	5.53 ± .51
	Post Values Congruence (Mean)	5.26 ± 1.5	5.14 ± 1.86
	Cardiac Rehabilitation Barriers Scale (Mean)	20.62 ± 11.9	16.57 ± 6.6

Note: Mean ± SD or Frequency (%). Study completers represent those participants who completed all study procedures.

Technical problems were encountered during the study for many of the participants. Once we initiated the intervention for more than half the participants, we discovered substantive technical issues with the mobile app that resulted in missing data for most participants. The research study team worked together to attempt to resolve these technical issues for future participants. However, we unfortunately uncovered yet further software challenges that ultimately interfered with our ability to collect and analyze participants' EMA data using the

mobile app. As mentioned previously, we offered the opportunity for participants to complete paper daily diary forms if they felt uncomfortable or otherwise were unable to use the mobile app. In total, nine participants were administered the paper form daily diaries; however, none of these participants returned their completed forms at the end of their study participation period. Therefore, the EMA data of those who used paper daily diary forms were also unavailable for analyses for the present study.

Feasibility of the Intervention.

The feasibility of the intervention was determined by assessing the recruitment process (i.e., the number of participants recruited by CVPR and research study staff), the intervention period (i.e., attendance to the live intervention sessions), and the measurement tools (i.e., EMA response rates, and follow up rates for the post-completion session). As previously discussed, the response rate for EMA measures was unavailable and uninterpretable due to technological difficulties encountered throughout the study.

The process for recruitment was feasible with the assistance of CVPR staff, who identified 46 eligible patients within their first four weeks of enrollment at CVPR. It was originally planned that only patients within the first two weeks of enrollment would be eligible to participate. However, it was later discussed and collaboratively decided by CVPR and research study staff that the eligibility criteria would be expanded to include patients within the first month (4 weeks) of CVPR enrollment. This decision was made following the first month of recruitment due to low enrollment in hopes of potentially increasing the intervention group sizes. Of the eligible patients ($N= 46$) who were identified and approached, 44 consented to participate in the pre-intervention session with the research study staff. This pre-intervention session focused on further gauging participant interest, providing additional information about the

program, orienting participants to the technology required for the study, and completing self-report outcomes measures. All participants who enrolled in the study ($N= 44$) successfully completed all pre-intervention self-report measures.

In contrast to the 100% completion rate for pre-intervention self-report measures, the overall attendance for the live intervention sessions over the course of the five-week study period was very low. Specifically, Of the twenty-two participants who initially planned to attend the live intervention sessions, only two (9.1%) attended all five intervention sessions. Furthermore, four of these (18.2%) attended two intervention sessions, two (9.1%) attended one intervention session, and fourteen (63.6%) did not attend any intervention sessions.

Over the five weeks, participants were sent reminders the day before each intervention session, as well as 30-minutes before the start time. Among the twenty-two participants (50%) who planned to view the pre-recorded videos of the sessions, a link to each video was sent to their email at the beginning of each week for them to view at their own pace. However, participants who opted to view the pre-recorded videos were encouraged to watch only one video each week in order to have ample time to practice learned skills as they progressed through rehab. Unfortunately, we were unable to collect data on whether participants viewed these videos without compromising the confidentiality of the participants.

Following the five-week intervention period, twenty-three participants (52.3% of the original sample; $N= 44$) followed up with research study staff for the post-intervention session. For post-completion outcomes measures, the response rates for outcomes measures were approximately 96% due to two participants not fully completing all questions on these measures.

All enrolled participants were invited to complete a post-completion qualitative interview at the end of the five weeks, or after dropping out of the study, in order to provide feedback on their experience. The follow-up rate for the post-completion qualitative interview was low and included five participants total, 11% of the original sample ($N= 44$).

The five participants who took part in the post-completion qualitative interview did so approximately one month after the five-week study period. Three of the five participants had opted to view the pre-recorded videos of the intervention at their own pace, and two of the participants reported watching only the first two videos and one reported watching only the first video. Two of the five participants who completed the interview had planned to attend the live intervention sessions; however, they were both unable to attend any of the live sessions. One of the participants who completed the interview had dropped out of the intervention during the second week of their study participation but was still willing to provide feedback on their experience.

Acceptability of the Telehealth Intervention

To assess the acceptability of the intervention, all enrolled participants were invited to participate in a post-completion semi-structured qualitative interview based on the Multi-Construct Theoretical Framework of Acceptability (TFA) of Healthcare Interventions (Sekhon, Cartwright, & Francis, 2017). This framework was developed to operationalize the construct of acceptability and outlines seven core constructs of acceptability to improve our understanding of participants' experiences with interventions conducted in healthcare settings. These constructs were then further refined and categorized into three major themes that were identified in the qualitative data collected from the present study. These major themes are outlined in Table 6, and further discussed in the following section to elucidate factors that may have impacted

participants' perspectives and willingness to engage in the intervention and procedures of the present study.

Overall, the intervention was found to be acceptable by the modest number of participants who provided feedback during the qualitative interviews ($n = 5$), as well as those who provided informal feedback throughout study participation. These participants reported that there were no barriers to participating and that they had positive experiences. Despite this, however, the overall attendance over the five weeks of the program and the research interview following the intervention was low. Among the four participants who attended at least one live intervention session, all of them actively contributed to discussions about the session content and asked questions throughout. They also appeared to actively apply the skills that were discussed in each session to their personal circumstances. For example, one participant reported benefit from learning about self-compassion in the context of CVPR and indicated that they were actively trying to be more self-compassionate by reminding themselves that this discomfort is normal, and they are not alone in their struggles. Some of the participants reported expanding on the practice exercises in the workbook. For example, one participant reported benefit from starting a journal with entries about bodily sensations, self-critical thoughts, and ideas for self-care activities. Of the four participants who attended at least one intervention session and completed the post-completion interview, each of them reported some familiarity with specific skills covered in the program (see Table 3).

Among all enrolled participants (including individuals who provided informal feedback throughout study participation), eleven reported benefits from the program (e.g., appreciation for reminders to practice self-care, enjoyment of the practice exercises in the workbook) despite sharing that they encountered some barriers to fully participating. These reported barriers

predominantly included technological difficulties, scheduling conflicts/time constraints, and trouble with remembering to watch the pre-recorded videos or to attend the live sessions. Among all enrolled participants, ten participants reported that they would have liked to have been able to engage more fully in the program (e.g., participating in more group meetings, watching more pre-recorded videos). Seven participants indicated that they would recommend the program to a loved one who was starting rehab.

Qualitative Findings: Post-Completion Interview

The theoretical framework of acceptability (TFA) consists of seven constructs that were used in the selection of post-completion interview questions of the present study (see Appendix D). These seven constructs included the following: 1.) *Self-Efficacy* (one's confidence that they could perform the behaviors required of the study); 2.) *Perceived Burden* (the perceived amount of effort required to participate in the intervention); 3.) *Opportunity Costs* (the extent to which participants feel they must give up benefits or values to engage in an intervention); 4.) *Intervention Coherence* (the extent to which a participant understands the intervention procedure and how it works); 5.) *Perceived Effectiveness* (the extent to which the intervention is perceived as likely to achieve its purpose); 6.) *Affective Attitude* (how a participant feels about the intervention in general); and 7.) *Suggestions for Further Improvement* (Sekhon, Cartwright, & Francis, 2017).

Three major themes were identified from the qualitative data gathered in the post-completion interviews, including: 1.) Engaging with the program content; 2.) Experiences of participating in the program; and 3.) Perceived changes after participating in the program (see Table 6). Overall, participants reported positive experiences with taking part in the intervention

and several expressed that they would have liked to have participated more fully if it had been possible.

1.) Engaging with the Content	2.) Experiences of Participating	3.) Perceived Changes after Participating
Understanding and practicing skills	Expectations of the program	Shifts in perspective on rehab
Acceptance of physical activity	Views on the program structure and content	Confidence to manage challenging and stressful situations
Experience of practicing mindfulness	Support from facilitators and peers	Motivation to attend rehab and maintain physical activity
Developing self-care and self-compassion	Practical aspects of the program	Reflection on values and valued-activity engagement
Understanding and identifying values	Suggestions for improvement	Alignment in personal goals and values

Table 4. Framework categories identified in the analysis.

Engaging with the program content. Of the four participants who attended at least one live intervention session, all appeared to be actively trying to familiarize themselves with the skills that were covered in the intervention and actively engaged in discussion with the facilitators of how these skills applied to their personal circumstances. Some of these participants expressed that it was not always easy to practice acceptance but found it helpful to focus on things that were still within their control. One example is Participant A (intervention participant), who talked about her difficulties with accepting her recent diagnosis of congestive heart failure but was actively trying to focus on things that she could do that were meaningful.

“I know I won’t get rid of this [diagnosis], but I keep looking for things to make me feel better. There was a time when I was having a hard time keeping up

with the exercises and we talked about my feelings about that. It was stressing me out because I wanted to go back to how things were before. Um, but it's okay to accept that- and you actually start to feel less stressed because you start to realize you're going to live with this. So now I focus on what matters when I feel stuck and stuff like that. I feel more motivated to do what I can do." (Participant B, intervention participant).

Another participant commented on their experience of engaging in mindfulness practice. At first, this participant talked about their sense of skepticism toward mindfulness, and then highlighted how their perception changed after reviewing this session content.

"When you're talking about things like mindfulness, it's not something that you talk about in everyday life. It's hard to picture it for yourself." (Participant E, intervention participant).

However, reading more about mindfulness in the workbook and having the opportunity to ask questions during live intervention sessions seemed to have led to a different understanding of mindfulness and its utility. In particular, some participants reported benefit from using mindfulness to manage stress related to increasing their exercise intensity at rehab. Participant B (intervention participant) described practicing mindfulness in situations where she felt scared to engage in physical activity due to her diagnosis of COPD and associated difficulties with dyspnea.

"I was having a hard time with the exercise. I made notes about how I felt [in the moment] and what was stressing me out the most. Then I refocused my attention to help me get through it." (Participant C, intervention participant).

Similarly, Participant A (intervention participant) reported benefit from practicing mindfulness skills to improve her emotional awareness.

“I think it was helpful for teaching me a lot about- I guess about how I’m feeling and how I express my feelings. It helped me see other ways for working on- for dealing with my feelings.” (Participant A, intervention participant).

Some participants commented on how the program helped motivate them by reminding them of why it was important to continue attending rehab. For example, Participant D (intervention participant) described feeling more motivated to attend rehab after reminding herself of her personal values and self-care goals.

“You know- what I got out of it [the program]- how to remind myself of what matters most when I felt stuck and how to redirect my mind to be able to focus on what I need to do in rehab.” (Participant D, intervention participant).

Another participant (Participant E, intervention participant) provided another example of utilizing values identification as a strategy for improving motivation to attend rehab and reflected on her priorities and personal values since starting rehab.

“I mean, it motivated me and helped me see that I’m doing this for my own health. I’m doing something for me. It helped me see that I have to set aside time for myself and take care of my health because it’ll help me in the future. The program helped me see that I need to support myself- to help myself make healthier decisions, and I didn’t have that before. It helped me see that I really needed what rehab could offer me.” (Participant E, intervention participant).

Experience of participating in the program. Many participants shared information about their personal experiences of taking part in the program either by completing the qualitative

interview or through informal conversations between participants and research study staff. It was noted that at least twelve participants described their experiences as overall pleasant and rewarding despite barriers they encountered that hindered their ability to fully engage in the program. Two participants who completed the qualitative interview reported not knowing what to expect from the program initially; however, they indicated that they found it helpful to discuss their personal experiences and progress in rehab during the live sessions they attended. This was further reiterated by participants who provided similar feedback during informal conversations with the research study staff in between sessions. Three of the four participants who attended at least one live session expressed a desire for larger group sizes to facilitate discussion, share ideas about how to apply learned skills, and to increase their opportunities for connecting with fellow CVPR patients who are experiencing similar challenges as them.

“So, yeah, because sometimes it can be hard to do the online thing, I would have liked it if I could have gone in person. Maybe during- maybe even after my exercise gets done.”

(Participant A, intervention participant).

Four of the participants who gave feedback were among the 21 participants who opted to view the pre-recorded videos. These four participants expressed appreciation for the flexibility in participating at their own pace during informal conversations with the research study staff. For example, Participant D (intervention participant) shared that the availability of pre-recorded videos made it easier for her to participate in the program due to her limited availability to attend live intervention sessions.

“I did the Zoom thing first and then they started sending me the emails [with the recordings]. When they did that, it was so much easier to click on the link and go to each video

than to have to remember to go to a class at a specific time- certain day.” (Participant D, intervention participant).

Six of the participants who gave feedback were among the 21 participants who opted to view the pre-recorded videos. These six participants initially planned to attend the live sessions and later requested to switch to receiving emails with links to the pre-recorded videos. This change was requested primarily due to a combination of technological difficulties with using the videoconferencing platform (i.e., WebEx), in addition to scheduling conflicts and time constraints. Furthermore, two of the six participants who requested to switch to viewing the pre-recorded videos indicated that they found this option to be more user-friendly when compared to using WebEx. In particular, these participants highlighted that viewing the pre-recorded videos was much simpler to navigate than WebEx. One participant (Participant D, intervention participant) emphasized that it was easier for her to incorporate viewing the pre-recorded videos into her weekly schedule because she was able to control when she wanted to view the video.

“I could do it [watch the pre-recorded videos] on my own time and that worked better for me because I work during the day and don’t get off until late evening.” Participant D (intervention participant).

Furthermore, Participant A (intervention participant) expressed that switching to viewing the pre-recorded videos made it easier for him to engage in the program by reducing his barriers to participating.

“Oh, I could never get on- join the online discussions. I couldn’t get those on my telephone. In fact, I needed help- You were there to help- You fixed it so I could get it [the videos] on my phone and that was a lot easier.” Participant A (intervention participant).

Of the fourteen participants who dropped out of the study, most ($N=10$) reported to the research study staff that they decided to discontinue the program due to difficulties using the videoconferencing platform (e.g., unfamiliarity and discomfort in using the app, accessibility issues), internet connectivity issues, and time constraints. Furthermore, one participant commented on the accessibility issues associated with using the videoconferencing platform. In particular, he indicated that the font size on his smartphone was too small for him to be able to read the email reminders and access the video conferencing app on his smartphone.

“I know I had problems getting the emails and- uh getting my name in the log in on the other thing [the WebEx mobile app] a lot.” Participant C (intervention participant).

Another participant expressed that it could be helpful in the future to offer participants more hands-on assistance with the technology required to participate in the program (e.g., navigating the WebEx app, accessing emails, clicking on links to watch pre-recorded videos, setting reminders on their phone). Participant B (intervention participant) commented that additional technology support could be especially helpful for individuals who are less familiar with using these digital platforms but would still like to participate.

“So, I would say in the future that you need to make that [the technology] easier for an individual, particularly an individual who is- for an older individual who’s not uh- digitally adept.” Participant B (intervention participant).

Although there were suggestions for improvement, four of the five participants who took part in the post-completion interview expressed their satisfaction with the program content. Additionally, each of the five participants (including one participant who dropped out of the intervention) reported that they would recommend the program to a loved one who was starting

rehab. Based on qualitative information gathered during the post-completion interview, four of these five participants appeared to have been well engaged with the program content (e.g., watching the videos, reading the workbook, practicing learned strategies) and expressed appreciation for the variety of practice activities the program had to offer. Ten of the overall sample ($N=44$) included participants who provided informal feedback throughout the study and participants who provided formal feedback during the qualitative interviews. At least ten of these participants reported benefit from reviewing the workbook during informal conversations with the research study staff and during the post-completion interview. For example, Participant D (intervention participant) described how the information provided in the workbook helped to remind them of potential skills they could use when encountering a difficult situation in rehab.

“It helped remind me that y’all are there to help. The worksheets- it helped me see that I had what I needed to push through it [feeling stuck]. It helped me see that rehab was important- it could help me get what I needed the most.” (Participant D, intervention participant).

One participant who participated in the post-completion interview shared that the program helped to ‘normalize’ the challenges they were experiencing when first starting rehab, and they felt that they were not alone in their struggles.

“So- the uh- the workbook and the videos were nice because it helped you feel like you’re not alone. When you first start out, you feel like it’s just you having trouble with it [the exercises at rehab], and it’s good to go back and to read the book because it reminds you that it’s not just you and you’re not alone. There are other people who- that feel like you do.” (Participant A, intervention participant).

As previously mentioned, there were substantial technological difficulties throughout the study and many participants expressed difficulty in using the mobile app for EMA (PACO). In addition, one participant who was able to use the mobile app indicated that they found the app inaccessible due to the small font.

“The app itself works, but I know I had problems getting my check marks on numbers and everything a lot of times.” (Participant D, intervention participant).

Furthermore, several participants informed research staff members that they disliked the frequency of the momentary assessment prompts, as well as the repetitiveness of the daily questions.

“I guess the surveys could be improved. Maybe you can do them like once a week instead of everyday before your session- or if you- I feel they the questions are too repetitive all the time. They’re the same questions over and over. And I know that it’s asking about how you feel, how do you think the program is helping you, but it just gets too repetitive.” (Participant D, intervention participant).

Perceived changes after participating in the program. This category describes the changes that occurred during and after engagement in the program from the perspective of the participants. Although intervention attendance was low, several participants expressed benefit from reviewing the workbook, including some participants who were unable to attend any of the intervention sessions. Some of these participants also provided examples on how they applied the practice exercises and strategies to their personal circumstances. Most of the changes that participants commented on appeared to center around participant’s perspectives on rehab.

“Yeah, I felt like it [the program] helped me reach my goals [in rehab]. The workbook had good reminders in it that helped motivate me. When I started rehab, I was particularly interested in- after having congestive heart failure, knowing how much physical activity I could do and be safe- and I achieved that. The worksheets helped me set some uh- goals like that.” (Participant C, intervention participant).

One participant who attended the first intervention session commented on how the program helped them understand the purpose of rehab, which led them to feel more confident in starting rehab.

“It helped me comprehend it a little bit better. I guess before I joined rehab- or- I was- um- before I was in rehab, I had a different idea and thought it’d be harder, but it really helped me know that it ain’t just me and I gotta take it one step at a time. It helped me understand the purpose of rehab and I think that can help people a lot as it is.” (Participant B, intervention participant).

Additionally, some participants expressed that they found the workbook helpful for offering a new perspective on physical activity in general. For example, Participant E (intervention participant) commented on how the program helped motivate them to maintain their physical activity outside of rehab.

“I didn’t go to as many workouts [at rehab] as I was supposed to. The worksheets kept me on track for a bit and uh- uh helped me stay the course. I got a familiarity with the workout equipment at rehab and I- I live over at [independent living facility] and we have our own physical exercise and workout center with the same kind of equipment and so it- I could do what

I was doing over there [at rehab] at home and I didn't have to drive across town to get there. I just had to keep myself motivated to keep on doing it." (Participant E, intervention participant).

There were several participants who shared how the program helped them achieve their personal goals. For example, Participant C (intervention participant) shared that the two live sessions she attended were helpful for reminding her to prioritize her self-care needs and shifting her attention toward her personal values.

"The whole point was how to take care of yourself first. You know, that's what I got out of it, and how to redirect my mind to be able to focus on what's most important. That's what I got out of it." (Participant C, intervention participant).

Furthermore, this participant shared how attending these two live sessions positively changed her perception of her ability to handle difficult situations that sometimes interferes with her motivation to keep attending rehab.

"Yeah, I got a lot of help in thinking about what mattered most. I feel more motivated to keep going [to rehab] because I know it's what's going to help me stay healthy for me and my family. I guess I felt it helped me um- and I feel like it moved me forward in my confidence to keep going- and I- my perception of it [rehab and exercise] and feelings about how I was going- if that makes any sense." (Participant E, intervention participant).

After attending one live intervention session, Participant A (intervention participant) commented on how the program prompted her to engage more in activities that aligned with her personal values, which she had found herself doing less of since experiencing a heart attack and starting rehab.

“Well, I’m doing more walking, I used to work quite a lot and I stopped all of a sudden. So, I’ve been walking more at rehab and home, and I’ve gone back to doing more social things that I was doing before, like church and family stuff- like I was before. I used to tell a lot of people I couldn’t come out and so and- because I didn’t feel good, you know? But that wasn’t helpful, I realize that now. I like that the book reminded me that and rehab and been helpful too.” (Participant A, intervention participant).

Baseline and Post-Completion Measures

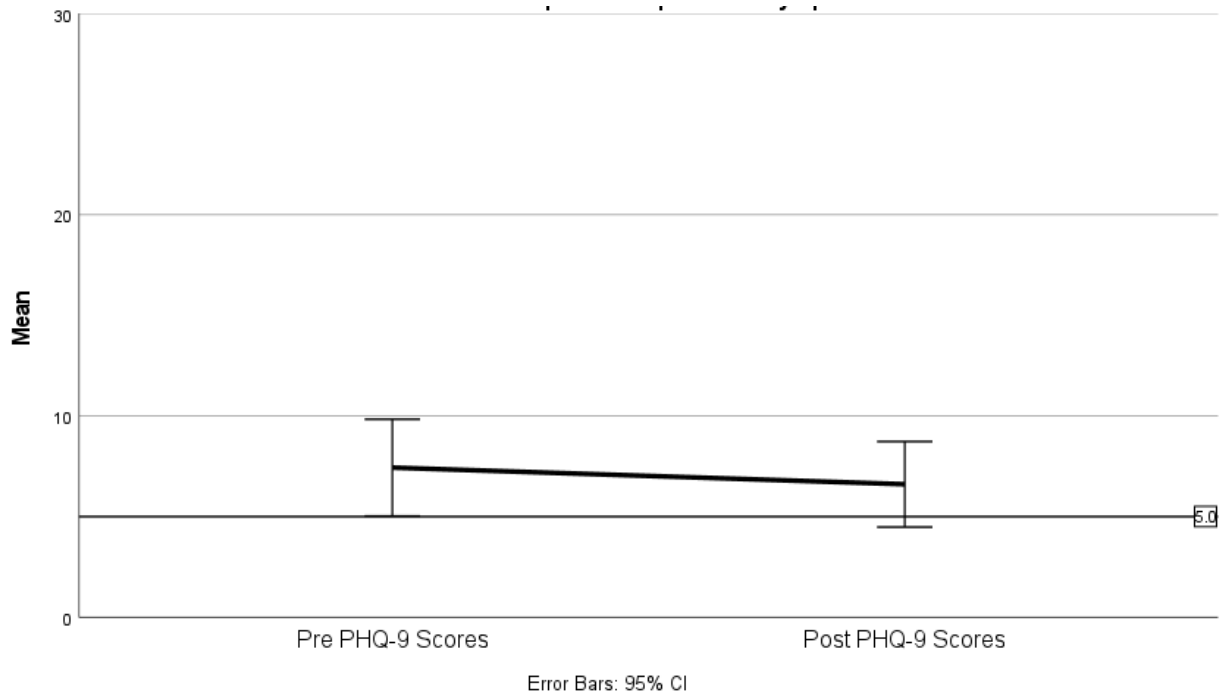
For the secondary and tertiary aims of the present study, linear regression and binary logistic regression models (predicting completion versus non-completion) were employed to explore possible associations between CVPR adherence, intervention participation, and potential changes in outcomes measures over time for exploratory purposes. T-tests were conducted to determine if any demographic variables (i.e., age, sex [1 = female, 2 = male [1 = White, 2 = Black or African American, 3 = Non-White Hispanic or Latinx], and education attainment [1 = high school education, 2 = some college or university, 3 = college or university graduate, 4 = post graduate study]) were significantly associated with each of the outcome variables, and statistically significant covariates were utilized as control variables.

Bivariate analyses showed that specific demographic variables including sex and age were associated with specific outcomes. Specifically, sex was associated with CVPR attendance, baseline PHQ-9 scores, and baseline values congruence; with participants identifying as female attending more CVPR sessions ($p = .022$, $\phi = .65$), and endorsing greater depression symptoms ($1 / p = .038$, $\phi = .33$), and lower congruence between values and CVPR attendance ($p = .024$, $\phi = -.492$.) at baseline. Furthermore, age was associated with GAD-7 scores, with younger participants endorsing greater anxiety symptoms at baseline ($p = .041$, $\phi = -.325$). Thus, sex and

age were controlled for in regression analyses predicting pre-post outcomes data and CVPR adherence (e.g., CVPR attendance and completion status).

Depressive Symptoms. Symptoms of depression were assessed using the Patient Health Questionnaire – 9 (PHQ-9). At baseline, participants obtained an average PHQ-9 score of 8.09 ($SD= 5.35, N= 44$) which fell within the mild range of depressive symptoms. Following the five-week intervention period, participants repeated the PQH-9 and obtained an average score of 6.61 ($SD= 4.91, N= 23$), which was slightly lower than baseline but still fell within the mild range of depressive symptoms (See Figure 2).

Figure 4: Pre- and Post-Completion Depression Scores



A linear regression was utilized to assess whether higher baseline PHQ-9 scores (more severe depression symptoms) were associated with lower intervention attendance. There was no significant association between baseline depression symptoms and the number of live intervention sessions attended by participants. Of note, analyses regarding intervention attendance only includes participants who opted to attend the live intervention sessions ($N= 23$), since the rate of viewing for the pre-recorded videos was unavailable. Analyses found that baseline depression scores were not significantly associated with the number of intervention sessions attended, $b= -.37, p= .71$.

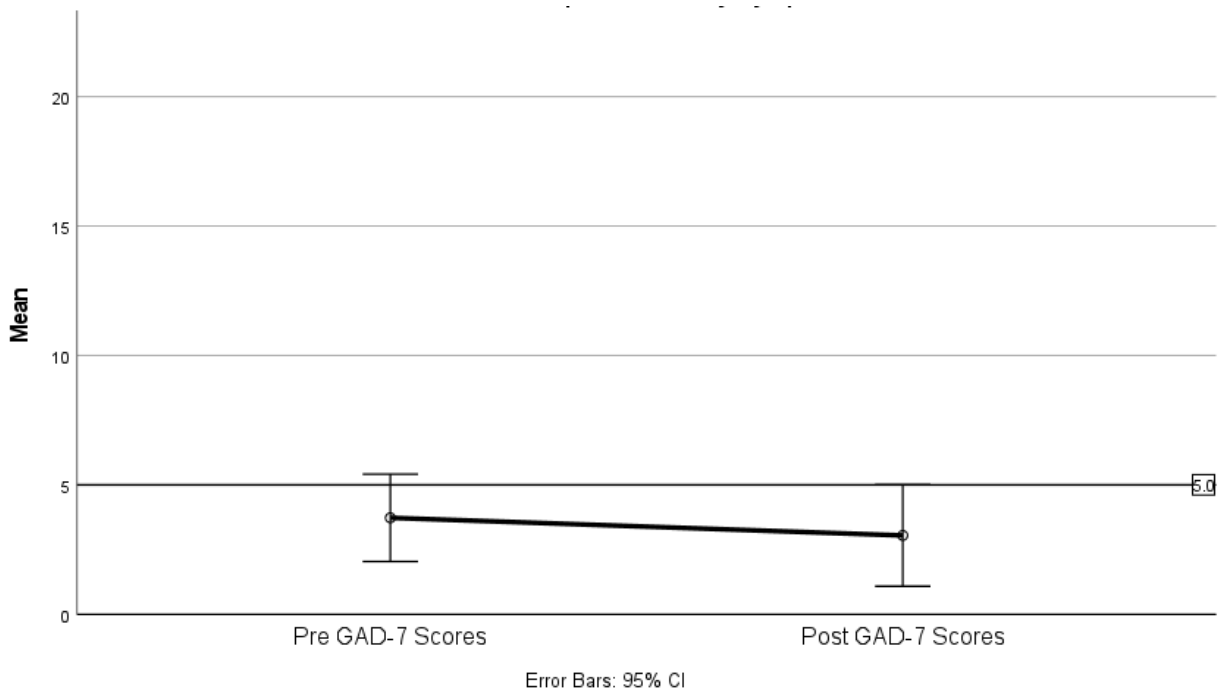
Similarly, linear regression was utilized to examine whether higher baseline depression scores were associated with lower CVPR attendance (i.e., the total number of CVPR sessions attended). Interestingly, there was no significant association between baseline PHQ-9 scores and CVPR attendance ($b= 1.19, p= .64$). Additionally, binary logistic regression was utilized to determine if participants with higher baseline depression were less likely to complete CVPR. Of note, CVPR completion status (i.e., completers versus non-completers) in this context is defined as whether the patients met their treatment goals as determined by their healthcare team, and whether they were successfully discharged from the CVPR program. There was no significant association between PHQ-9 scores at baseline and CVPR adherence ($b= -.693, p= .09$). Together, these findings are different from past research that has established a strong association between higher depression symptoms and lower adherence to CVPR (i.e., fewer sessions attended, CVPR completion status).

For exploratory purposes, an ANCOVA was used to examine whether greater participation in the intervention (i.e., the number of live intervention sessions attended) was associated with reduced depression at the end of the five weeks, controlling for baseline scores.

However, a significant association was not observed between intervention attendance and post-completion depression symptoms ($F[1,10]= .405, p= .55, \eta p^2= .05$).

Anxiety Symptoms. Anxiety symptoms were assessed using the Generalized Anxiety Disorder Screener – 7 (GAD-7). At baseline, participants obtained a mean GAD-7 score of 4.95 ($SD= 4.95$), which fell below the clinical cutoff of 10 and indicated minimal anxiety symptoms. A total of 22 participants completed the GAD-7 again following the five-week intervention period and obtained mean GAD-7 score was 3.05 ($SD= 4.42$), which also fell below the clinical cutoff for this measure and indicated minimal symptoms of anxiety (see Figure 3).

Figure 5: Pre- and Post-Completion Anxiety Symptoms



A linear regression was utilized to assess whether higher baseline anxiety symptoms (higher GAD-7 scores) were associated with lower intervention attendance. However, there was

no significant association between baseline GAD-7 scores and intervention attendance ($b = -.316$, $p = .159$). Furthermore, linear regressions were performed to assess the possible associations between baseline anxiety symptoms and CVPR adherence, in order to determine if greater symptoms of anxiety at baseline were associated with lower CVPR attendance. However, there were no significant associations between baseline GAD-7 scores and CVPR attendance ($b = -.316$, $p = .16$).

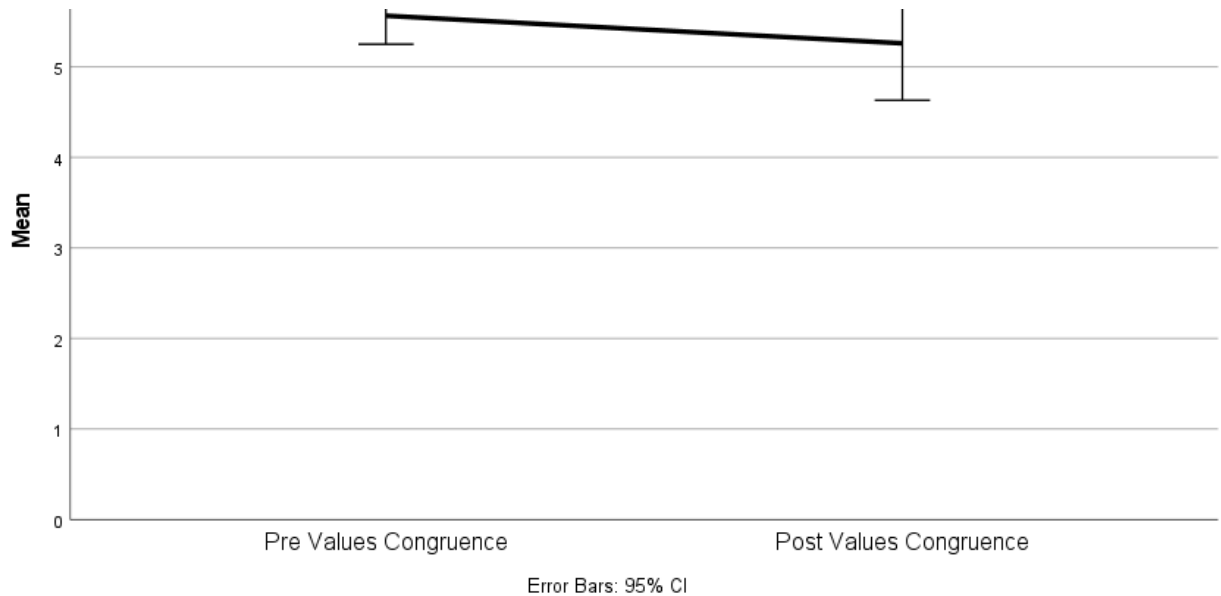
Binary logistic regressions were also utilized to determine if baseline anxiety symptoms predicted CVPR completion status; however, there was not a significant association between anxiety symptoms and CVPR completion ($b = .150$, $p = .29$). Similar to depression, greater anxiety symptoms have been long established as a predictor for poor CVPR adherence; however, the results of the present study are inconsistent with previous findings.

Lastly, an ANOVA was used for exploratory purposes to determine whether higher intervention attendance was associated with lower anxiety scores at the end of the five-week study period, while also controlling for baseline GAD-7 scores. However, intervention attendance was not associated with significant changes in pre-post anxiety symptoms ($F[1,10] = .086$, $p = .78$, $\eta^2 = .01$).

Values Congruence. For the exploratory aims of the study, participants were asked to rate the degree to which their CVPR attendance was congruent with their personal values at baseline and completion ($N = 42$). At baseline, participants reported an average congruence between their personal values and CVPR attendance of 5.45 ($SD = .97$) on a 6-point Likert scale, with a value of 1 representing the lowest congruence and 6 representing the highest congruence. Following the five-week study period, participants who completed post-completion measures ($N = 22$)

reported an average values congruence of 5.26 ($SD= 1.45$) on the same scale, which was similar to baseline scores (see Figure 4).

Figure 6: Pre- and Post-Completion Values Congruence



For the secondary aim of the study, linear regression was utilized to determine if higher values congruence at baseline was associated with greater intervention attendance; however, there was not a significant association between these variables ($b= .846, p= .17$). The possible association between higher values congruence at baseline and CVPR attendance was also explored, but a significant association between these variables was not observed ($b= -4.29, p= .59$). Binary logistic regression then revealed that baseline values congruence was not significantly associated with CVPR completion status ($b= -.85, p= .08$). Finally, an ANOVA was utilized to examine the potential influence of intervention participation on pre-post measures of values congruence. Interestingly, we found that participation in the live intervention was

significantly associated with positive changes in values congruence from baseline to completion ($F[1,8]= 10.91, p= .01, \eta p^2= .61$). This result was different from the overall sample of individuals who completed the study (i.e., including both individuals who participating in the live sessions and those who viewed pre-recorded videos), who demonstrated decreases in values congruence from baseline to completion (see Table 5).

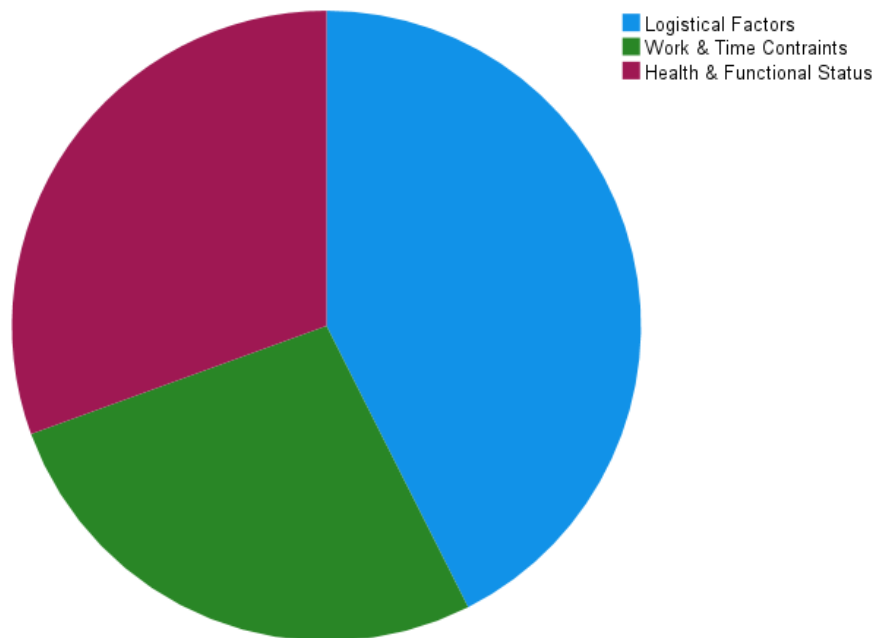
Barriers to Completion. Participants who completed follow-up outcome measures at the end of the five-week study period were asked to complete twelve items of the Cardiac Rehabilitation Barriers Scale (CRBS). To reiterate, the purpose of this measure was to provide additional insight into potential barriers that may have negatively impacted both CVPR and intervention adherence. Furthermore, this measure only included items that were selected based on the most relevant subscales to both cardiac and pulmonary rehabilitation patients since this measure was originally developed and validated for use with cardiac patients.

Following the five-week intervention period, participants who participated in the follow-up session ($N= 12$) obtained an average CRBS score of 20.05 ($SD= 11.98$). There are no specific clinical cutoffs for this measure; higher total scores on this measure indicate greater barriers to CVPR attendance, with possible scores ranging from 1-72. Appendix C displays the specific items representing twelve common barriers to attending CVPR, which can be further categorized into three domains or subscales: 1.) Logistic factors (e.g., transportation difficulties); 2.) Conflicts with work schedule and time constraints (e.g., family and caregiving responsibilities); and 3.) Comorbidities and functional status (e.g., pain and fatigue, exercise intolerance).

Regarding the present study, participants most often reported that family responsibilities and time constraints were the biggest barriers to attending CVPR (see Figure 5). The possible association between total CRBS scores and intervention participation were explored using linear

regression to determine if greater perceived barriers to CVPR was negatively associated with intervention participation (i.e., the number of intervention sessions attended). However, there was not a significant association between perceived barriers and adherence intervention participation ($b = -.05, p = .20$). Linear regressions were then utilized to examine whether greater perceived barriers were associated with lower CVPR adherence (i.e., the number of CVPR sessions attended); however, there was not a significant association between these variables ($b = 11.66, p = .94$). Similarly, binary logistic regression also did not demonstrate a significant association between perceived barriers and CVPR completion status ($b = -.01, p = .78$).

Figure 7. Cardiac Rehabilitation Barriers Scale: Sum of Domains



Limitations of Mobile EMA

As outlined in the original aims and hypotheses, the present study intended to explore processes of change in variables that may have provided useful information on preliminary

outcomes of the intervention to be used for future research. However, this process did not go as smoothly as planned and many participants encountered technical difficulties that hindered their ability to respond to EMA prompts on the mobile app. Overall, the research study staff was only able to collect approximately 3.05% of all EMA survey prompts due to substantial technical difficulties that occurred over the course of the study. Power analyses were not conducted given the primary aim of the study was to establish the feasibility and acceptability of the intervention. However, expert guidelines suggest that longitudinal data from participants with five or more observations can be included in an EMA analysis (Bolger & Laurenceau, 2013). Therefore, these data collected using the mobile app for EMA was considered uninterpretable and excluded from the final analyses of the present study.

For this component of the present study, most participants ($N= 35$, 79.5%) had attempted to use their personal smartphone device to respond to EMA prompts. The remainder of the enrolled participants ($N= 9$, 20.5%) had opted to use a paper daily diary form at the beginning of the study. As noted above, these participants were asked to set alarms to remind them to complete the paper daily diary forms to respond to EMA prompts on the same schedule as those using their smartphone. Throughout the duration of the study, several participants mentioned to research study staff that they preferred the paper daily diary forms due to their lack of familiarity with downloading and using mobile apps on their smartphone. Unfortunately, none of the nine participants returned the paper daily diary forms to the research study staff at the end of the five-week period. Therefore, EMA data gathered using paper daily diary forms were also unavailable for analyses in the present study.

Chapter 4: Discussion

Several studies have examined the role of values-based principles for promoting sustainable health behavior changes across a variety of patient populations living with chronic illnesses (e.g., cardiovascular disease, cancers, chronic pain, HIV, epilepsy; Spatola et al., 2014; Gregg et al., 2007; Lundgren et al., 2008; Dahl et al., 2011). Furthermore, it has been well established that integrating personal values into specific behavioral goals can be a helpful tool for reinforcing positive changes in their behavior and reducing unhelpful patterns of avoidance (Lejuez et al., 2011). This is especially pertinent for patients with diagnoses of chronic illnesses, which often require individuals to make difficult lifestyle changes (e.g., increasing physical activity, eating healthy, practicing stress management).

Patients diagnosed with chronic cardiovascular and pulmonary diseases are frequently challenged to make significant changes in their health behaviors and lifestyle habits while also experiencing significant functional impairment (e.g., chronic pain and fatigue). The population of patients with chronic cardiopulmonary diseases also experience high levels of barriers to medical care, which can prevent patients from accessing supportive services and intervention programs that could potentially ease some of the burden of making these difficult behavioral changes. Among these underutilized programs includes cardiopulmonary rehabilitation (CVPR), which has long been established as a critical component of medical care for the short- and long-term management of chronic cardiopulmonary diseases that is often underutilized (Johnston & Grimmer-Somers, 2010; De Vos et al., 2013). It is important that researchers continue to explore potential strategies and interventions for improving utilization of CVPR services in order to promote adherence and positive changes in health behaviors that could ultimately lead to improved health outcomes for this patient population.

There is a growing body of research focused on addressing the prominent levels of psychological distress that is often reported by CVPR patients. Symptoms of depression and anxiety are very commonly experienced by CVPR patients; these psychological difficulties have long been established as barriers to motivation, engagement in secondary prevention programs, and long-term maintenance of health behaviors (Busch et al., 2015). Therefore, it is necessary that researchers continue examining the feasibility and acceptability of utilizing established therapeutic approaches and strategies to address these symptoms and improve the psychological well-being of this patient population in order to promote CVPR adherence.

Feasibility and Acceptability of the Intervention

The primary aim of this study was to assess the feasibility and acceptability of a values-based telehealth intervention developed based on the basic tenets of Acceptance and Commitment Therapy (ACT). However, it is difficult to determine the feasibility and acceptability of the intervention based on the low attendance to the live intervention sessions and substantial technical difficulties which precluded many participants from fully engaging in this study. Nevertheless, participants expressed satisfaction and appreciation for certain components of the intervention including the opportunity to gain awareness of the impact of specific thoughts and feelings on their behavior (e.g., fear of physical activity resulting in long-term avoidance and deconditioning). Furthermore, participants expressed that they enjoyed reviewing the workbook (see Appendix E) and watching the pre-recorded videos as they found it easier to find time to engage in practice exercises and reflect on session content on their own time.

It is likely that the perceived burden of participating in the present study was too high based on overall feedback and response rates. This may have been due to a combination of factors including: 1.) the burden of learning and using new technology; 2.) finding time to attend

intervention sessions or view pre-recorded videos; and 3.) asking participants to respond to daily EMA questions. If this study were repeated, it would be important to consider ways to reduce participant burden by offering additional technological support, decreasing the number of EMA prompts, and/or reducing the number of intervention sessions in the program. Several participants who provided feedback suggested that they benefitted from attending even just 1-2 sessions or by reviewing the session content (e.g., reading the workbook, watching the pre-recorded videos) on their own time. Therefore, it is possible that condensing the session content and reducing the number of intervention sessions would have reduced participant burden and increased overall attendance.

Participant feedback indicated that converting the intervention to be fully asynchronous and self-guided may have mitigated many of the challenges and burdens experienced throughout the study. Abbreviated versions of psychotherapy treatments focused on providing psychoeducation and promoting values-consistent behavior using motivational interviewing (MI) techniques have been effective for improving CVPR attendance; however, these studies were conducted either in-person or over a single telephone call (Cossette et al., 2012). Therefore, it is possible that condensing the intervention content to 1-2 sessions would be similarly effective in a CVPR population. Future research could focus on developing a modified, self-guided version of the intervention in order to reassess its feasibility and acceptability.

Group sizes for the telehealth intervention were unfortunately much smaller than we previously hoped for, averaging 1-2 participants for live sessions. It is possible that achieving larger group sizes could have offered more opportunities for participants to make connections with fellow patients and allowed them to reflect on each other's experiences and normalize the challenges frequently experienced when first starting CVPR (e.g., increasing physical activity).

In addition, larger group sizes could have allowed participants the opportunity to learn from other patients' experiences by listening to how other participants integrate their personal values into their CVPR goals. Furthermore, participant feedback indicated that larger group sizes may have been a more rewarding experience overall, which may have motivated participants to attend more regularly. As such, it could be important to explore additional strategies for boosting enrollment and retention for future iterations of the present study to assess the feasibility and acceptability of the intervention more adequately.

Participants reported technological difficulties that negatively impacted their ability to attend the live intervention sessions. These difficulties included the inaccessibility of the mobile platforms for individuals with severe visual impairment. For example, the small font size of the mobile app for WebEx prevented participants from logging into the software for the scheduled intervention sessions. Additionally, many participants reported lack of familiarity in using the technology that was required to participate in the study, which led them to discontinue participation in the live sessions.

Participants provided feedback that highlighted specific changes in the study procedures that could have addressed some of the technological barriers to attending the live intervention sessions. For example, some participants provided feedback that they would have likely engaged in the intervention more fully if the group meetings were offered on-site at CVPR instead of remotely via WebEx. It is possible that in-person offerings could have mitigated the substantial technological difficulties many participants encountered in the present study. Furthermore, "zoom fatigue" is another important consideration for future research. In particular, participants may have felt overburdened with attending the virtual sessions due to the recent, rapid expansion of telehealth services since the start of the Covid-19 pandemic. Therefore, it may be helpful to

collect additional qualitative data regarding participants' perceptions of this recent increase in the utilization of telehealth services for future assessment of the feasibility and acceptability of the intervention. A key area for future research would include the randomization of participants into specific intervention groups to compare outcomes across telehealth, in-person, and standard care groups.

Participants also provided the feedback that additional training on the study procedures and hands-on support from the research study staff may have been helpful for addressing technological barriers, especially for patients with less familiarity with using the data collection and videoconferencing platforms. At the beginning of the five-week study period, participants were offered the opportunity to ask questions, practice using the technology required in the study, and encouraged to reach out to the research study staff with future questions. However, it is possible that periodic check-ins with participants could have been helpful in encouraging them to ask more questions regarding the technology. Furthermore, scheduling periodic check-ins with participants could have provided the researchers with additional information regarding their experiences in taking part in the study. For example, the researchers may have collected additional data and participant feedback regarding the accessibility of the technology in order to troubleshoot and explore potential solutions to these barriers. Participants indicated that the technology was not accessible for individuals with vision and hearing impairments. Potential solutions to these accessibility issues include helping visually impaired participants increase the font size on their mobile device and utilizing closed captioning services for hearing impaired individuals. In addition, rather than utilizing email reminders, it could have been helpful to call patients ahead of intervention sessions to confirm they have access to the necessary technology and are able to navigate the videoconferencing platform.

Reliable internet access is another important consideration for assessing the feasibility and acceptability of telehealth interventions. Many participants encountered substantial technical difficulties and challenges with accessing the intervention sessions. It is possible that digital inequity and variable internet access across participants may have influenced the results of the present study. Future iterations of the present study should involve taking steps to ensure participants are able to access the intervention by providing an option to attend the session by phone if needed, so they can still benefit from the support of fellow CVPR patients and therapeutic strategies taught in the intervention (see Table 3). Furthermore, it could be helpful to identify facilities with free internet access (e.g., public libraries, parks, and community centers) and provide this information to participants without access to reliable internet. However, it is important to take the necessary steps to protect patients' health information, including utilizing videoconferencing platforms with built-in privacy and security features such as WebEx. Lastly, in-person group meetings as well as asynchronous, self-guided offerings of the intervention may also mitigate technological barriers to accessing the intervention, as previously highlighted.

It should also be noted that prior to the Covid-19 pandemic, the research lab conducting this study was involved in psychoeducational classes and participatory action research with ECU Health CVPR staff and patients which focused on improving psychosocial programming. These initiatives focused on exploring the utility of values-exploration in the context of CVPR participation, including a qualitative analysis of personal values that patients found most consistent with their CVPR goals (Ellis, Midgette, Freeman, Capiaghi, & Whited, 2019; Ellis, Freeman, Midgette, & Whited, 2017). At the time, regular presence of the researchers and on-site initiatives likely served as reminders for study involvement and positively influenced response rates for prior studies prior to the Covid-19 pandemic. The regular presence of the researchers

and collaboration with CVPR staff likely influenced how participants interacted with previous studies. Therefore, it is possible that research participation for future studies will gradually improve over time as the research lab re-establishes their regular presence on-site at CVPR.

Regarding the present study, the researchers noticed that participants were more willing to meet and learn about the study if they were initially approached by CVPR staff and provided warm handoffs to the study staff, compared to when the research study staff approached patients. This observation emphasizes the importance of interdisciplinary collaboration and involving key community members in settings where research opportunities are not the cultural norm of the organization (Hendy & Barlow, 2012).

Outcomes Measures

For exploratory purposes, this study aimed to examine preliminary outcome data including depression and anxiety symptoms and congruence between personal values and CVPR goals. Interestingly, pre-intervention depression and anxiety symptoms did not influence CVPR attendance and completion. These results are different from studies that have previously demonstrated the pervasiveness and negative consequences of these symptoms on CVPR adherence. The baseline depression and anxiety scores of the present study were lower than the average scores typically observed in this population; therefore, it is possible that baseline scores did not influence CVPR adherence due to ceiling effects and minimal changes in in these outcomes. However, it is also important to note that these analyses were underpowered due to the small sample size.

One factor for consideration in future studies is the examination of long-term outcomes following participation in the intervention. One of the established advantages of interventions

based on Self-Determination Theory (SDT; Ryan & Deci, 2000) or third-wave cognitive-behavioral therapies is the preliminary evidence which suggests that they may be effective for promoting long-term, sustainable health behavior changes in populations of patients with chronic illnesses. For the present study, self-reported symptoms of depression and anxiety, and perceived barriers to cardiac rehabilitation were not significantly associated with CVPR attendance or completion status. While these factors did not change significantly over the five-week period, it is possible that participants who participated in the intervention would be more likely to maintain health behaviors they adopted from CVPR (e.g., regular engagement in physical activity, eating healthily) over the long-term because they have better integrated these behaviors in their important areas of their life. In the future, it may be helpful to gather data on health outcomes and mood measurements following CVPR completion to try and obtain long-term, comprehensive measurements of values-based behavior change following participation in the intervention.

Results from the values congruence question may support preliminary effectiveness of the telehealth intervention in promoting values-driven behavior in the context of CVPR. We also observed differences in values congruence scores when comparing individuals who participated in the live sessions to those who viewed the pre-recorded sessions individually. Specifically, we observed that self-reported congruence between personal values and CVPR goals significantly increased from baseline to completion over the course of intervention participation. Conversely, we observed that average values congruence scores decreased in the overall sample of individuals who completed the study (i.e., including those who participated in the live sessions and those who viewed the pre-recorded videos). Therefore, it is possible that participation in the live intervention may have beneficial for promoting values-consistent health behavior in the

context of CVPR; however, this is not possible to definitively determine from this study. As previously mentioned, the measurement of values congruence in this context is challenging because there is no validated measure of this construct in the literature. In particular, using a single item self-report measure may not be an ideal way to measure values congruence. The perception of personal values and specific behaviors is a complex construct; a single item could be interpreted in a multitude of ways by participants. However, the findings from this study accentuate the importance of closer examination of what dynamic aspects of valued-based behavior change and perception related to valued-activity engagement are potentially impacting CVPR adherence. Overall, it seems plausible that incorporating personal values in CVPR goals could foster longer-term maintenance of health behaviors (e.g., physical activity, healthy eating), which is consistent with Self-Determination Theory (SDT; Ryan & Deci, 2000).

It is important to note that the sample size of the participants who attended the live intervention sessions was smaller than anticipated and resulted in less power to detect effects than desired. Therefore, future research should further investigate whether values congruence is associated with improved outcomes and longer-term maintenance of health behaviors, as well as the preliminary effects of the telehealth intervention on promoting values-driven behavior in the context of CVPR. Results from values congruence question may also support the explanation that participants who enrolled in the study may have already perceived their goal of attending CVPR to be consistent with their personal values. At baseline, participants averaged 5.45 on a 6-point Likert scale. Therefore, the average self-report of congruence between personal values and CVPR attendance would likely not change much over the course of the intervention for many participants who enrolled in the study. All enrolled participants were approached within the first month (4-6 weeks) of their CVPR program and invited to participate in the study. Therefore, it is

possible that we may have recruited patients who were already highly motivated for engagement in CVPR, were not facing as many external barriers, and already perceived their CVPR participation to be meaningful and valuable.

Another limitation of the present study was related to momentary data collection. As previously discussed, we were unable to obtain EMA data to assess changes in mood and experiential avoidance across participation in the intervention due to technological difficulties and software malfunctions related to the mobile app for EMA. The extent of the technological difficulties encountered were somewhat unexpected given the high response rates of participants in a previous study that was conducted at this CVPR facility using the same mobile app (80% response rate for prompts 3x per week; Ellis, Midgette, Whited, & Schoemann, 2022). Furthermore, another study using similar data collection tools in a sample of older adults with breast cancer had a 57% response rate (Ratcliff et al., 2014). Another EMA study of oncology patients undergoing stem cell transplantation reported compliance rates of 87%; however, the study included a single item measuring fatigue three times a day for three days (Hacker & Ferrans, 2006).

The studies mentioned above along with the present study demonstrate the need for researchers to carefully consider the length, frequency, and timing of EMA surveys to reduce participant burden in chronic disease populations where patients are recovering from acute medical events and functional impairment and/or are receiving intensive therapies. In the future, it would be important to address this issue by exploring alternative platforms and procedures for EMA data collection in this patient population. Furthermore, it may also be helpful for future research to combine CVPR attendance data and same-day EMA self-reports to try and obtain the

most accurate and comprehensive information regarding momentary predictors of CVPR adherence as possible, as previously planned for this study.

Strengths & Directions for Future Research

Many participants provided positive feedback regarding the intervention materials and appreciation of the support from the research team. Furthermore, intervention feedback was consistently positive across participants who attended all five intervention sessions, participants who attended very few sessions (1-2 sessions), and participants who did not attend any live sessions but reported that they reviewed the workbook and/or viewed the pre-recorded videos. Participants who provided feedback on the intervention most often remarked on their satisfaction and appreciation of intervention content that normalized their struggles in making health behavior changes, challenged them to work through difficult situations using learned coping skills, and encouraged them to be self-compassionate toward themselves throughout their CVPR experience.

Exploration of asynchronous, self-guided intervention strategies for promoting CVPR adherence and addressing barriers to participation was supported by qualitative findings of the present study. The present study offered multiple platforms and modalities for participating in the intervention to reduce participant burden and to gather important data regarding the pros and cons of different platforms. Through examination of qualitative feedback, we learned that participants would have preferred the intervention be delivered in-person with larger group sizes, or asynchronously using self-guided videos and practice exercises. This feedback was reiterated by participants who dropped out of the intervention given our efforts to collect qualitative data for these individuals in order to incorporate their perspectives in the overall findings. The next version of this trial would aim to further explore the feasibility, acceptability, and preliminary

effectiveness of an asynchronous, self-guided version of the interventions using qualitative data, outcomes data, and EMA methodology. Furthermore, this research would aim to examine and compare the effects of an in-person version of the intervention with an asynchronous, self-guided program.

The present study utilized a small sample size of 5 participants who completed the qualitative interview following the intervention period. Furthermore, the present study involved a diverse group of participants who were overall representative of the demographic makeup of Eastern North Carolina, where the study was held. Future repetitions of this research would aim to replicate findings across greater numbers of participants and would aim to recruit a sample that is more representative of the average population of CVPR patients nationwide. The present research also highlighted potential strategies to improve retention and expand access to the technologies required to participate in a telehealth intervention. For example, participant feedback highlighted the utility of providing additional instructions and technology support throughout the intervention period. Future repetitions of this research would address barriers by identifying locations with public internet access, as well as ensuring that the technology is accessible to individuals with vision and hearing impairments. It is possible these strategies could improve retention in future versions of this trial by addressing the technology barriers that participants noted in the present research.

We also observed group differences in participant responses to the values congruence question. Specifically, we found that values congruence scores decreased over time in the overall sample of individuals who participated in the post-completion session (i.e., the sample that included individuals who participated in live sessions and those who viewed the pre-recorded sessions individually). However, we found that values congruence scores increased significantly

for the group of individuals who participated in the live intervention sessions. Values congruence was measured using a single-item measure that was specifically developed for use in this research. It is possible that participation in the live intervention sessions resulted in different perceptions of the concept of values-congruence when compared to the group of individuals who viewed the pre-recorded sessions individually. In future versions of this trial, we would aim to examine specific factors that potentially influence one's perception of values-congruence and explore possible associations with specific health behaviors over time in this population using longitudinal measures and EMA methodology.

Conclusions

Taken together, this brief values-based telehealth intervention focused on promoting CVPR adherence appeared to be overall acceptable for CVPR patients. Based on the technological challenges encountered in the current study, this intervention would likely be more feasible following several modifications including: 1.) in-person offerings of the intervention; 2.) increased group sizes; 3.) additional guidance and technical support throughout intervention participation; 4.) using a more accessible videoconferencing platform for individuals with visual impairments; and 5.) and utilizing a different platform for EMA data collection to assess preliminary outcomes of the intervention.

This feasibility and acceptability study suffered from attrition like many other intervention studies and technological issues that interfered with the ability for participants to fully engage in the intervention. Furthermore, these technological issues limited our ability to analyze preliminary outcomes data. However, participants provided overall positive feedback on the aspects of the intervention they engaged with (e.g., reviewing the workbook, watching a pre-recorded video, attending a live intervention session) despite these limitations. Participants

provided helpful feedback regarding their preferences, challenges encountered, and suggestions for improvement that will be helpful for future repetitions of this research. The qualitative data and participant feedback offers valuable insight into future targets for research and proposed modifications to the intervention for conducting future clinical trials. Based on the results, future studies could potentially benefit from reassessing the feasibility, acceptability, and preliminary outcomes of the telehealth intervention. These results especially highlight the potential benefits of developing an asynchronous, self-guided version of the intervention to contribute to the development of an accessible intervention focused on promoting CVPR adherence through the incorporation of values-consistent behavior, which would be further explored in future repetitions of this research.

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APPENDIX A – EMA Negative and Positive Mood Assessment

Indicate to what extent you feel this way right now, that is, at the present moment.

1 (“Very slightly or not at all”) -----2-----3-----4-----5-----6 (“Extremely”)

1. Sad
2. Lonely
3. Jittery
4. Nervous
5. Angry
6. Hostile
7. Happy
8. Excited

APPENDIX B – EMA Experiential Avoidance Assessment

To what extent do you agree with the following statements, right now, in the current moment?

1 (“Strongly disagree”) -----2-----3-----4-----5-----6 (“Strongly agree”)

1. I’m avoiding doing something because it might make me feel badly
2. I really wish I could have no painful feelings or thoughts
3. I’m procrastinating
4. I’m trying to distract myself from something or not think about it
5. I’m “turning off my emotions”

APPENDIX C – Cardiac Rehabilitation Barriers Scale (CRBS)

To what extent do you agree with the following statements?

1 (“Strongly disagree”) -----2-----3-----4-----5-----6 (“Strongly agree”)

“I missed some sessions because...”

1. ...of distance (e.g., not located in your area, too far to travel)
2. ...of cost (e.g., gas)
3. ...of transportation problems (e.g., access to car, public transportation)
4. ...of family responsibilities (e.g., caregiving)
5. ...of severe weather
6. ...of travel (e.g., holidays, vacation, business trip)
7. ...of time constraints (e.g., too busy, inconvenient appointment time)
8. ...of work responsibilities
9. ...I find exercise tiring or painful
10. ...I don't have the energy
11. ...other health problems prevent me from going
12. ...I am too old

APPENDIX D – Post-Completion Interview Outline

Participant ID: _____

Date: _____

- 1.) How comfortable did you feel using the technology (mobile EMA app, Cisco WebEx, YouTube; if applicable)? Did you encounter any difficulties using the technology? _____

- 2.) What are some reasons you did (or did not) participate in the program (or attend the sessions)? _____

- 3.) In your own words, what do you think was the overall purpose or aim of the program? _____

- 4.) What did you learn from the program? Were there aspects of the program that you found helpful? Were there aspects of the program you did *not* find helpful? _____

- 5.) What aspects of the program did you like the most? What was your favorite activity or session? _____

- 6.) Can you tell us more about your experience of taking part in the program? Have your perspectives of cardiopulmonary rehab changed as a result of taking part in the program? If the answer is 'Yes', what changed? _____

7.) How well do you think the program helped you in reaching your goal of attending cardiopulmonary rehab? _____

8.) What do you think could be improved about the program? _____

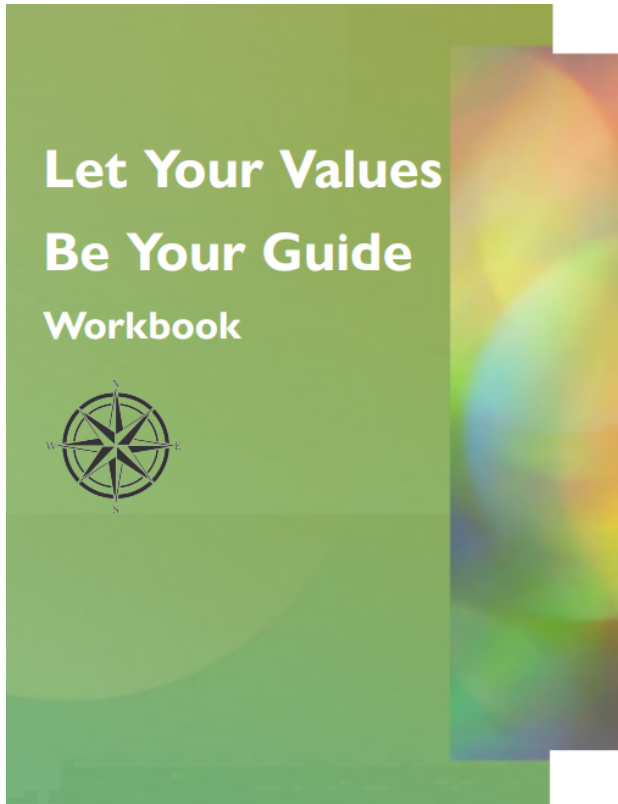
9.) Would you recommend the program to someone you care about if they were starting cardiopulmonary rehab? Why or why not? _____

10.) On a scale from 1-10 (1 'no effort at all', 10 'extreme effort'), how much effort do you think it took for you to participate in the program? Why did you give this rating? ____

For participants who discontinued or dropped out of the intervention:

1.) What are some reasons why you decided to discontinue the program? _____

2.) Is there anything that would have made it easier for you to participate in the program? ____



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Introduction to the Program

Welcome to 'Let Your Values Be Your Guide'! This is a five-week program aimed to help people in cardiac and pulmonary rehab make meaningful and long-lasting life-style changes.

We will accompany you on this journey where you will learn about your personal values and identify ways to incorporate these in your daily activities. You will also learn about practicing acceptance and compassion (or kindness) for yourself.

With each topic you will encounter something new, and we encourage you to approach the content and exercises with openness and curiosity. We will be there to help you in case you need any clarification or support!

Thank you for taking part in this program.

How to Use this workbook

In order to get the most out of this program, we encourage you to do the practice exercises. These exercises should not take more than 5-10 minutes.

It is important that during each session you follow along in your workbook, complete the reflections by filling in the answer blanks, and complete the brief practice exercises.

For each of the five weeks, there will be: 1) An overview of the topic discussed, 2) Practice exercises, and 3) Reminders and opportunities to ask questions.

We would like you to reflect on the things you learned during the sessions and to start implementing some changes in your life with openness, curiosity, and kindness towards yourself, at your own pace.

Acceptance & Values

What comes to mind when you think of acceptance? In your mind, what does it mean to be accepting of something? _____

Acceptance does **NOT** mean:

- You have given up
- You are okay with what you are going through
- You have no painful thoughts or feelings

Acceptance **≠** Approval

Acceptance & Values

Take a look at your problem list. How long have you experienced these problems? Write down the length of time by the side of each problem.

Consider how these problems impact your daily life. What has been difficult to accept about these problems?

In what ways are these problems holding you back from living the life you want to live? _____

Acceptance & Values

Acceptance means being **OPEN** to painful or uncomfortable experiences. Instead of avoiding these experiences, fighting them or getting overwhelmed by them, we let them be and learn to manage them. This does not mean we like them, but simply that we make room for these experiences.

Take some time to think about some problems you are facing that are holding you back from living the life that you truly want to lead. Write them down in the space below:

Problem List

- 1.
- 2.
- 3.
- 4.

Acceptance & Values

Being diagnosed with a chronic illness, such as heart or lung disease can be extremely difficult. It is normal to experience difficult emotions after receiving a diagnosis of chronic illness. However, you can learn to manage these feelings to live a fulfilling life.

What are some ways you deal with having a chronic illness?

Chronic illness comes with many challenges such as pain, uncomfortable feelings (for example, being out of breath), fatigue, and restrictions on what you can do or eat. How has your life changed since being diagnosed with a chronic illness?

Acceptance & Values

The goal of acceptance is to build a life that is rich and meaningful **around** illness, pain, and negative thoughts and emotions—rather than a life **free** of pain, illness, stress, etc.

Learning to live with and effectively manage chronic illness allows for more time and energy to devote to the things we find valuable, or meaningful.

Fill in the blank: "I have heart (or lung) disease, but I can still _____

_____."

Acceptance & Values

Imagine that a newscaster is telling a story about your life. Think about how you'd want them to describe you. How would you want them to describe the way you spend your time?

What kind of romantic partner, family member, and/or friend you are? _____

What is most important to you? _____

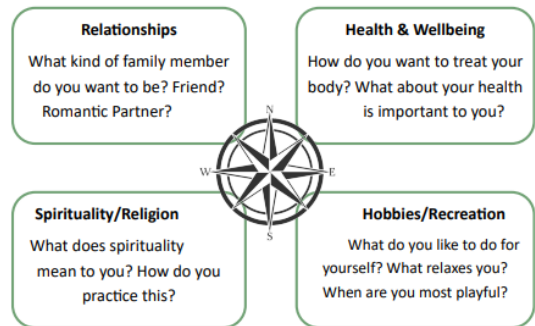
What strengths do you have? _____

Acceptance & Values

What are values?

- Values are a way of living that is important, rewarding, and fulfilling to you
- Values come from your lived experiences
- Values guide what is going to feel meaningful and enjoyable to you

Below are different life areas that people choose to value. These may help you identify your own values:



Acceptance & Values

If we've never needed to pay much attention to a value before, we should choose activities that fill our favorite buckets along with our neglected buckets



Write down some of your values (what's important in your life) underneath the buckets below. What are activities that help fill multiple buckets (including your health bucket)?



Defusion & Mindfulness

Defusion is about:

- Learning about the way we view ourselves and our situation
- Noticing thoughts rather than avoiding them or getting caught up in them
- Letting thoughts come and go rather than holding onto the thought
- *Not letting our thoughts hold us back*

By being more aware of how our thoughts affect us, we can begin to shape them in a positive or helpful way.

Defusion & Mindfulness

Imagine you are driving a bus to a destination of your choice (somewhere important to you).

1. What value are you trying to head toward? Fill this in as the destination of the bus (at the top of the bus).
2. What passengers (thoughts & feelings) get in your way? Write down the kinds of things they say to you in the speech bubbles.



Defusion & Mindfulness

Think about a time when you were feeling distressed or badly about yourself.

1. What was the situation? _____

Example: "I was having a really hard time doing the exercises at rehab because I was feeling out of breath and tired."

2. What were you feeling during this situation?

Example: "Frustrated and scared."

3. What was your mind telling you? _____

Example: "There's no point because I'm never going to get better."

4. What did you do next? _____

Example: "I skipped rehab later that week."

Defusion & Mindfulness

Someone with chronic illness may have the thought "I will always feel bad" or "Any form of exercise makes my symptoms worse."

Constantly having these thoughts makes them feel like truths. These thoughts can hold you back from doing things that can improve your health in the long run, like staying motivated to attend rehab. *Pick a distressing thought about your health and write it down:* _____

How does this thought hold you back? _____

Next time an unhelpful thought pops into your head, try saying "thanks for that brain." After all, your brain thinks it's helping.

Remember:

- These thoughts and feelings are temporary
- Thoughts are **not** facts
- We have control over what we do, despite having these thoughts and feelings

Defusion & Mindfulness

What does it mean to you to 'be present' or 'mindful'?

Negative and unhelpful thoughts can distract us from what's happening in the moment and what's important. It can be hard to stay present when dealing with chronic illness or when thinking about what's happened or what could happen to us.

Being mindful (or present) helps us:

- Stay focused on what's happening in the moment, which can help us fully participate in things that are important to us
- Let thoughts come and go without getting caught up in them
- Let feelings be as they are without trying to control them

Being mindful does **not** mean:

- Being calm or stress-free
- Having an empty or blank mind (no thoughts)
- Being perfect

Defusion & Mindfulness

You can practice defusion (or not letting your thoughts hold you back) in a number of different ways. Try practicing these techniques for a few minutes each day and see if you thoughts seem as powerful (or distressing) as they did when you began.

Mindful Doing the Dishes

1. Look at the dishes you are cleaning.
2. Notice any natural reactions (how you feel) about doing the task.
3. Notice the smells of the soap, the feeling of the water, the sounds of scrubbing.
4. Notice any thoughts that come up and bring it back to the task



Try your own: Consider your values, or what's important to you. What is one activity you can do mindfully? _____

Some ideas to help you get started: 1) *eating mindfully* (eat your food slowly and focus on its flavor, smell, and texture); 2) *move mindfully* (walk for a few minutes and notice the feeling of the ground beneath your feet); 3) *connect with someone you love* (be present for each other and consider what it feels like to spend time with this person).

Defusion & Mindfulness

You can practice defusion (or not letting your thoughts hold you back) in a number of different ways. Try practicing these techniques for a few minutes each day and see if you thoughts seem as powerful (or distressing) as they did when you began.

Leaves on a Stream

When the thought pops up, imagine placing it on a leaf floating down a gentle stream and watching as it disappears.



Notice Five Things

1. Look around and notice five objects you can see.
2. Notice five things you can feel in and around your body.
3. Listen carefully and notice three sounds you can hear.

Committed Action & Goal Setting

Our values (or what's important to us) drives our actions and motivates our goals. Refer back to page 12 and what values you chose to focus on.

- Examples of valued activities: 1) socializing with loved ones; 2) intimacy with a spouse or partner; 3) going to work; 4) playing with children and grandchildren; 5) being involved in community events; 6) going to church; and 7) exercising

Think about if there is anything you value that you have put on hold due to your chronic illness. What are three valued activities that would help you live according to this value? 1. _____

2. _____
3. _____



YOUR CORE VALUES ARE LIKE A COMPASS.
A USEFUL TOOL TO HELP YOU MAKE DECISIONS.
UNSURE WHICH DIRECTION TO GO?
CONSULT THE COMPASS TO INFORM YOUR CHOICE.

Committed Action & Goal Setting

While it's important to have awareness of your values, it is also essential to translate that understanding into committed action—acting in accordance to what's most important to you. But first, we must consider the difference between our values and goals:

VALUE
Guides us in the <u>direction</u> we are moving
Such as traveling <u>West</u>
An ongoing process
EXAMPLE: I value being a healthy person There are times when I am more or less healthy I must continue to eat healthy & exercise to <u>stay</u> healthy
GOAL
<u>Checkpoints</u> or <u>accomplishments</u> along the way
Such as the <u>cities that we stop at</u> while traveling West
Can be accomplished or " checked off " of a list
EXAMPLE: I ate a healthy meal & exercised today I did something healthy today I can create another goal because <u>this one is done</u>

Committed Action & Goal Setting

Set Your Goals—Plan and Prioritize

It's easy to lose sight of your priorities when dealing with a difficult problem such as managing a chronic illness. Some days, every little action takes an unbearable amount of effort.

You may find yourself having limited energy to complete daily responsibilities—including getting up in the morning, doing chores, going to work, going to rehab, and maintaining your relationships.

People with chronic illness walk a fine line between underdoing it and overdoing it. It's easy to push yourself too hard on days when you feel good. There are three steps to pacing yourself:

1. Make a list of some things that you tend to overdo
2. Make a time limit for the activity and then STOP and REST
3. Keep track of how you are doing (how many times did you stop yourself from overdoing it?).



Committed Action & Goal Setting

Four steps toward committed action:

1. What is a high priority area of your life for change? _____

Example: "I used to love spending time outdoors and I haven't really felt like doing this since having my heart attack."

2. Why is this life area important to you (what are your values in this life area)? _____

Example: "My hobbies are important to me, like fishing and going for walks, and these are activities I used to be able to do with my family. Being active outside was also good for my health."

3. What is your goal in this life area (what do you hope to accomplish)? _____

Example: "I want to improve my health in cardiac rehab so I can spend more time with my family outdoors and sharing my hobbies with them."

4. What is an action that ties your personal values with your goal? _____

Example: "I'm going to walk by the fishing pond with my grandchildren this afternoon."

Committed Action & Goal Setting

Using SMART Goals—A Guide for Goal Setting

Specific	Measurable	Achievable	Realistic	Timely
S	M	A	R	T
G	O	A	L	S
What do you want to do?	How will you know when you've reached it?	Is it in your power to accomplish it?	Can you realistically achieve it?	When exactly do you want to accomplish it?

My goal is: _____

How will I know if I've improved from the previous day or week? _____

I will achieve this goal by doing the following: _____

This goal helps me because: _____

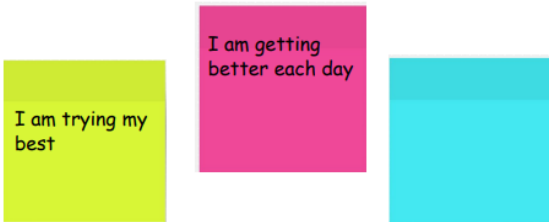
I will complete this goal by (date)? _____

Committed Action & Goal Setting

Questions to consider while setting goals:

1. Does this goal take me where I want to go? Does it enrich my life?
2. Am I prepared to make the commitment to reach this goal?
3. Am I willing to shift my habits to reach this goal?
4. What are some things that might interfere (or get in the way) of me achieving this goal?
5. What is the smallest, easiest step I can begin with to start working toward my goal?
6. What are some helpful reminders if you're having trouble reaching your goal?

Use positive self-statements to help reach your goals! **Write your own in the blank stick note:**



Problem-Solving & Values Clarification

Unhealthy coping strategies tend to feel good in the moment, but have long-term negative consequences. Healthy coping strategies may not provide instant relief, but they lead to longer-lasting positive outcomes. Below are some examples of healthy and unhealthy coping strategies:

Examples of unhealthy coping strategies:	Examples of healthy coping strategies:
<ul style="list-style-type: none"> • Drug or alcohol use • Overeating • Procrastination • Sleeping too much or too little • Social withdrawal • Self-harm • Aggression 	<ul style="list-style-type: none"> • Exercise • Talking about your problem • Healthy eating • Seeking professional help • Relaxation techniques (e.g. deep breathing) • Using social support • Problem-solving techniques

What is an unhealthy coping strategy that you have used in the past?
Why was it unhelpful? _____

What is an example of a healthy coping strategy that you have used?
Why was this helpful? _____

Problem-Solving & Values Clarification

Look back on your problem list that you wrote down on page 6. When facing a problem, you can either:

1. Take steps to solve this problem (problem-focused coping)
2. Learn ways to deal with negative feelings that come from this problem (emotion-focused coping)



Problem-Solving & Values Clarification

What is a problem you are currently dealing with in rehab?

Examples: "I am too tired to exercise", "I think rehab is boring", "I'm self-conscious about the way I look when I exercise", "I don't have the stamina to exercise"

How does this problem affect your life and what does it stop you from doing (or being)? _____

What is your goal and what actions do you plan to take to achieve this goal? _____

What values underlie your goal (why is this goal important to you)? _____

Problem-Solving & Values Clarification

Your values (or what's important to you) help guide you when making decisions and solving problems, which is helpful when considering possible solutions.

When you feel stuck (like a problem isn't going away), it's often a sign that something needs to change in your life. What current thoughts, feelings, or behaviors do you engage in that keep you stuck, or make things worse in the long run? _____

Change is sometimes scary, but it's also necessary for getting unstuck. Try the following when feeling stuck:

1. Be present and willing to experience the bad (and good)
2. Start with small changes (remember to use SMART goals)
3. Consider what's important to you (your values)
4. Be kind to yourself!



Self-Compassion & Self-Care

What comes to mind when you think of self-compassion? What does it mean to be kind to yourself? _____

What comes to mind when you think of self-care? What does it mean to care for yourself? _____

To have compassion is to:

- Notice when a person is suffering
- Be moved by one's suffering
- Feel the desire to help the person who is suffering
- Offer understanding and kindness rather than judging them harshly

Self-compassion involves being warm and understanding toward ourselves when we suffer, fail, or feel inadequate

- Self-compassion is **not** self-pity or self-indulgence

Problem-Solving & Values Clarification

Getting Unstuck

Write down where you feel stuck right now: _____

Why do you feel stuck? _____

Where do you want to go or be? Or what do you want your life to look like in a year? _____

What choices or options do you have? Consider the pros and cons to each: _____

Which option is aligned with your values and takes you a step toward your vision for the future? _____

What is a small step you could take to start moving in the direction you want to see in your future? _____

Self-Compassion & Self-Care

What are some ways you comfort and care for yourself during difficult situations? _____

What are some ways you comfort and reassure loved ones who are dealing with difficult situations? _____

Oftentimes we are more critical and harder on ourselves when we are struggling. Next time you are struggling with a difficult situation, try treating yourself like you would a loved one.

Self-compassion is:

 <p>Mindfulness Recognizing when stressed or struggling, without overreacting or being judgmental towards yourself.</p>	 <p>Self-kindness Being supportive and understanding towards yourself during a hard time, rather than being self-critical.</p>	 <p>Humanity Recognizing that you are not alone in the mistakes you make or the difficulties you might experience.</p>
Seeing self objectively	Non-judgment of the self	We all make mistakes

Self-Compassion & Self-Care

Self-compassion means having an attitude of kindness and consideration toward yourself. This is different from **self-care**, which are the actions we take to care for our needs.

- Practicing self-care means that you are being mindful of your own needs, so you are better able to do the things you care about

Fill in the blank: "I care for myself by _____
 _____."
 _____."



Self-Compassion & Self-Care

Taking Self-Compassion Breaks

What are ways you could be more kind with yourself? Especially as you are trying to make difficult changes in rehab. Write down some ideas in the blank space: _____

Think of a situation in your life that is difficult that is causing you stress. Now say to yourself:

1. "This is a moment of suffering" or "This is really hard"
2. "Suffering is a part of life" or "I'm not the only one who struggles with this" or "We're all just trying to do our best with what we have"
3. "May I be kind to myself" or "May I forgive myself" or "May I be patient"

Is there another comforting, or self-compassionate, phrase you can say to yourself when you are struggling? _____

Self-Compassion & Self-Care

Prioritizing self-care helps keep your bucket full so you have energy to do what you need to do. Taking care of yourself also helps you be more present in your daily life. The key is to figure out what fills your bucket back up—and then do those things!

There are many different ways we can practice self-care. Here are some questions to consider every now and then to ensure that we are prioritizing our needs:

Physical health: <ul style="list-style-type: none"> • Are you getting enough sleep? • Is your diet fueling your body and giving you the energy and nutrients it needs? • Are you moving regularly? 	Mental health: <ul style="list-style-type: none"> • Are you making time for things that are important to you? • Do you have healthy ways to deal with your emotions?
Social needs: <ul style="list-style-type: none"> • What are you doing to nurture your close relationships? 	

Examples of Values

Circle the values that you relate to the most:

1. Being active
2. Independence
3. Family
4. Self-care / Self-Exploration
5. Health
6. Challenge
7. Work
8. Spirituality
9. Commitment
10. Persistence
11. Helping Others
12. Leisure
13. Friends
14. Acceptance
15. Adaptability
16. Socializing
17. Responsibility

Examples of Valued Activities

Below is a list of activities that may fit with your personal values. Circle the activities you would like to try or do more of:

1. Talk to a friend on the phone
2. Visit a friend
3. Exercise
4. Stretch your muscles
5. Go for a long walk in the park, or somewhere else that's peaceful
6. Get out of your house, even if you just sit outside
7. Go for a drive in your car
8. Sleep or take a nap
9. Cook your favorite dish or meal
10. Go outside and play with your pet
11. Watch a funny movie (start collecting funny movies to watch when you're feeling overwhelmed)
12. Listen to the radio
13. Play a game with a friend or loved one
14. Do a puzzle with lots of pieces
15. Go shopping
16. Get a haircut
17. Go to a sporting event
18. Watch television
19. Read a book

Examples of Valued Activities

Below is a list of activities that may fit with your personal values. Circle the activities you would like to try or do more of:

20. Drink a cup of coffee or tea
21. Visit a museum
22. Go to the mall or the park and watch other people; try to imagine what they're thinking about
23. Pray or meditate
24. Go to church, temple, synagogue, or other place of worship
25. Join a group at your place of worship
26. Call a family member you haven't spoken to in a long time
27. Sing
28. Listen to some upbeat, happy music (start collecting happy songs for times when you're feeling overwhelmed)
29. Take photographs
30. Plant a garden
31. Knit, crochet, or sew—or learn how to
32. Paint your nails
33. Take a bubble bath or shower
34. Work on your car, truck, motorcycle, or bicycle
35. Sign up for a class
36. Make a list of 10 things you're good at or that you like about yourself
37. Write a letter to someone who has made your life better and tell them

APPENDIX F – Intervention Session Recordings

Session 1 – Acceptance & Values: https://youtu.be/_tM5WEr_nQI

Session 2 – Cognitive Defusion & Mindfulness: <https://youtu.be/Dwh9oqlLmxw>

Session 3 – Committed Action & Goal-Setting: <https://youtu.be/s8D6bOtBQMc>

Session 4 – Problem Solving & Values Clarification: https://youtu.be/Fj8I_B2UqbQ

Session 5 – Self Compassion & Self-Care: <https://youtu.be/lQqdGK7nKf4>

APPENDIX G: IRB Approval Letter



EAST CAROLINA UNIVERSITY

University & Medical Center Institutional Review Board

4N-64 Brody Medical Sciences Building· Mail Stop 682

600 Moye Boulevard · Greenville, NC 27834

Office 252-744-2914 · Fax 252-744-2284

rede.ecu.edu/umcirb/

Notification of Initial Approval: Expedited

From: Social/Behavioral IRB
To: [Emily Midgette](#)
CC: [Matthew Whited](#)
Date: 2/24/2022
Re: [UMCIRB 21-002532](#)
Feasibility and Acceptability of a Values-Based Telehealth Intervention to Promote Adherence in Cardiopulmonary Rehabilitation Patients

I am pleased to inform you that your Expedited Application was approved. Approval of the study and any consent form(s) occurred on 2/23/2022. The research study is eligible for review under expedited category # 6, 7. The Chairperson (or designee) deemed this study no more than minimal risk.

As the Principal Investigator you are explicitly responsible for the conduct of all aspects of this study and must adhere to all reporting requirements for the study. Your responsibilities include but are not limited to:

1. Ensuring changes to the approved research (including the UMCIRB approved consent document) are initiated only after UMCIRB review and approval except when necessary to eliminate an apparent immediate hazard to the participant. All changes (e.g. a change in procedure, number of participants, personnel, study locations, new recruitment materials, study instruments, etc.) must be prospectively reviewed and approved by the UMCIRB before they are implemented;
2. Where informed consent has not been waived by the UMCIRB, ensuring that only valid versions of the UMCIRB approved, date-stamped informed consent document(s) are used for obtaining informed consent (consent documents with the IRB approval date stamp are found under the Documents tab in the ePIRATE study workspace);
3. Promptly reporting to the UMCIRB all unanticipated problems involving risks to participants and others;
4. Submission of a final report application to the UMCIRB prior to the expected end date provided in the IRB application in order to document human research activity has ended and to provide a timepoint in which to base document retention; and

5. Submission of an amendment to extend the expected end date if the study is not expected to be completed by that date. The amendment should be submitted 30 days prior to the UMCIRB approved expected end date or as soon as the Investigator is aware that the study will not be completed by that date.

The approval includes the following items:

Name	Description
BIPQ.pdf	Surveys and Questionnaires
CRBS.docx	Surveys and Questionnaires
Crisis Resources.docx	Additional Items
Dissertation proposal_Midgette final.docx	Study Protocol or Grant Application
Dissertation Qualitative Interview.docx	Interview/Focus Group Scripts/Questions
EMA BIPQ Consequence.docx	Surveys and Questionnaires
EMA Questions Mood and EA.docx	Surveys and Questionnaires
GAD-7_Anxiety-updated_0.pdf	Surveys and Questionnaires Informed-Consent 2.11.22 EM.docx
Consent Forms patient-health-questionnaire.pdf	Surveys and Questionnaires
Recruitment Flyer 2.1.22.docx	Recruitment Documents/Scripts

|

For research studies where a waiver or alteration of HIPAA Authorization has been approved, the IRB states that each of the waiver criteria in 45 CFR 164.512(i)(1)(i)(A) and (2)(i) through (v) have been met. Additionally, the elements of PHI to be collected as described in items 1 and 2 of the Application for Waiver of Authorization have been determined to be the minimal necessary for the specified research.

The Chairperson (or designee) does not have a potential for conflict of interest on this study.

APPENDIX H: Informed Consent Document



Informed Consent to Participate in Research Information to consider before taking part in research that has no more than minimal risk.

Title of Research Study: Feasibility and Acceptability of a Values-Based Telehealth Intervention to Promote Adherence in Cardiopulmonary Patients

Principal Investigator: Emily Midgette, M.A., and Ashlan McNinch, M.A. (Person in Charge of this Study)
Faculty Supervisor: Matthew C. Whited, Ph.D., Associate Professor of Psychology at East Carolina University
Institution, Department or Division: East Carolina University Psychology Department
Address: 237 Rawl Building, East Carolina University, Greenville, NC, 27858
Email Address: midgettee13@students.ecu.edu
Telephone #: 252-328-6283

Participant Full Name: _____ Date of Birth: _____
Please PRINT clearly

Researchers at East Carolina University (ECU) and Vidant Cardiopulmonary Rehabilitation study issues related to society, health problems, environmental problems, behavior problems and the human condition. To do this, we need the help of volunteers who are willing to take part in research.

Why am I being invited to take part in this research?

The purpose of this research is to investigate your experiences of taking part in a virtual intervention, and to understand the relationships between mood and illness perception on participation and outcomes in cardiopulmonary rehab. You are being invited to take part in this research because you are currently a patient enrolled in cardiopulmonary rehab at Vidant. The decision to take part in this research is yours to make. By doing this research, we hope to learn about barriers to participation in cardiopulmonary rehab, and how programming may reduce these barriers.

If you volunteer to take part in this research, you will be one of about 60 people to do so.

Are there reasons I should not take part in this research?

You should not participate in this research if you are under 18 years of age or cannot speak English.

What other choices do I have if I do not take part in this research?

You can choose not to participate. Choosing not to participate will not affect your cardiac or pulmonary rehabilitation program. If you choose not to participate, you will receive the same cardiac or pulmonary rehabilitation program as anyone else in the program.

Where is the research going to take place and how long will it last?

The research will be conducted at the Vidant Medical Center Cardiovascular and Pulmonary Rehabilitation program. You will need to meet with our research team twice during the study, while attending your normal rehab sessions. You will also be asked to attend one, 45-minute workshop per week on your personal computer or mobile device for five weeks (five workshops total). You will attend these workshops with other participants, and everyone will be provided with a manual with information about the five workshops. During this time, you will also be answering brief

series of questions on a mobile device three times per week for five weeks (15 times total). These surveys only take 2-5 minutes to complete. After five weeks, you will be asked to meet with our research team one last time to discuss your feedback and experiences of taking part in the workshops. The total amount of time you will be asked to volunteer for this study is a total of approximately five hours over the next five weeks.

What will I be asked to do?

You will be asked to do the following:

Phase 1: You will be invited to meet with our research team in order to receive materials for the weekly online group workshops. You will complete a brief measure about your current mood, your understanding of your medical condition, and barriers to attending cardiopulmonary rehabilitation. We will also be assessing how consistent your goal to attend cardiopulmonary rehabilitation is consistent, or in line with, your personal values (or what's important to you). This initial session will last approximately 15-20 minutes.

- During this initial session, you will be given a manual with information about each workshop topic, including practice exercises.
- Using your personal smartphone, we will assist you in downloading a mobile application, which will allow us to ask you questions throughout the day regarding your mood and perception of your medical condition. If you do not have a smartphone, you will be provided with one to use for the duration of the study.

Phase 2: You will then attend five weekly online group workshops (45-minutes each) on your personal computer or mobile device that will focus on discussing your motivations for attending cardiopulmonary rehabilitation and setting goals for yourself.

- If you do not have a computer or mobile device to attend these workshops, you will be able to watch pre-recorded videos covering the same topics during your regularly scheduled cardiopulmonary rehab sessions.
- During this five-week period, you will answer brief surveys (2-5 minutes) three times per week (15 times total) about your mood and perception of your medical condition.

Phase 3: At the end of the five weeks, you will meet with our research team again (20-25 minutes) for a brief interview in which you will be asked questions about your feedback and experiences of taking part in the workshops. These brief interviews will be audio recorded and later deleted after the study is complete. At the end of the five weeks, the research team will access your attendance data from the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR) reporting site. Information regarding patient outcomes and attendance is collected and entered into the secure AACVPR reporting site as part of standard care at Vidant CVPR. You will not need to do anything for this part of the research study.

What might I experience if I take part in the research?

We don't know of any risks (the chance of harm) associated with this research. Any risks that may occur with this research are no more than what you would experience in everyday life. We don't know if you will benefit from taking part in this study. There may not be any personal benefit to you, but the information gained by doing this research may help others in the future. By participating in this research study, you may experience benefits from learning more about yourself through the monitoring process and group workshops.

Will I be paid for taking part in this research?

We will be able to pay you for the time you volunteer while being in this study. You will receive a \$10.00 Greenphire debit card or a \$10.00 gift card to either Walmart or Starbucks for participating in the initial session. You will also receive a second \$10.00 Greenphire debit card or a \$10.00 gift card to either Walmart or Starbucks after the 15 days of study participation. You will receive a workshop manual and weekly online group workshops free of charge.

Will it cost me to take part in this research?

It will not cost you any money to be part of the research; however, participation in the online group workshops via Cisco WebEx and monitoring using the Personal Analytics Companion (PACO) mobile app does involve minimal data usage. Access to Wi-Fi will eliminate the need to use data on your smartphone.

Who will know that I took part in this research and learn personal information about me?

ECU and the people and organizations listed below may know that you took part in this research and may see information about you that is normally kept private. With your permission, these people may use your private information to do this research:

- Any agency of the federal, state, or local government that regulates human research. This includes the Department of Health and Human Services (DHHS), the North Carolina Department of Health, and the Office for Human Research Protections.
- The University & Medical Center Institutional Review Board (UMCIRB) and its staff have responsibility for overseeing your welfare during this research and may need to see research records that identify you.
- People designated by Vidant Medical Center and Vidant Health.
- If you are a patient at ECU or Vidant, a copy of this form will be placed in your medical records.
- Members of the research team.

If information is shared, it will not be individual data and will be averages of data across research participants.

How will you keep the information you collect about me secure? How long will you keep it?

Data collected from this study will be kept securely for seven years. All identifying information (e.g., your name and email address) will be separated from responses after completing the mobile monitoring and destroyed prior to the end of the seven-year period.

HIPAA Privacy Authorization Statement

The purpose of the information to be gathered for this research study is to better understand the feasibility and acceptability of a values-based telehealth intervention aimed toward improving CVPR adherence, and to examine daily changes in mood that may affect adherence. When taking part in research, protected health information (PHI) is collected, used, and shared with others who are involved in the research. Federal laws require that researchers and health care providers protect your PHI. Also, federal laws require that we get your permission to use collected PHI for the research. This permission is called authorization.

The individuals who will use or disclose your identifiable health information for research purposes include the Principal Investigator (Emily Midgette) and other members of the research team. Individuals who will receive your identifiable health information for research purposes include:

- Research investigators to conduct and oversee the research [project](#)
- Principal investigator and research team members to participate in the various research [activities](#)
- UMCIRB to provide continuing review of the research [project](#)
- Institutional officials in connection with duties for monitoring research activity
- Other providers involved in your care during research procedures, outpatient/inpatient stays during which research is being performed, or physician office visits during which research is being [performed](#)

The type of information accessed for this research study includes CVPR attendance data from the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR) reporting site. Patient outcomes and attendance data are collected and [entered into](#) the secure AACVPR reporting site as part of standard care at Vidant CVPR. The information will be used and disclosed in such a way as to protect your identity as much as possible; however, confidentiality cannot be absolutely guaranteed. Someone receiving information collected under this

Authorization could potentially re-disclose it, and therefore it would no longer be protected under the HIPAA privacy rules (federal rules that govern the use and disclosure of your health information). There is not an expiration date for this Authorization.

You may not participate in this study if you do not sign this Authorization form. You may revoke (withdraw) this Authorization by submitting a request in writing to Emily Midgette (Principal Investigator) at midgettee13@students.ecu.edu. However, the research team will be able to use any and all of the information collected prior to your request to withdraw your Authorization. You will not be able to see your PHI in your medical record related to this study until the study is complete. If it is necessary for your care, your PHI will be provided to you or your physician.

To authorize the use and disclosure of your health information for this study in the way that has been described in this form, please sign below and date when you signed this form. A signed copy of this Authorization will be given to you for your records.

If you have questions about the sharing of PHI related to this research study, call Emily Midgette (Principal Investigator) at 252-328-6308. If you have questions about your rights as someone taking part in research, you may call the ECU University and Medical Center Institutional Review Board (UMCIRB) at phone number 252-744-2914 (Monday through Friday, 8:00am-5:00pm). You may also call the Vidant Health Center for Research and Grants at 252-847-1177. If you would like to report a complaint or concern about this research study, you may call the Director for Human Research Protections, at 252-744-2914 and the Vidant Health Risk Management Office at 252-413-4473. In addition, if you have concerns about confidentiality and privacy rights, you may phone the Privacy Officer at East Carolina University at 252-744-5200 and the Privacy Officer at Vidant Health at 888-777-2617.

What if I decide I don't want to continue in this research?

You can stop at any time after it has already started. There will be no consequences if you stop, and you will not be criticized. We understand there are a variety of situations that may necessitate withdrawal from the study and will gladly assist you should you decide that you do not wish to continue. You will not lose any benefits that you have already received.

Who should I contact if I have questions?

The people conducting this study will be able to answer any questions concerning this research, now or in the future. You may contact the Principal Investigators at 252-328-6308 (days, between 8am and 5pm), or by email at midgettee@students.ecu.edu or mcninch20@students.ecu.edu. You may also contact the Faculty Supervisor, Dr. Matthew Whited by email at whitedm@ecu.edu or by phone at 252-328-6308. You will be provided with a copy of this form after you decide whether to sign it.

If you have questions about your rights as someone taking part in research, you may call the Office of Research Integrity & Compliance (ORIC) at phone number 252-744-2914 (days, 8:00 am-5:00 pm). You may also call the Vidant Health Center for Research and Grants at 252-847-1177. If you would like to report a complaint or concern about this research study, you may call the Director of the ORIC, at 252-744-1971 and the Vidant Health Risk Management Office at 252-413-4473.

Is there anything else I should know?

Most people outside the research team will not see your name on your research record. This includes people who try to get your information using a court order. One exception is if you agree that we can give out research information with your name on it. Other exceptions are information about child abuse or neglect and harm to yourself or others.

Identifying information will be deleted from your responses and, after such removal, the deidentified information could be used for future research studies without additional informed consent from you or your Legally Authorized Representative (LAR). However, there still may be a chance that someone could figure out the information is about you.

I have decided I want to take part in this research. What should I do now?

The person obtaining informed consent will ask you to read the following and if you agree, you should sign this form:

- I have read (or had read to me) all of the above information.
- I have had an opportunity to ask questions about things in this research I did not understand and have received satisfactory answers.
- I know that I can stop taking part in this study at any time.
- By signing this informed consent form, I am not giving up any of my rights.
- I have been given a copy of this consent document, and it is mine to keep.

Participant's Name (PRINT)	Signature	Date
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Person Obtaining Informed Consent: I have conducted the initial informed consent process. I have orally reviewed the contents of the consent document with the person who has signed above and answered all of the person's questions about the research.

Person Obtaining Consent (PRINT)	Signature	Date
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