A RANDOMIZED CONTROLLED TRIAL COMPARING A COMPANION DOG WALKING INTERVENTION TO AN ATTENTION CONTROL EDUCATION INTERVENTION ON THE PSYCHOLOGICAL HEALTH OF ADULT INTENSIVE CARE UNIT SURVIVORS: THE POOCH STUDY

DISSERTATION IN
Nursing

Presented to the Faculty of the University of
Missouri-Kansas City in partial fulfillment of
the requirements for the degree

DOCTOR OF PHILOSOPHY

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2024

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ABSTRACT

Intensive care unit (ICU) survivors are at risk for persistent anxiety and depression after hospital discharge that contribute to the psychological component of post intensive care syndrome (PICS). Quality evidence supporting innovative home and community-based interventions that improve psychological health in ICU survivors is needed. The use of companion dogs to improve the health and wellbeing of ICU survivors is a novel strategy not previously explored in the ICU survivor population. The purpose of this randomized controlled trial (RCT) was to evaluate the feasibility and acceptability of a companion dog walking intervention compared to an attention control education intervention for adult ICU survivors and to compare outcome trends related to depression, anxiety, serum cortisol, and quality of life (QOL). A prospective, single-masked (participant), two-arm RCT was conducted. Adult ICU survivors were recruited from two acute care hospitals using consecutive sampling and out-patient clinics via recruitment flyers. Potential participants were identified, contacted, consented, and screened for eligibility prior to being discharged home from the hospital. Those meeting inclusion criteria were enrolled, masked, and

randomly assigned (1:1) to an eight-week companion dog walking intervention or an attention control education intervention. The dependent variables of depression, anxiety, serum cortisol, and QOL were assessed at baseline, at week 4, and at the end of the 8-week intervention. Study feasibility and acceptability was assessed at the end of the 8-week study. Of the 2,191 patients screened, 210 (9.6%) met initial inclusion criteria, of which 143 (68%) received recruitment flyers, 25 (17.5%) communicated interest, and 10 (7%) enrolled. Results suggest the current protocol supports successful masking of participants and collection of measurements and data points, while protocol revisions are necessary to improve recruitment, intervention fidelity by participants, and attrition. Study processes and interventions were acceptable for both those in the attention control education group and companion dog walking intervention group. Analysis and interpretation of exploratory outcomes were limited due to the small sample size. While definitive trends were lacking, results suggest companion dog walking may have the potential to influence aspects of health in adult ICU survivors and future research is warranted.

APPROVAL PAGE

The faculty listed below, appointed by the Dean of the School of Nursing and Health Studies, have examined a dissertation titled "A Randomized Controlled Trial Comparing a Companion Dog Walking Intervention to an Attention Control Education Intervention on the Psychological Health of Adult Intensive Care Unit Survivors: The POOCH Study" presented by Lindsey C. Nelson, candidate for the Doctor of Philosophy degree, and certify that in their opinion it is worthy of acceptance.

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ACKNOWLEDGEMENTS

My PhD journey would not have been possible without the amazing support I received along the way. First, I want to thank my family. To my husband, thank you for your unwavering encouragement and understanding, and for your willingness to tackle this adventure as a family. To my two sons, who were both born during my time at UMKC, I love you so much; you motivate me to be the best I can be, and I cannot thank you enough for your patience and unconditional love. To my parents, thank you for your infinite encouragement and words of wisdom and for lending a hand in countless ways. To my mother, thank you for your help making the dog bandanas; any project with you is always a good time. To my father, thank you for joining me on the many rides and the conversations along the way. I want to thank my friends and colleagues for their never-ending encouragement and for always "checking in" to see how I was doing.

I would like to thank my committee members for their continuous support, encouragement, insight, and expertise. My chair, Dr. Lasiter, you have been an incredible mentor. You gave me autonomy to learn and navigate on my own yet were always there guiding me in the right direction. I hope to collaborate again in the future. Thank you to the nurses that helped with recruitment; this study would not have been possible without you. Finally, I want to acknowledge SIGMA who supported The POOCH Study with grant funding from the Doris Bloch Research Award and the University of Missouri-Kansas City's Women's Council for their monetary gift from their Graduate Assistance Fund. These two organizations continue to make research possible for students and novel researchers such as myself. I would not have been able to conduct The POOCH Study without their support.

CHAPTER 1

INTRODUCTION

Background

Approximately 26.9% of hospital admissions involve intensive care unit (ICU) treatment or care (Barrett et al., 2014). Advancements in healthcare knowledge and technology have led to a decrease in ICU mortality rates and an increase in survival rates (Zimmerman et al., 2013). Although ICU survivors have lived through a critical illness or injury, they are at risk for developing post intensive care syndrome (PICS) (Elliot et al., 2014; Needham et al., 2012). Post-intensive care syndrome refers to new or worsening physical, psychological, cognitive, and/or social sequelae that can persist in ICU survivors after hospital discharge (Elliot et al., 2014; Needham et al., 2012). The burden associated with ICU survival and PICS is tremendous. Post intensive care syndrome can adversely affect physical function, the ability to complete daily activities, and quality of life (QOL) (Elliot et al., 2014; Held & Moss, 2019; Wilson et al., 2018). Adult ICU survivors have an increased risk of mortality, higher hospital and healthcare costs following hospital discharge (Brown et al., 2019; Hill et al., 2016; Lone et al., 2016), can experience social isolation (Kang & Jeong, 2018), and often face challenges returning to work and a decline in family income (Griffiths et al., 2013; Su et al., 2021). Lone et al. (2016) followed ICU survivors (*n* = 5,259) for five years after discharge and found they have more hospital admissions, a 10% higher mortality rate, and a 51% higher mean hospital cost compared to patients who experienced a general hospital admission. A systematic review focused on return to employment after critical illness showed only 56% of survivors returned to work at 12-months post hospital discharge (McPeake et al., 2019). Griffiths et al. (2013) followed ICU

survivors for 12-months after discharge and found 33% did not return to the job or salary they had before their ICU stay, and 28% of survivors reported a negative impact on family income after their ICU admission. Overall, an estimated 60% of adult ICU survivors experience PICS (Marra et al., 2018).

Significance

The Society of Critical Care Medicine (SCCM) has recognized PICS as a public health concern in need of innovative treatment and prevention strategies that extend beyond the acute care setting (Elliot et al., 2014; Needham et al., 2012). Currently, there are no evidence-based standardized recovery strategies (Brown et al., 2019; Elliot et al., 2014; Held & Moss, 2019; Lasiter et al., 2016), and the strategies in place are limited to formal settings (Geense et al., 2019; Holod et al., 2022; Jensen et al., 2015; Lasiter et al., 2016). A systematic review and meta-analysis of non-pharmacological PICS interventions by Geense et al. (2019) revealed current interventions are lacking a holistic approach and are limited by a focus on outcomes rather than process. Similarly, Holod et al. (2022) conducted a systematic review summarizing home-based interventions for ICU survivors after discharge and found a lack of such interventions and a need to assess feasibility of home-based interventions.

Psychological conditions such as depression and anxiety can last from weeks to years after hospital discharge (Marra et al., 2018; Davidson & Harvey, 2016; Griffiths et al., 2013) and researchers have found detection of anxiety and depression in ICU survivors is often delayed (Jackson et al., 2014; Marra et al., 2018; Wunsch, 2014). Additionally, intervention research has centered predominantly on physical health and physical function outcomes

(Geense et al., 2019), while those interventions focused on anxiety and depression outcomes lack strong evidence (Nikayin et al., 2016; Rabiee et al., 2016).

A strategy not yet explored in the ICU survivor population is companion dogs as facilitators of human health and wellbeing. Companion dogs have been linked to improving human health in adult populations experiencing conditions similar to ICU survivors such as anxiety (Bolstad et al., 2021; Hughes et al., 2019), depression (Hughes et al., 2019; Krause-Parello, 2012), lack of social support and loneliness (Krause-Parello, 2012) and low physical activity and function (Hughes et al., 2019; Mičková et al., 2019; Ortmeyer & Robey, 2019; Richards et al., 2015). Although there are encouraging results in research involving companion dogs, most evidence is cross-sectional, intervention studies and randomized controlled trials (RCTs) are lacking (Nelson et al., 2024), and research findings are inconsistent with positive, negative, and neutral effects being reported (Glenk et al., 2017; Hughes et al., 2019; Nelson et al., 2024).

The POOCH Study (com**p**ani**o**n d**o**g walking for I**C**U survivor **h**ealth) addressed the need for high-quality intervention research and the need to explore intervention processes by conducting a feasibility and acceptability study with an RCT design. The study also addressed the need for innovative holistic strategies outside the confines of formal settings through the implementation of an intervention founded in Engel's Biopsychosocial Model that optimized the role of ICU survivors' personal companion dogs to facilitate psychological wellbeing. Additionally, this study examined early recognition and intervention for post-ICU psychological conditions (Jackson et al., 2014; Kang et al., 2020). Finally, this study contributed to the nursing discipline by aligning with its scope and standards of practice that calls nurses to provide holistic care, optimize positive outcomes, facilitate healing and

recovery, and lead innovative strategies (American Association of Colleges of Nursing, 2006; American Nurses Association, 2015; Eaton et al., 2019).

Innovation

The POOCH Study was innovative in the following ways:

- The role of companion dogs had not been explored in the ICU survivor population before and was a new approach aimed at improving psychological symptoms associated with PICS.
- The application of an intervention founded in Engel's Biopsychosocial model had not been examined in the ICU survivor population and provided a novel approach to planning, implementing, and assessing PICS interventions.
- Process assessment is lacking in PICS intervention literature and is necessary to improve strategies and outcomes (Geense et al., 2019). The POOCH Study focused on intervention feasibility and acceptability which is an essential component of understanding and improving PICS recovery strategies.
- Home-based interventions for ICU survivors are limited and require research to develop and test these interventions (Holod et al., 2022). The POOCH Study contributed to this gap in the literature.

Purpose

The purpose of this RCT was to assess the feasibility and acceptability of a companion dog walking intervention compared to an attention control education intervention on depression, anxiety, serum cortisol, and QOL in adult ICU survivors. This study introduced a novel and innovative approach for addressing PICS and results will inform

future research and interventions that facilitate psychological wellbeing and recovery in ICU survivors through human-companion animal interaction.

Research Questions and Aims

Research Questions

Primary Research Questions

1. What is the feasibility of conducting an RCT comparing a companion dog walking intervention to an attention control education intervention on depression, anxiety, serum cortisol, and QOL in adult ICU survivors?
    a) To what extent did the recruitment procedure produce study participants?
    b) How many participants met inclusion and exclusion criteria?
    c) What were the obstacles to recruitment?
    d) What was the attrition rate of participants?
    e) To what extent were participants masked to their group assignment?
    f) To what extent was the fidelity of the intervention maintained by participants?
    g) To what extent were measurements completed?
    h) What was the extent and pattern of missing data?
2. What is the acceptability of participating in an RCT comparing a companion dog walking intervention to an attention control education intervention on depression, anxiety, serum cortisol, and QOL for adult ICU survivors?
    a) What was the acceptability of the time spent in the study and per session?
    b) What was the acceptability of completing the measurement tools?
    c) What was the acceptability of the intervention?

d) To what extent did study participants intend to continue the intervention after the end of the study?

e) What suggestions for improvement did participants have?

f) What reasons did participants report for wanting to participate in the study?

Exploratory Research Questions

1. What are the differences in depression between and within a companion dog walking intervention compared to an attention control education intervention for ICU survivors?
2. What are the differences in anxiety between and within a companion dog walking intervention compared to an attention control education intervention for ICU survivors?
3. What are the differences in quality of life between and within a companion dog walking intervention compared to an attention control education intervention for ICU survivors?
4. What are the differences in serum cortisol between and within a companion dog walking intervention compared to an attention control education intervention for ICU survivors?

Research Aims

Primary Aims

1. To evaluate the feasibility of a companion dog walking intervention compared to an attention control education intervention for adult ICU survivors.

2. To evaluate the acceptability of a companion dog walking intervention compared to an attention control education intervention for adult ICU survivors.

Exploratory Aims

1. To compare a companion dog walking intervention to an attention control education intervention on efficacy trends related to depression in adult ICU survivors.
2. To compare a companion dog walking intervention to an attention control education intervention on efficacy trends related to anxiety in adult ICU survivors.
3. To compare a companion dog walking intervention to an attention control education intervention on efficacy trends related to quality of life in adult ICU survivors.
4. To compare a companion dog walking intervention to an attention control education intervention on efficacy trends related to serum cortisol in adult ICU survivors.

Feasibility and Acceptability Research

Feasibility and acceptability studies are an important initial step for developing and informing future large-scale studies by focusing on study processes (e.g., recruitment, retention, data analysis, resource utilization, safety), participant perceptions, and preliminary exploration of participant response (Arain et al., 2010; Hertzog, 2008; Sekhon et al., 2017). The POOCH Study focused on feasibility and acceptability because companion dogs have not been explored in the ICU survivor population, RCTs involving companion dogs are limited, and recruitment strategies for ICU survivors vary across the ICU survivor literature. Consequently, this feasibility and acceptability study informs the planning and delivery of a large-scale study and provides unique insight for future research and practice involving ICU survivors and companion animals.

A key feature of a feasibility study is that the outcomes of interest are not the focus (Arain et al., 2010; Hertzog, 2008; Thabane et al., 2010), nor is significance testing (Thabane et al., 2010). Smaller sample sizes are adequate for addressing research questions pertaining to feasibility and acceptability and therefore feasibility studies do not necessitate a fully powered sample size (Arain et al., 2010; Hertzog, 2008; Eldridge et al., 2016). Consequently, feasibility and acceptability studies may be underpowered to test clinically meaningful hypotheses (Thabane et al., 2016). For this reason, hypothesis development is not appropriate (Arain et al., 2010; Eldridge et al., 2016). While the outcome(s) of interest can be preliminarily explored, results must be interpreted with caution (Thabane et al., 2010).

Randomized Controlled Trials

The RCT design is intended to naturally minimize the effect of confounding variables through random group assignment (Friedman et al., 2015). When groups are comparable at baseline, changes between groups are likely due to the intervention rather than a confounding variable (Friedman et al., 2015). The RCT is the gold standard design due to its ability to control for confounding factors and determine causality (Joanna Briggs Institute, 2013; Sidani, & O'Rourke, 2022). The current body of knowledge regarding the impact of companion dogs on human mental health relies heavily on evidence from cross-sectional studies (Nelson et al., 2024); a study design that does not allow for causal inference but does allow for the generation of testable research questions. One argument for the lack of RCTs is that masking and randomization of participants to an animal intervention and control group would be almost impossible (Krause-Parello et al., 2019). The POOCH Study used an RCT design to conduct a high-quality study, address gaps in the literature, and determine if the study protocol led to an acceptable and feasible intervention in this population.

Attention Control Groups

A required component of any RCT is a control group. A control group allows for a standard by which the intervention group can be compared and enhances internal validity (Aycock et al., 2017). An attention control group receives the same amount of time and attention from the researcher (LaFave et al., 2019), but the activities themselves do not require the same time or intensity as the intervention group (Aycock et al., 2017). When attention control activities are equivalent in time and intensity as the intervention group, it is referred to as an attention placebo control (Aychock et al., 2017). It is critical the attention control group is not assigned any activities that could alter the outcome variables.

Using an attention control group was chosen for this study because attention controls facilitate participant retention better than using standard care (Aycock et al., 2017; LaFave et al., 2019). Researchers have also found attention controls in the form of health education are appropriate for those with depression (Kinser, 2013) and anxiety (Chen et al., 2012; Haddad et al., 2020a). Further rationale for this form of control is because social interaction has the potential to improve depression (Kuczynski et al., 2022; Kim & Jung, 2022) and anxiety (Poghosyan et al., 2022; Weziak-Bialowolska et al., 2022). Attention control groups also help researchers determine if the intervention of interest is effective above the influence of social interaction (LaFave et al., 2019). From an ethical standpoint, attention controls are often favored because they have the potential to provide some benefit to participants compared to standard care control or placebo control (Aycock et al., 2017; Hedman et al., 2011; LaFave et al., 2019). Due to the potential influence on depression and anxiety, both groups received the same dose of researcher interaction.

Definition of Terms

The key terms used throughout this dissertation include 'ICU survivor' and 'companion dog'. Companion animal is a term used synonymously with pet. Companion animals are interwoven into their human owners' daily lives and provide companionship or company but do not have specialized training or specific responsibilities to fulfill (Howell et al., 2022). The term companion dog is species-specific to canines and includes all dog breeds.

ICU survivor refers to an individual who lived through a critical illness or injury that required ICU care and who was discharged from the hospital (excluding those discharged to hospice) (Hanifa et al., 2018; Held & Moss, 2019; Needham et al., 2012). The term ICU survivor is synonymous with critical care survivor.

CHAPTER 2

LITERATURE REVIEW

Chapter two is composed of two sections. The first section is a review of the literature pertaining to ICU survivors, including the rationale for choosing this sample population and PICS symptoms of depression and anxiety. The second section is a scoping review accepted for publication in *People and Animals: The International Journal of Research and Practice* titled, "Companion Dogs and Depression, Anxiety, and Posttraumatic Stress Disorder in Adults ICU Survivors: A Scoping Review" (Nelson et al., 2024). The scoping review explored what is known from the literature about companion dogs facilitating the mental health of adults and ICU survivors.

Intensive Care Unit Survivors

Intensive care unit survivors are at risk for developing PICS, the physical, cognitive, psychological, and social deficits experienced after critical illness and care. The term PICS was developed and formally recognized in 2010 when SCCM held a stakeholders' conference to discuss the increasing evidence demonstrating long-term impairments in ICU survivors (Needham et al., 2012). A follow-up SCCM stakeholders' conference took place in 2012 where PICS was declared a public health concern (Elliot et al., 2014). These conferences helped lay the foundation for PICS research and the field has been advancing ever since.

Post intensive care syndrome is a multidimensional burden (Elliot et al., 2014), and an estimated 25% of adult ICU survivors experience symptoms in more than one PICS domain (Marra et al., 2018). Physical symptoms associated with PICS include reduced lung function, ICU acquired weakness (Held & Moss, 2019; Vanhorebeek et al., 2020), sexual

dysfunction (Griffiths et al., 2006; Held & Moss, 2019), and sleep disturbances (Altman et al., 2018). Physical symptoms are linked to decreased physical activity and increased functional disability and mortality (Wieske et al., 2015). Intensive care unit acquired weakness has been found to occur in approximately 40% of ICU survivors and can persist for up to five years in certain ICU survivor populations (e.g., sepsis) (Wieske et al., 2015). Intensive care unit survivors experiencing cognitive impairment encounter difficulty with memory, judgement, concentration, problem-solving, and completing complex tasks (Held & Moss, 2019). Evidence suggests 25%-33% of ICU survivors continue to experience cognitive impairment similar to those with mild Alzheimer's disease or moderate traumatic brain injuries one year after hospital discharge (Pandharipande et al., 2013). Psychological impairments include depression, anxiety, and post-traumatic stress disorder (PTSD) (Elliot et al., 2014). Additionally, research shows that ICU survivors are at increased risk of self-harm and suicide (Fernando et al., 2021). Social challenges reported by ICU survivors include relationship strain, social isolation, and difficulty returning to employment and a sense of pre-ICU normalcy (Kang & Jeong, 2018).

Current evidence supports the need to focus on the PICS symptoms of anxiety and depression. Anxiety and depression are the two most common psychological conditions experienced by ICU survivors and can last for weeks to years (Davidson & Harvey, 2016; Griffiths et al., 2013; Marra et al., 2018). Approximately 30-50% of ICU survivors continue to experience anxiety and/or depression one year after discharge (Calsavara et al., 2021; Nikayin et al., 2016; Rabiee et al., 2016) which can negatively impact QOL (Nikayin et al., 2016; Rabiee et al., 2016) and employment (McPeake et al., 2019). Additionally, Hatch et al. (2018), conducted a large-scale multi-center study (n=2,731) that included 26 different ICUs

and found depression to increase the two-year mortality rate of ICU survivors by 47% compared to survivors not experiencing depression. Most PICS interventions are focused on physical rehabilitation and physical health outcomes (Geense et al., 2019), and strong evidence supporting anxiety and depression interventions is lacking (Nikayin et al., 2016; Rabiee et al., 2016).

Anxiety and depression are closely intertwined, often occur simultaneously, and one condition frequently influences the other (e.g., anxiety symptoms can lead to symptoms of depression and depression symptoms can lead to symptoms of anxiety) (Kalin, 2020). Depression and anxiety are both regulated by the pre-frontal limbic system, indicative of a neurobiological connection (Kovner et al., 2019). Due to the close link between anxiety and depression, measuring both conditions, but as separate variables, is suggested (Beuke et al., 2003; Cosci & Fava, 2021).

Strategies that facilitate early recognition and treatment of anxiety and depression are necessary. Research suggests ICU survivors have an increased risk for anxiety and depression within the first 3-6 months after discharge (Jackson et al., 2014; Marra et al., 2018; Wunsch, 2014) and persistent depression is more likely when ICU survivors experience severe depression at 2-3 months post-discharge (Jackson et al. 2014; Weinert & Meller, 2006). Research has also shown low to moderate physical activity such as walking at least three times per week for 30-40 minutes is adequate in decreasing depression in clinical and general populations, and improved depression symptoms have been found in studies with exercise programs spanning 4-12 weeks (Stanton & Reaburn, 2014). Although methodological limitations exist and specific activity guidelines are lacking in research examining physical activity to improve anxiety, research demonstrates promise that physical

activity can improve symptoms of anxiety in general and clinical populations as well (Jayakody et al., 2014; Stonerock et al., 2015). Therefore, The POOCH Study intervention was delivered two to four weeks post-hospital discharge over an eight-week period to examine early recognition and treatment for anxiety and depression.

The results of this study fill a gap in the current literature and inform future research and recovery strategies focused on improving psychological symptoms of anxiety and depression in the adult ICU survivor population.

Companion Dogs and Depression, Anxiety, and Posttraumatic Stress Disorder in Adult ICU Survivors: A Scoping Review

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Abstract

Intensive care unit (ICU) survivors are at risk for developing persistent psychological sequelae that have been linked to decreased quality of life and increased mortality after hospital discharge. Standardized evidence-based treatments are lacking, mainly focus on physical rather than psychological recovery, and often occur in formal settings. Benefits of human–companion dog relationships have not been explored in the ICU survivor population before. Thus, the purposes of our review were to summarize the literature focused on the influence of companion dogs on depression, anxiety, and posttraumatic stress disorder (PTSD); identify what is known about the potential role companion dogs play in the well-being of adult ICU survivors; and inform future research and practice. We conducted a scoping review using Arksey and O'Malley's framework. The databases PsycInfo, PubMed, and Cumulative Index to Nursing and Allied Health Literature (CINAHL) were systematically searched for publications related to companion dogs' impact on depression, anxiety, and PTSD in human adults. Of 1,505 sources identified, 39 were included for review. Depression was the most frequently reported condition, whereas the greatest effects were reported for PTSD. Cross-sectional designs yielding inconsistent results were prevalent, and mechanisms were suggested but seldom tested. Findings suggest companion dogs have the potential to facilitate the unique needs of ICU survivors, but further research is needed.

Multidisciplinary research using ICU survivor samples, longitudinal and experimental designs, theoretical foundations, and more consistent measurement across studies are necessary. Nurses and health care professionals are in an optimal position to assess and discuss supportive relationships that facilitate recovery, including companion dogs, and to encourage intentional physically appropriate activities with companion dogs to optimize mental health benefits.

*Keywords***:** ICU survivor, dogs, depression, anxiety, posttraumatic stress disorder, post–intensive care syndrome

Intensive care unit (ICU) survivors are individuals who have lived through a critical illness or injury requiring ICU-level care and have been discharged from the hospital (Needham et al., 2012). Although ICU survivors have overcome their acute illness/injury, approximately 60% develop new or worsening long-term physical, cognitive, psychological, and/or social sequelae, known as post–intensive care syndrome (PICS) (Marra et al., 2018). The Society of Critical Care Medicine declared PICS a public health concern over 10 years ago (Elliott et al., 2014), but effective, standardized, evidence-based treatments are lacking and often occur in formal settings (Geense et al., 2019; Lasiter et al., 2016).

Depression, anxiety, and posttraumatic stress disorder (PTSD) are the most common psychological conditions experienced by ICU survivors (Davidson & Harvey, 2016; Marra et al., 2018) and the prevalence 12 months after discharge is approximately 20–35% (Du et al., 2024; Rabiee et al., 2016), 40% (Nikayin et al., 2016), and 16–23% (Righy et al., 2019) respectively. Impacts include decreased quality of life (Nikayin et al., 2016; Rabiee et al., 2016) and employment (McPeake et al., 2019) and increased chronic systemic inflammation and ischemic heart disease (Seligowski et al., 2022). ICU survivors are at increased risk of self-harm and suicide (Fernando et al., 2021) and those with depression have higher 2-year mortality rates than those without depression (Hatch et al., 2018). Interventions for PICS most often center on physical rehabilitation (Geense et al., 2019), and those focused on the psychological health and recovery of ICU survivors lack strong evidence (Nikayin et al., 2016; Rabiee et al., 2016). In a time when access to mental health resources is lacking (Brown et al., 2023; Timmons et al., 2023) and artificial intelligence (AI)–mediated mental health care is on the rise (Timmons et al., 2023), innovative, feasible, easy-to-implement

strategies that include personal connection are needed to support ICU survivors' psychological health.

Companion animals have been linked to human health benefits (Brooks et al., 2018; Carr et al., 2020). The terms *companion animal* and *pet* are synonymous but are distinguished from service and therapy animals. Companion animals are part of their human owners' daily lives and offer companionship but are not trained to perform specific therapeutic tasks (Howell et al., 2022). Companion animal studies have shown promising but also negative and neutral effects (Brooks et al., 2018; Hughes et al., 2019), and mechanisms explaining how companion animals provide benefits to human health remain undefined.

Companion animal research often includes diverse types of pets without differentiating between species (Brooks et al., 2018; Hughes et al., 2019; Kerman et al., 2019), despite findings suggesting species matters. When comparing pet species, Mueller et al. (2021) found owners of "other" pets (e.g., fish, bird) had higher odds of anxiety than cat or dog owners. Compared with cat ownership, dog ownership has been linked to more depressive symptoms (Sharpley et al., 2020), more physical (Levine et al., 2013) and social support benefits (Antonacopoulos & Pychyl, 2010), higher well-being and happiness (Bao & Schreer, 2016), and less insomnia (Xin et al., 2021). Dog-walking in particular has shown promising human health benefits (Ortmeyer & Robey, 2019; Westgarth et al., 2014). With dogs already in 38.5% of U.S. households (American Veterinary Medical Association [AVMA], 2018), the human–dog relationship must be better understood to optimize health—and to consider how companion dogs might offer an innovative, widely accessible way to improve outcomes in ICU survivors.

There is a limited understanding of the influence companion dogs have on human health and ICU survivors; accordingly, a scoping review was conducted (Levac et al., 2010). Scoping reviews are intended to map and summarize the literature on broad/emerging topics, identify gaps, and make recommendations for future research and practice (Arksey & O'Malley, 2005; Levac et al., 2010). While the initial aim of our scoping review was to explore what is known about ICU survivor mental health and companion dogs, a preliminary literature search revealed companion animals have not been studied in the ICU survivor population. Two studies have explored animals in the context of an ICU hospital admission: a pilot study examining the feasibility of therapy dog visitation for patients during their ICU stay (Branson et al., 2020) and a qualitative study exploring how a personal pet visitation program augmented patient-provider communication during chronic, critical, and end-of-life care (Yamasaki, 2018). We thus broadened our aim to explore the impact of companion dogs on symptoms of depression, anxiety, and PTSD in human adults. Although notable differences exist between depression, anxiety, and PTSD symptoms (American Psychiatric Association [APA], 2022), we included all three mental health outcomes in our review because 63%–71% of ICU survivors experience at least two of these mental health conditions, and 36%–66% experience all three (Huang et al., 2016; Teixeira et al., 2021). For our scoping review to act as a steppingstone in understanding the potential role companion dogs may have in the mental health of ICU survivors, all three mental health outcomes were included. Additionally, while previous scoping reviews have focused on companion dogs and human health (Carr et al., 2020; Costa et al., 2022; Toohey & Rock, 2011), ours is the first to center on mental health.

Objectives

The purpose of this scoping review was to summarize the literature on the impact of companion dogs on human depression, anxiety, and PTSD to guide future research to improve mental health in adult ICU survivors. Our objectives were to describe the body of research focused on the effect companion dogs have on depression, anxiety, and PTSD in adult humans; identify mechanisms that have been proposed to explain those effects; and identify gaps and opportunities for future research and practice.

Method

The scoping review was conducted following Arksey and O'Malley's (2005) framework: (1) identify the research problem and question; (2) identify studies; (3) select studies; (4) chart the data; and (5) collate, summarize, and report results. Three additions of Levac et al. (2010) were applied: include a minimum of three reviewers, use an iterative approach, and propose future research implications. We developed and followed a protocol (not registered; available on request) and applied the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) checklist (Tricco et al., 2018). No ethical approval was required for this review.

Identifying and Selecting Relevant Studies

With a health science librarian, we conducted a systematic literature search in the PsycInfo, PubMed, and Cumulative Index to Nursing and Allied Health Literature (CINAHL) databases and searched reference lists (see Appendix A for our search strategy). Congruent with the scoping review purpose (Levac et al., 2010), eligibility was broadly inclusive, including quantitative, qualitative, and mixed-methods research studies; literature

reviews; critical commentaries and editorials; and grey literature (i.e., unpublished dissertations).

We did not filter for publication year but ended searches on February 24, 2023. In alignment with the review objectives, eligible sources focused on adults (age ≥18) and the effect companion dogs have on depression, anxiety, and/or PTSD (the psychological conditions experienced most frequently by ICU survivors). When other pets were included, we retained sources if they differentiated between companion dogs and other companion animals in reporting outcomes. Due to limited resources, we only included publications available in English. Sources focused on therapy dogs, service dogs, temporary dog visitations, robotic pets, and/or grief following a companion dog loss were excluded.

Results were imported into Zotero and Microsoft Excel. After duplicates were removed, each title and abstract were independently screened by at least two authors for inclusion. Three authors screened all full text articles. Meeting weekly over 18 months, all three authors participated in the iterative process of selecting articles, extracting and comparing data, and drafting and revising the report.

Charting the Data

A data extraction matrix was developed collectively by the authors. We tested interrater agreement by charting data from three articles into the matrix independently and comparing and resolving differences. Each author then charted data from their assigned subset of articles including source, discipline, study location, design/intervention, purpose, population, measures/variables, results, theory, and mechanisms. We presented our progress and discussed charting questions weekly.

Collating, Summarizing, and Reporting Results

We summarized, then categorized the articles based on mental health outcome. Each study was summarized as to study purpose, population, measurement tools used, findings or conclusions, and underlying mechanisms (Table 2.1). Key results were further summarized in narrative form. Consistent with Arksey and O'Malley's framework, we did not conduct a quality appraisal.

Results

Of 1,505 sources, 39 were retained for review after removing duplicates and screening titles, abstracts, and full-text sources for eligibility (Figure 2.1).

Description of Sample

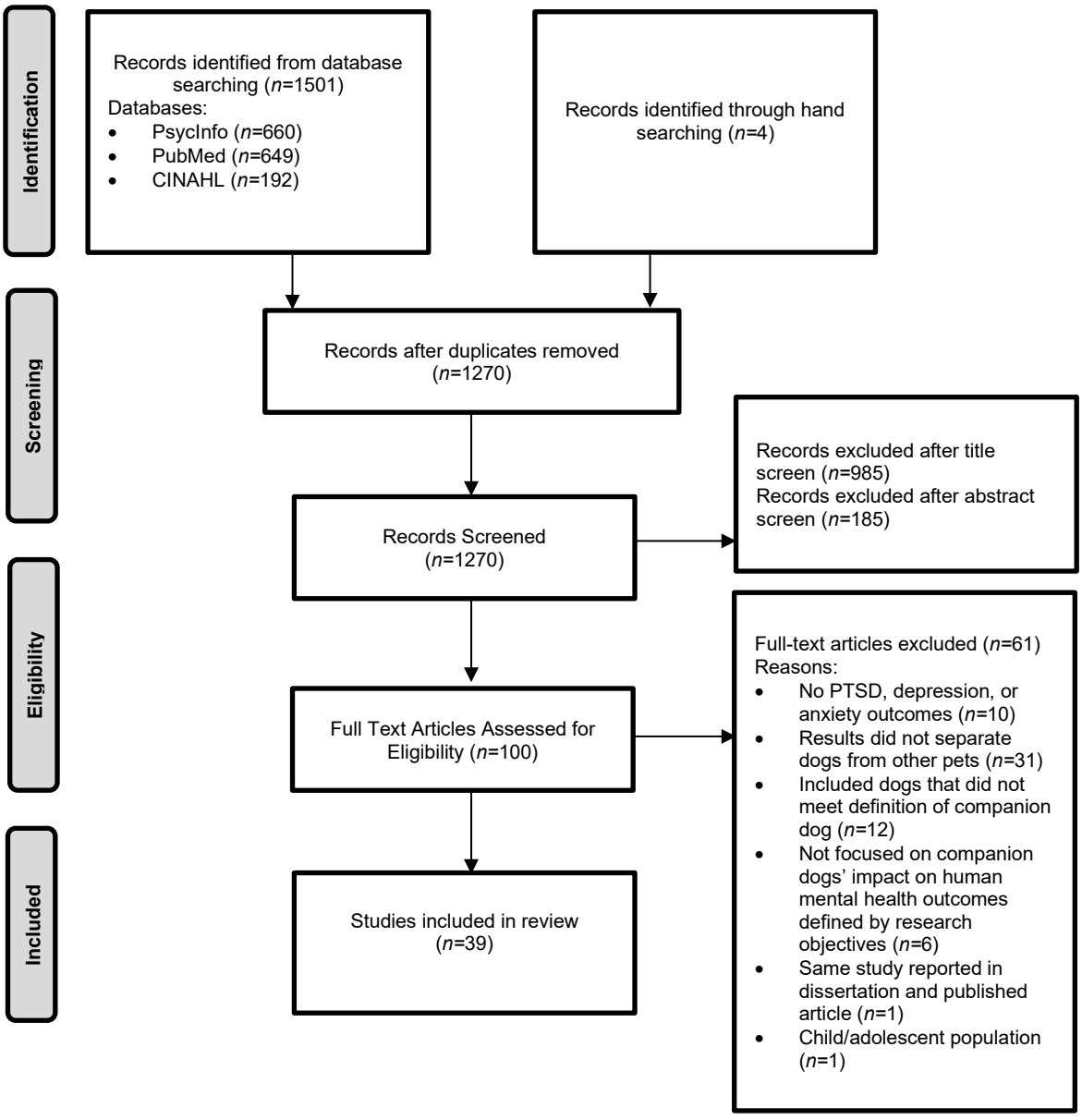
The 39 selected sources were published between 1996 and 2023, with 25 published since 2016. Most studies were conducted in the United States (*n*=19), United Kingdom (*n*=4), Australia (*n*=3), and Canada (*n*=3). Represented disciplines included psychology (*n*=16), public health (*n*=10), medicine (*n*=9), exercise science (*n*=5), veterinary medicine (*n*=5), nursing (*n*=4), and environmental science (*n*=1). Sample sizes were 4 to 13,347 (*n*=60,219).

We reviewed primary research studies (*n*=28), secondary data analyses (*n*=10), and one editorial. Sources were published in peer-reviewed journals, except one unpublished doctoral dissertation. Most studies were quantitative (*n*=31) and used a cross-sectional design (*n*=25). Five studies were mixed-methods sequential studies that followed cross-sectional surveys with semi-structured interviews (*n*=3), or quasi-experimental designs supplemented with qualitative surveys or anecdotal reports (*n*=2). The three qualitative studies used

interviews or focus groups. The editorial included an embedded case history. For a summary of study characteristics, please see Table 2.1.

Figure 2.1

PRIMSA flow diagram of the article selection process (Page et al., 2021).



Narrative Summary of Results

Overarching Themes

Theoretical Frameworks. Only three authors specified a theory as a basis for or influence on the research. Campbell et al.'s (2016) study used a "mobile methods" approach founded on the mobilities paradigm, which centers on movement as a lens through which to understand people and society (Sheller & Urry, 2006). Role strain/role enhancement theories were used by Cline (2010) to explain how responsibilities required to care for a dog may provide a buffer against stress and thus improve well-being. Anderson (2017) used stress theory and attachment theory in their dissertation to explain how companion dogs may improve stress by acting as a social support coping strategy.

General Mechanisms. Mechanisms to explain how companion dogs benefit health varied and in most cases were related to general health outcomes (Table 2.1). Less frequently, authors proposed or tested mechanisms specific to depression, anxiety, or PTSD. Mechanisms were typically discussed to introduce and support a study and/or to explain results. Hypothesis testing occurred infrequently (n = 7). Human–animal bonds (n = 14), social support (n = 16), and physical activity (n = 12) were the most frequently identified mechanisms to explain effects of companion animals on human mental health.

Human–animal bond refers to the mutually supportive relationship that forms between dogs and their owners (Hill et al., 2020) and is one of the suggested pathways to human mental health benefits. This mechanism was most frequently framed in terms of attachment theory, which explains how and why humans seek support, connection, proximity, and security in close relationships with others (Ainsworth, 1989; Keefer et al., 2014). Dogs can act as attachment figures for their owners, leading to positive health and

well-being (Keefer et al., 2014). Attachment to a companion dog was a commonly measured variable (n = 12) (Table 2.1).

Social support was another mechanism proposed to explain how interacting with a companion dog improves well-being, either directly as a form of dog-to-human social support (Ingram & Cohen-Filipic, 2019; Miltiades & Shearer, 2011; Tatschl et al., 2006) or indirectly by facilitating social support between a dog owner and other humans (Campbell et al., 2016; Hajek & König, 2020; Mein & Grant, 2018; Min et al., 2019; Powell et al., 2019; Scanlon et al., 2021).

Physical activity was the third commonly explored mechanism, with improved mental health attributed to physical activities with a companion dog (e.g., playing or walking with the dog). Such physical interactions also impacted mental well-being through positive exposures to nature (Campbell et al., 2016; Mein & Grant, 2018; Scanlon et al., 2021), improved perceptions of one's neighborhood (Mein & Grant, 2018), and improved sleep (Hajek & König, 2020).

Dog owners also reported that having a companion dog improved well-being by reducing stress and promoting a sense of responsibility and purpose (Kruger et al., 2014; Scanlon et al., 2021). Others described how a companion dog helped them develop a sense of consistency and normalcy and adherence to routines (Ingram & Cohen-Filipic, 2019; Muldoon et al., 2017; Scanlon et al., 2021). Neurobiological mechanisms were discussed (n = 4) but not measured: researchers described improved oxytocin, serotonin, and cortisol levels as potential pathways of improved mental health in companion dog owners. Friedmann et al. (2003) and Ortmeyer and Robey (2019) measured heart rate variability (HRV), a biomarker of physical and mental health (Kim et al., 2018), and found evidence suggesting

companion dogs may be linked to higher HRV in their owners. Several authors proposed that the benefit of companion dog ownership is multifactorial (Campbell et al., 2016; Carr et al., 2019; Dunn et al., 2018; Hajek & König, 2020; Lentino et al., 2012; Mein & Grant, 2018; Sharpley et al., 2020).

Depression-Focused Studies

Because we were interested in the way companion dogs might offer a future focus to improve mental health in ICU survivors, we categorized studies by common post-ICU mental health challenges: depression, anxiety, and PTSD. For each, we identified study characteristics, themes, and results (see Table 2.2 for a summary of results). The first, depression, is a serious mood disorder lasting at least two weeks with symptoms affecting thinking, feeling, and response to daily activities (APA, 2022). Symptoms often include persistent sadness, helplessness, fatigue, despair, and difficulty sleeping or concentrating. Subsets of depression symptoms include depressed mood, anhedonia, and somatic symptoms.

Study Characteristics. Depression was an outcome of focus in 36 articles. Four studies inferred depression from qualitative responses and 33 measured depression as a variable. Participants were community dwelling adults (n = 11); community dwelling adults of a specific age group (n = 7); military veterans (n = 3); those with health conditions (n = 9); and those identifying with specific sociodemographics (n = 6). Seven articles had a primary aim to explore depression (Cline, 2010; Enmarker et al., 2015; Miltiades & Shearer, 2011; Min et al., 2019; Puskey & Coy, 2020; Sharpley et al., 2020; Siegel et al., 1999), while the remaining 26 articles also measured the effects of companion dogs on depression but did so among other variables of mental, social, and physical health.

Depression was measured using psychometrically tested self-report instruments, except Mueller et al. (2021) who used a dichotomous yes/no self-report variable. The Center for Epidemiologic Studies-Depression Scale (CES-D) was the most frequently used measure (n = 16) and the only depression-specific measure used in more than two studies. Five studies measured depression with tools that evaluated anxiety and depression together. In total, nine different depression measures were used (Table 2.1).

Table 2.1

Study Characteristics, Purpose, Measurements, Results, and Mechanisms

Author/ Year	Journal/ Discipline/ Location of Study	Study Design	Sample/ Population	Purpose	Mental Health Topic	Measurement Tools	Results	Mechanism
Albright et al. (2022)	IJERPH Psychology, Psychiatry United States	Secondary data analysis Longitudinal Observational cohort study	Community dwelling older adults (65 years and older) (*n* = 535)	To investigate the relationship between pet ownership and health, physical activity, and depression in older adults.	Depression	GDS-15	NONSIGNIFICANT; No significant association between dog ownership and depression in older adults. Findings not influenced by sex, race, or geographic location.	n/a
Anderson (2017)	ProQuest Psychology United States	Cross-sectional survey	Military veterans with PTSD (*n* = 34)	To compare self-reported stress scores of military veterans with PTSD who own a dog to veterans who do not own a dog. To examine the relationship between self-reported stress scores to the level of attachment to a dog in participants who owned a dog.	PTSD	PSS LAPS	NONSIGNIFICANT; No significant association between dog ownership and perceived stress in veterans with PTSD. Level of attachment to dog not predictive of perceived stress.	n/a
Antonaco-poulos & Pychyl (2010)	Anthrozoös Psychology Canada	Cross-sectional survey	Community dwelling adults living alone (≥18 years) (*n* = 132)	To explore the impact of pet ownership on loneliness and depression levels in individuals living alone.	Depression	CES-D LAPS	MIXED: Dog owners and nonowners living alone did not have significantly different levels of depression. Level of attachment to dog and human social support did not predict depression levels. 84.2% of dog owners reported their dog had a strong positive impact.	Social support (supported by results) Human–animal bond (not supported by results)

Barcelos et al. (2020)	Scientific Reports Neuroscience, Psychology United Kingdom	Qualitative Focus Groups	Dog owners (*n* = 35)	To identify the most important dog–human related activities as reported by dog owners and develop a framework.	Depression	n/a	N/A; Developed framework of 58 human–dog related activities linked to specific hedonic well-being, life satisfaction, and eudemonic well-being. Examples improving depression: exercise, routine, social interaction, playing with dog, teaching dog, tactile interaction.	Social support Physical activity Human–animal bond Responsibility
Batty et al. (2017)	BMJ Public Health United Kingdom	Secondary data analysis Longitudinal Prospective cohort study	Community dwelling adults (≥50 years) (*n* = 8,785)	To examine the prospective relationship between biomarkers of aging and animal companionship in older adults.	Depression	CES-D	NONSIGNIFICANT; No significant association between dog ownership and depression in older adults who owned a dog compared to older adults who did not.	Human–animal bond Physical activity
Bennett et al. (2015)	Anthrozoös Psychology, Public Health Australia	Longitudinal Intensive experience sampling methodology	Community dwelling older adults (≥65 years) (*n* = 68)	To determine if psychosocial well-being was associated with the nature or number of human–animal interactions (not ownership itself) and to determine if differences existed between interactions with cats and dogs.	Depression Anxiety	DASS	Depression: NONSIGNIFICANT; No statistically significant group differences in depression between dog owners and non–dog owners. Anxiety: MIXED; No anxiety differences between dog owners and non–dog owners. Frequency of dog presence was moderately negatively related to anxiety and contributed variance to lower levels of anxiety in dog owners.	n/a

Bergen-Cico et al. (2018)	The Journal of Alternative and Complementary Medicine Public Health, Social Work, Psychology United States	Mixed methods Quasi-experimental with wait-list control; 12-month follow-up Qualitative survey Intervention: Structured dog training program—Veterans train, care for, and adopt a companion dog. Weekly, 90-minute dog training sessions over 12–18 months	Military veterans with PTSD symptoms (*n* = 48)	To determine the effect of a dog ownership and training program on perceived stress, self-compassion, isolation, self-judgment, and PTSD symptoms.	PTSD	PCL-M and PSS	POSITIVE; Improved PTSD symptom management since enrolling in Dogs2Vets program (open-ended responses). Intervention group scored significantly lower on PTSD and PSS at baseline and at follow-up compared to those in the control.	n/a
Bradley & Bennett (2015)	Anthrozoös Psychology, Public Health Australia	Mixed methods Cross-sectional survey with Follow-up interviews	Adults with chronic pain (≥18 years) (*n* = 173)	To examine if companion animal owners differ from nonowners in the pain experienced from chronic pain conditions. To determine how often participants use companion animals for pain management. To examine how useful owners find this strategy to be. To determine if benefits depend on characteristics of the animal.	Depression Anxiety	DASS	Depression: MIXED; No significant difference in depression between dog owners and nonowners or between dog owners who used pet interaction to manage pain and those who did not. No significant association between owner's depression and dog personality traits. Significantly lower levels of depression in dogowners reporting higher dog friendliness. Qualitative reports: dogs help depression, provide emotional support. Anxiety: POSITIVE; Significantly lower levels of anxiety in dog owners reporting higher dog friendliness.	n/a

Campbell et al. (2016)	Anthrozoös Physical Therapy New Zealand	Qualitative Mobile method approach Semi-structured interviews	University-affiliated healthy adults (≥18 years) (*n* = 10)	To explore perception of well-being and health related to dog walking. To understand how dog walking impacts social and emotional health.	Depression	n/a	POSITIVE: Dog walking prevented depression by giving owner purpose and sense of responsibility.	Physical activity Sense of Purpose/ Responsibility
Carr et al. (2019)	IJERPH Nursing, Physical Therapy Canada	Feasibility study Cross-sectional survey	Adult clinic patients with chronic lower back pain (*n* = 56)	To evaluate the feasibility of a survey that evaluates the relationship between dog ownership and well-being.	Depression	PROMIS depression SF4 LAPS	POSITIVE: Significantly fewer depression symptoms for dog owners compared to non–dog owners.	Human–animal bond Oxytocin
Cline (2010)	Journal of Social Psychology Sociology United States	Secondary data analysis Cross-sectional survey	Community dwelling adults (*n* = 201)	To examine the relationship between depression and multiple roles and to determine the effect of dog ownership on this relationship.	Depression	CES-D	MIXED: No significant association between dog ownership and depression; association not mediated by social support satisfaction, physical activity, age. Benefit of dog ownership on depression was greater for singles compared to those married and women versus men.	Social support (not supported by results) Physical activity (not supported by results)
Dunn et al. (2018)	Journal of Cardiovascular Nursing Nursing United States	Longitudinal Prospective observational study	Adults with ischemic heart disease (≥ 21 years) (*n* = 122)	To examine dog walking and dog ownership and their relationship with Phase II and home-based cardiac rehabilitation, hopelessness, and depression.	Depression	PHQ-9	NONSIGNIFICANT; No significant difference in depression scores between dog owners and nonowners when analysis adjusted for sex and age.	Physical activity
Enmarker et al. (2015)	Aging & Mental Health Nursing Norway	Secondary data analysis Cross-sectional survey	Community dwelling older adults (≥65 years) (*n* = 12,093)	To compare self-rated depression symptoms of older adult male and female non–pet owners and pet owners, cat owners, and dog owners.	Depression	HADS-D	NEGATIVE: Significantly higher levels of depression in dog owners compared to nonowners. Gender did not impact depression scores.	Social Support
Fraser et al. (2020)	Anthrozoös Psychology, Social Science New Zealand	Secondary data analysis Cross-sectional survey	Community dwelling adults (≥ 18 years) (*n* = 13,347)	To describe the personality and demographic characteristics of New Zealand pet owners. To examine if pet type and pet ownership are associated with well-being and health measures.	Depression Anxiety	KPDS-6	Depression: NEGATIVE; Depression significantly more likely in dog owners than nonowners. Anxiety: NONSIGNIFICANT; No significant difference in anxiety between dog owners and non-owners.	n/a

Friedmann et al. (2003)	The American Journal of Cardiology Biology, Nursing, Medicine United States. Canada	Secondary data analysis; from the parent study Cardiac Arrhythmia Suppression Trial (CAST)	Adults with acute MI within the last 2 years (*n* = 102)	To determine if altered cardiac autonomic modulation (demonstrated by increased heart rate variability [HRV]) explains the long-term benefits observed in pet owners.	Depression	SDS	NONSIGNIFICANT; No significant difference in depression between dog owners and non–dog owners. The differences in HRV between pet owners and nonowners not due to differences in depression.	Physiological differences: Heart rate variability (supported by results)
Fritz et al. (1996)	Psychological Reports Veterinary Science, Public Health United States.	Cross-sectional survey	Adult care givers of Alzheimer patients (*n* = 244)	To determine the extent to which companion animals modulate psychological health in caregivers of Alzheimer patients.	Depression	GDS LAPS	NEGATIVE; Women (aged 40–59 years) with high levels of dog attachment had significantly higher levels of depression and greater prevalence of depression compared to women not highly attached to their dogs.	Social support
Hajek & König (2020)	Aging & Mental Health Gerontology, Public Health Germany	Secondary data analysis Cross-sectional survey	Community dwelling older adults without a partner (≥65 years) (*n* = 1,160)	To identify if dog owners, cat owners, and non–pet owners differ in depressive symptoms, social isolation, and loneliness in older adults without a partner.	Depression	CES-D	MIXED; Dog ownership not associated with depression. Male dog owners had significantly fewer depressive symptoms than male nonowners.	Social support Physical activity
Ingram & Cohen-Filipic (2019)	Journal of Psychosocial Oncology Psychology United States	Mixed methods Cross-sectional survey Open-ended questions	Adults diagnosed with cancer in the last 3 years (*n* = 122)	To determine if the human–companion dog bond is associated with well-being for people with cancer. To explore the perceived benefits, challenges, and needs coinciding with the human–companion dog relationship.	Depression	CES-D LAPS	MIXED: Attachment to dog not significantly associated with depression. Treatment status moderated the relationship between attachment and depression: Participants who finished cancer treatment and with higher attachment levels had significantly lower levels of depression. Participants with ongoing treatment and higher attachment levels had significantly higher levels of depression. Qualitative reports: dog ownership enhances emotional well-being and comfort yet can cause feelings of worry and guilt.	Social support Human–animal bond (not supported by results)

Irani et al. (2006)	American Journal of Transplantation Psychology, Medicine Switzerland	Cross-sectional survey	Adult lung transplant recipients (*n* = 89)	To examine the association between companion animal owners and physiological and mental health indicators with comparison to nonowners in lung transplant recipients.	Depression	HADS-D	NONSIGNIFICANT; No significant difference in depression between dog owners, cat owners, and nonowners.	n/a
Kruger et al. (2014)	Southern Medical Journal Psychiatry, Medicine United States	Mixed methods: Semi-structured interviews Surveys	Military veterans with HIV/AIDS (*n* = 29)	To explore the impact of dog ownership on perceived well-being in military veterans with HIV/AIDS.	Depression	PHQ-9 LAPS	POSITIVE: 97% of participants had overall positive experience related to dog ownership. 14% of participants reported ever feeling dog was a burden. Participants believed dogs improve well-being and quality of life.	Responsibility Physical activity Human–animal bond Stress reduction
Lass-Hennemann et al. (2020)	IJERPH Psychology Germany	Cross-sectional survey	Adults working in high-risk occupations (*n* = 580)	To describe the relationship between pet ownership and psychopathological symptoms and health-benefiting factors. To measure differences between dog owners and non–dog pet owners.	PTSD	IES-R LAPS	NON-SIGNIFICANT; No significant difference in PTSD between dog owners and non–dog owners.	Sense of coherence (not supported by results) Trait resilience (not supported by results) Locus of control (not supported by results)
Lentino et al. (2012)	Journal of Physical Activity and Health Exercise Science, Public Health United States	Cross-sectional survey	Community dwelling adults (≥18 years) (*n* = 916)	To compare physical activity level and health and behavioral outcomes of dog owners who do and do not walk their dog, and non–dog owners.	Depression	CES-D	POSITIVE; Non–dog owners experienced significantly greater odds of clinical depression compared to dog owners. Non–dog owners experienced 50% greater odds of clinical depression compared to dog owners who regularly walked their dogs. Dog owners who walked their dog ≥ 600 MET/minute/week had 40% lower odds of depression compared to dog owners who walked their dog less.	Physical activity

Martin et al. (2021)	PLoS One Psychology United States	Cross-sectional survey	Community dwelling adults (≥18 years) (*n* = 1,535)	To investigate the differences in social support, depression, anxiety, and happiness of dog owners compared to those who did not own a dog but were interested in owning a dog during the COVID-19 pandemic.	Depression Anxiety	CES-D GAD PAS	Depression; POSITIVE; Dog owners had significantly lower depression scores compared to interested dog owners. Anxiety: NONSIGNIFICANT; No significant difference in anxiety between dog owners and interested dog owners.	Social support
McConnell et al. (2011)	Journal of Personality and Social Psychology Psychology United States	Study 1: n/a (does not meet inclusion criteria) Study 2: cross-sectional survey Study 3: n/a (does not meet inclusion criteria)	Community dwelling adults (*n* = 56)	To examine if dog owners experience more benefit when they perceive their dog to fulfill social needs better.	Depression	CES-D Attachment Style	MIXED; No significant difference in depression scores between dog owners and nonowners. Significantly lower levels of depression for dog owners with more human social fulfillment. When controlling for human social fulfillment, significantly lower levels of depression in dog owners with more dog social fulfillment.	Social Support
Mein & Grant (2018)	BMC Geriatrics Public health United Kingdom	Secondary data analysis Cross-sectional survey	Civil servants (59–79 years) (*n* = 6,575)	To explore associations between dog ownership and sleep, health (mental and physical), exercise, and perception of neighborhood compared to other pet owners (mainly cats).	Depression	CES-D Attachment	NONSIGNIFICANT; No significant difference in depression between dog owners and nonowners.	Physical activity
Miltiades & Shearer (2011)	Anthrozoös Social Work, Gerontology United States	Cross-sectional survey	Community-dwelling adults (*n* = 117)	To examine the relationship between the ability to care for a pet, pet attachment, and depression in a sample of dog owners.	Depression	CES-D LAPS	MIXED; Significant positive association between attachment to dog and depression. Significant negative association between ability to care for dog and depression. Widowhood was significantly associated with depression in dog owners.	Human–animal bond (not supported by results)

Min et al. (2019)	IJERPH Public Health, Environmental Health, Veterinary Science Korea	Cross-sectional survey	Community dwelling young adults (19–39 years) (*n* = 654)	To assess the association between dog owners' attitudes toward their dog and owners' depression symptoms.	Depression	CES-D	POSITIVE; Significant positive association between dog owners' depression symptoms and unfavorable attitudes toward their dogs.	Human–animal bond (supported by results) Oxytocin
Mueller et al. (2021)	Health Psychology and Behavioral Medicine Developmental Science, Veterinary Science United States	Secondary data analysis Cross-sectional survey	Community dwelling adults (*n* = 1,267)	To compare the sociodemographic factors, contextual factors, and health indictors between pet owners and non–pet owners in the United States.	Depression Anxiety	Yes/No	Depression: NEGATIVE; Dog ownership was significantly associated with depression. Unemployed dog owners had twice the odds of having depression compared to non–dog owners. Dog ownership not related to odds of having depression for those employed. Anxiety: NONSIGNIFICANT; No significant association between dog ownership and anxiety	Physical activity
Muldoon et al. (2017)	JMIR Mental Health Psychiatry, Behavioral Science, Public Health, Medicine United States	Cross-sectional survey	Adults living with HIV (≥18 years) (*n* = 252)	To examine the relationship between dog ownership and depression in persons living with HIV.	Depression	CES-D	POSITIVE; Non–dog owners had 3 times higher odds of depression compared to dog owners.	Social support Routine

Ortmeyer & Robey (2019)	IJERPH Medicine, Physiology United States	Mixed method; Quasi-experimental, anecdotal reports; feasibility study Intervention: Participant cared for foster dog. Opportunity to adopt after study. 3-month study with repeated measures	Military Veterans (≥50 years) (*n* = 4)	To determine the feasibility of a companion dog foster program and the effect on physical activity and function, HRV, balance, and quality of life in older veterans.	Depression PTSD	CES-D PSS	Depression: POSITIVE; Significant difference in depression between pre and post intervention scores. One participant reported dog pulled them out of depression. PTSD: POSITIVE; All participants with improved PSS after dog adoption. Participant with baseline PTSD had most improvement in outcome measures and only participant with improved HRV.	Human–animal bond Physical activity
Powell et al. (2019)	BMC Public Health Veterinary Science, Sport and Exercise Science, Public Health, Animal welfare Australia	Quasi-experimental; 3-armed controlled trial Intervention: Participants self-selected groups (dog adoption; dog adoption after study; no dog adoption). 8-month study with repeated measures	Community dwelling adults (≥18 years) *(n* = 71)	To examine changes in mental well-being among community dwelling adults following dog adoption.	Depression Anxiety	KPDS-10	Depression: NONSIGNIFICANT; No significant association between acquiring a dog and depression. Anxiety: NONSIGNIFICANT; No significant association between acquiring a dog and anxiety.	Physical activity Human animal bond Social support Oxytocin and cortisol
Puskey & Coy (2020)	Anthrozoös Psychology United States	Study 1: Cross-sectional survey Study 2: Cross-sectional survey	Study 1: Community dwelling adults (*n* = 142) Study 2: Community dwelling adults (*n* = 264)	To evaluate if pet presence–pet preference alignment relates to depression and to examine the association with personality.	Depression	CES-D	NONSIGNIFICANT; Pet preference not significantly associated with depression for dog owners. Pet presence not significantly associated with depression for those who prefer dogs.	n/a

Scanlon et al. (2021)	Anthrozoös Veterinary Medicine, Sociology, Psychology United Kingdom	Qualitative Face-to-face semi-structured interviews	Homeless dog-owning adults (n = 20)	To explore the nature of the human–companion animal bond in homeless dog owners. To explore the impact of this relationship on the owners and their dogs.	Depression Anxiety	n/a	Depression & Anxiety: MIXED; Dogs positively impacted their owner's mood, depression, stress, anxiety, substance abuse, and self-harm by providing companionship, consistency, reciprocal love, security and warmth, a sense of purpose and responsibility, and facilitating social interaction with other people. Dog owners reported feelings of worry and anticipatory grief when discussing dog's well-being.	Social support
Sharpley et al. (2020)	Journal of Affective Disorders Neuroscience, Sports and Exercise Science, Public Health, Medicine, Behavioral Science England	Secondary data analysis Longitudinal data collection	Community dwelling adults (≥50 years) (n = 7,617)	To examine associations between pet ownership and depression symptoms in older adults.	Depression	CES-D	MIXED; Odds of dog ownership significantly positively associated with level of depression. Mood, anhedonia, and somatic symptoms statistically associated with higher odds of dog ownership. No change in depression over time between dog owners and nonowners.	Serotonin Oxytocin
Siegel et al. (1999)	AIDS Care Psychiatry United States	Cross-sectional survey	Gay and bisexual adult men (n = 1,872)	To examine the impact of animal companionship on depressive symptoms for those at risk for HIV/AIDS. To examine the relationship between animal ownership, attachment, and depression.	Depression	CES-D	NONSIGNIFICANT; No statistical group differences in depression between dog owners, cat owners, and pet owners.	n/a

Silva et al. (2021)	Pain Medicine Behavioral Sciences, Biomedical Sciences, Education, Health Sciences Portugal	Cross-sectional survey	Adults with fibromyalgia (*n* = 106)	To investigate the association between dog ownership and psychological adjustment (anxiety and depression) in patients with fibromyalgia. To assess if levels of human social support moderated the association.	Depression Anxiety	HADS-D HADS-A	Depression: POSITIVE; Dog owners with high levels of perceived social support had significantly lower levels of depression compared to dog owners with low levels of perceived social support. Emotional closeness with dog significantly associated with lower depression. Anxiety: POSITIVE; Dog owners with high levels of perceived social support had significantly lower levels of anxiety compared to dog owners with low levels of perceived social support. Stroking/ patting dog significantly associated with lower anxiety.	Physical activity Social support
Stern et al. (2013)	Society and Animals Psychiatry and Psychology United States	Cross-sectional survey	Military veterans with PTSD (*n* = 30)	To examine the self-reported physical and mental health benefits of companion dogs in adult veterans with PTSD.	Depression PTSD	BDI PCL-M LAPS	Depression: POSITIVE; Participants felt less depressed since acquiring dog. PTSD: MIXED; Participants were calmer, less lonely, less worried, less angry/irritable, had improved feelings about self, got more exercise, and enjoyed nature more since acquiring a dog. No improvements in the burden of memories, flashbacks, nightmares, or being with people.	n/a
Tatschl et al. (2006)	American Journal of Preventive Medicine Medicine Austria	Letter to Editor	n/a	To extoll the benefits of companion dogs on human health (depression, hypertension) with brief case scenarios.	Depression	n/a	N/A: Author's opinion: Dog adoption improved physical and mental health of patient, including depression.	Physical activity

Xin et al. (2021)	Animal Science Journal Medicine China	Cross-sectional survey	Community dwelling individuals (≥12 years) (*n* = 756) (participants <19 years = 16)	To examine the influence of pets on psychological stress during COVID-19.	Depression	DASS	NONSIGNIFICANT; No significant difference in depression between dog and cat owners.	n/a

Key: Bartholomew and Horowitz's Measure of Attachment Style (Attachment Style); Beck Depression Inventory (BDI); Center for Epidemiologic Studies Depression Scale (CES-D); Depression Anxiety and Stress Scale (DASS); Generalized Anxiety Disorder Scale (GAD); Geriatric Depression Scale (GDS); Hospital Anxiety and Depression Scale-Anxiety (HADS-A); Hospital Anxiety and Depression Scale-Depression (HADS-D); Human Immunodeficiency Virus (HIV)/Acquired Immunodeficiency Syndrome (AIDS); Impact of Event Scale-Revised (IES-R); *International Journal of Environmental Research and Public Health* (IJERPH); Kessler Psychological Distress Scale (KPDS); Lexington Attachment to Pets Scale (LAPS); Patient Health Questionnaire-9 (PHQ-9); Perceived Stress Scale (PSS); PROMIS depression short form 4 (SF4); Pet Attitude Scale (PAS); PTSD Checklist-Military Version (PCL-M); Self-Rated Depression Scale (SDS); Self-report using dichotomous yes/no (yes/no); Self-reported level of attachment (Attachment)

Table 2.2

Summary of Mental Health Topics and Results

	Mental Health Topic			Results		
Articles	**Depression**	**PTSD**	**Anxiety**	**Negative**	**Nonsignificant**	**Positive**
Albright et al. (2022)	X				X	
Antonacopoulos & Pychyl (2010)	X				X	
Batty et al. (2017)	X				X	
Cline (2010)	X				X	
Dunn et al. (2018)	X				X	
Friedmann et al. (2003)	X				X	
Irani et al. (2006)	X				X	
Mein & Grant (2018)	X				X	
Siegel et al. (1999)	X				X	
Xin et al. (2021)	X				X	
Hajek & König (2020)	X				X	X
McConnell et al. (2011)	X				X	X
Miltiades & Shearer (2011)	X				X	X
Campbell et al. (2016)	X					X
Carr et al. (2019)	X					X
Kruger et al. (2014)	X					X
Lentino et al. (2012)	X					X
Min et al. (2019)	X					X
Muldoon et al. (2017)	X					X
Tatschl et al. (2006)	X					X
Ingram & Cohen-Filipic (2019)	X			X		X
Barcelos et al. (2020)	X			X		X
Enmarker et al. (2015)	X			X		
Fritz et al. (1996)	X			X		
Puskey & Coy (2020)	X			X		
Sharpley et al. (2020)	X			X		
Fraser et al. (2020)	X		O	X	O	
Mueller et al. (2021)	X		O	X	O	
Powell et al. (2019)	X		O		X O	
Martin et al. (2021)	X		O		O	X
Bennett et al. (2015)	X		O		X	O
Bradley & Bennett (2015)	X		O		X	X O
Scanlon et al. (2021)	X		O			X O
Silva et al. (2021)	X		O			X O
Ortmeyer & Robey (2019)	X	✓				X ✓
Stern et al. (2013)	X	✓			✓	X ✓
Bergen-Cico et al. (2018)		✓				✓
Anderson (2017)		✓			✓	
Lass-Hennemann et al. (2020)		✓			✓	

Key: X = depression, O = anxiety, ✓ = PTSD

The summary does not indicate a causal relationship between dogs and mental health outcomes. The summary of results indicates level of mental health symptoms only. "Positive" indicates companion dogs were linked with lower levels of mental health symptoms, "negative" indicates companion dogs were linked with higher levels of mental health symptoms, and "nonsignificant" indicates companion dogs were not significantly linked with mental health symptoms.

Impact of Companion Dogs on Depression. We identified four themes in the articles focused on depression (Table 2.3).

Table 2.3

Themes Across Depression Articles

Article/Year	Dog Ownership and Depression	Social Factors	Physical Activity	Personal and Dog Characteristics
Albright et al. (2022)	X			X
Antonacopoulos & Pychyl (2010)	X	X	X	
Barcelos et al. (2020)		X	X	
Batty et al. (2017)	X			
Bennett et al. (2015)	X	X		X
Bradley & Bennett (2015)	X	X		X
Campbell et al. (2016)			X	
Carr et al. (2019)	X	X		
Cline (2010)	X	X	X	X
Dunn et al. (2018)	X		X	
Enmarker et al. (2015)	X	X		X
Fraser et al. (2020)	X			
Friedmann et al. (2003)	X			
Fritz et al. (1996)	X	X		
Hajek & König (2020)	X			X
Ingram & Cohen-Filipic (2019)		X		
Irani et al. (2006)	X			
Kruger et al. (2014)		X	X	
Lentino et al. (2012)	X		X	
Martin et al. (2021)	X	X		
McConnell et al. (2011)	X	X		
Mein & Grant (2018)	X			
Miltiades & Shearer (2011)		X		X
Min et al. (2019)				X
Mueller et al. (2021)	X			X
Muldoon et al. (2017)	X			
Ortmeyer & Robey (2019)			X	
Powell et al. (2019)	X			
Puskey & Coy (2020)				X
Scanlon et al. (2021)		X	X	X
Sharpley et al. (2020)	X			
Siegel et al. (1999)	X			
Silva et al. (2021)		X		X
Stern et al. (2013)		X	X	
Tatschl et al. (2006)			X	
Xin et al. (2021)	X			

Table 2.3 displays all depression-related articles and how each article contributed to the identified depression-related themes.

Dog Ownership and Depression. Twenty-four studies sought to determine if depression levels differed between dog owners and non–dog owners and most (n = 15) found no significant difference. When differences were detected, some reported depression to be

significantly higher in dog owners compared to nonowners (n = 6), while others reported depression to be significantly lower (n = 3).

Social Factors. Sixteen articles examined the influence of social factors on depression. The relationship between the companion dog and human owner was examined in five studies. Four studies quantified this relationship by measuring attachment, while Silva et al. (2021) used the Monash Dog-Owner Relationship Scale, a multidimensional tool measuring the perceived quality of the dog–owner relationship. Researchers examining pet attachment and depression in dog owners reported no significant association (Antonacopoulos & Pychyl, 2010; Ingram & Cohen-Filipic, 2019) and significant positive association (Fritz et al., 1996; Miltiades & Shearer, 2011). Silva et al. (2021) found the closer dog owners felt to their dog, the lower their depression scores.

Seven articles reported findings on the connection between human social support, companion dogs, and depression. Overall, dog owners reported having higher levels of human social support compared to non–dog owners (Carr et al., 2019; Martin et al., 2021), a finding that supports the assertion that companion dogs may facilitate human–human connections. Four studies reported a significant negative association between human social support and depression in dog owners compared with non–dog owners (Carr et al., 2019; McConnell et al., 2011; Miltiades & Shearer, 2011; Silva et al., 2021), indicating dog owners with greater human social support may benefit from companion dogs more than those with less human social support. McConnell et al. (2011) found both human social support and companion-dog social support provide direct yet independent influences on depression in dog owners. Just two studies reported no significant relationship between human social support and depression in dog owners (Antonacopoulos & Pychyl, 2010; Cline, 2010).

Dog owners consistently reported perceived benefits of dog ownership and linked the benefits to the social support and companionship their dog offered (Antonacopoulos & Pychyl, 2010; Bradley & Bennett, 2015; Ingram & Cohen-Filipic, 2019; Kruger et al., 2014; Scanlon et al., 2021; Stern et al., 2013) and to the social connections their dog facilitated with other people (Ingram & Cohen-Filipic, 2019; Scanlon et al., 2021).

Physical Activity. Ten studies reported the effects of physical activity on depression in dog owners. In qualitative responses, dog owners reported positively on the mental health and well-being effects from physical activity with their dog (Antonacopoulos & Pychyl, 2010; Campbell et al., 2016; Kruger et al., 2014; Ortmeyer & Robey, 2019; Scanlon et al., 2021; Stern et al., 2013). In quantitative studies, results were inconsistent. Cline (2010) found physical activity had no mediating effect on depression and dog ownership, and Dunn et al. (2018) found no significant differences in depression between dog owners who did and did not regularly walk their dogs. In contrast, Lentino et al. (2012) found dog owners who walked their dog a minimum of 600 MET-min/week had 40% lower odds of depression than non–dog owners.

Personal and Dog Characteristics. Eleven articles examined the impact individual characteristics of dog owners and their dogs have on depression. Owner characteristics included age (Cline, 2010; Miltiades & Shearer, 2011), gender (Cline, 2010; Enmarker et al., 2015; Hajek & König, 2020), marital status (Cline, 2010; Miltiades & Shearer, 2011), race, geographic location (Albright et al., 2022), and employment status (Mueller et al., 2021); personality type such as extraversion (Mueller et al., 2021; Puskey & Coy, 2020), agreeableness, neuroticism, and conscientiousness (Puskey & Coy, 2020); and pet preference (Puskey & Coy, 2020), attitude toward pets (Min et al., 2019), and ability to care for one's

dog (Miltiades & Shearer, 2011). Dog characteristics included friendliness, affection, and disobedience (Bradley & Bennett, 2015).

Many of the personal characteristics were examined in only a single study, or results were inconsistent. Studies suggested, in terms of depression, that companion dogs may be more beneficial for those who are single (Cline, 2010), employed (Mueller et al., 2021), and those with more favorable perceptions toward their dog (Bradley & Bennett, 2015; Min et al., 2019). Findings conflicted on gender (Cline, 2010; Enmarker et al., 2015; Hajek & König, 2020), but were consistent in not supporting a significant relationship between dog owners' personality type and depression (Puskey & Coy, 2020; Miltiades & Shearer, 2011) or dog owner's age and depression (Cline, 2010; Miltiades & Shearer, 2011).

The influence of the dog owner's health status on depression was unclear. Individuals unable to meet the needs of their dogs or in poorer health experienced higher levels of depression (Miltiades & Shearer, 2011), and those with a diagnosis of cancer reported feeling worry and guilt toward their dog (Ingram &Cohen-Filipic, 2019). We further examined the depression study results based on study populations. Findings remained inconsistent in studies that compared depression levels of dog owners to non–dog owners in populations with specific health conditions. Researchers examining populations with cardiac-related diagnoses (Dunn et al., 2018; Friedmann et al., 2003) and those who had received a lung transplant (Irani et al., 2006) found no significant link between dog ownership and depression; researchers who focused on individuals with HIV/AIDs (Kruger et al., 2014; Muldoon et al., 2017) and those with chronic lower back pain (Carr et al., 2019) found dog ownership was linked to lower levels of depression; and Silva et al. (2021) found dog owners

with fibromyalgia had higher levels of depression compared to non–dog owners with fibromyalgia.

Mechanisms. Eight articles discussed mechanisms that account for how companion dogs might improve symptoms of depression. The most frequently mentioned mechanism was the antidepressant effect of dog walking as a form of exercise and physical activity (Cline, 2010; Dunn et al., 2018; Ingram & Cohen-Filipic, 2019; Sharpley et al., 2020; Stern et al., 2013; Tatschl et al., 2006). The human–animal bond and social support were other suggested mechanisms. Sharpley et al. posited the human–animal bond improves oxytocin levels and improves feelings toward self, which can have antidepressant effects. Meanwhile, Ingram and Cohen-Filipic's study did not support their hypothesis that the strength of the owner–dog bond would be associated with improved depressive symptoms. In terms of social support, Carr et al. proposed companion animals improve depression by decreasing feelings of loneliness and increasing access to human companionship. In a related but different approach, Min et al. suggested companion animals may improve depressive symptoms by acting as a source of cognitive social capital, which can be protective against depression (Ehsan & De Silva, 2015). Cognitive social capital is defined as shared beliefs, values, and narratives that can be drawn on to access resources, connections, or opportunities within a social network (Ehsan & De Silva, 2015). Min et al. pointed out the antidepressant effects of companion dogs center on an owner's ties to other humans through shared perceptions and attitudes about their dog and dog ownership rather the human–animal relationship itself.

Anxiety-Focused Studies

Anxiety is characterized by frequent and recurring feelings of extreme worry and dread that interfere with everyday life. People with anxiety have difficulty controlling their

worries, leading them to feel on edge and restless; they have sleep disturbances, and they have difficulty concentrating. These symptoms can be exacerbated during difficult life events, like an ICU admission, and can slowly worsen over time (APA, 2022). Although a moderate genetic component to anxiety exists, nongenetic risk factors have been identified such as stress exposure and trauma that negatively impact emotional regulation and cognition (Kovner et al., 2019). Anxiety and depression occur together frequently, which is likely due to a shared regulatory location in the prefrontal limbic system (Kovner et al., 2019).

Study Characteristics. Of the 39 articles reviewed, eight reported findings about companion dogs' influence on anxiety. Studies were conducted with community dwelling adults (n = 4), community dwelling older adults (n = 1), adults with fibromyalgia (n = 1) and chronic pain (n = 1), and adults experiencing homelessness (n = 1). Seven studies used self-report tools to measure anxiety (all of which also included a measure of depression), and one study inferred anxiety from qualitative responses. A total of five different measurement tools were used to measure anxiety (Table 2.1).

The eight studies addressing anxiety reflected a variety of purposes. Mueller et al. (2021) and Fraser et al. (2020) aimed to distinguish dog owners from non–dog owners sociodemographically and determine whether pet ownership was associated with well-being. Powell et al.'s (2019) 3-armed controlled trial examined the effect of dog acquisition on mental well-being. In interviews, Scanlon et al. (2021) explored the human–companion animal bond from the perspective of homeless dog owners. Martin et al. (2021) and Silva et al. (2021) measured associations between dog ownership and indicators of well-being. Bradley and Bennett (2015) used online surveys and interviews to investigate owners' chronic pain management through interactions with their companion animals. Bennett et al.

(2015) queried the impact of number and quality of human–animal interactions (HAI) on psychosocial well-being.

Impact of Companion Dogs on Anxiety. Anxiety results also varied. Mueller et al., Martin et al., and Fraser et al. found no significant association between dog ownership and anxiety, and Powell et al. found no association between acquiring a dog and anxiety. Dog owners experiencing homelessness in Scanlon et al.'s study reported their dog positively impacted their mood, stress, and anxiety, yet also reported increased worry about their dog's well-being.

Two of the studies revealed nonsignificant results for the primary research question while further analysis revealed notable findings. Bradley and Bennett found no statistical difference in anxiety between pet owners and nonowners with chronic pain, but when dog owners were analyzed separately, the more friendly the dog was rated the less anxiety was reported by the dog owner. Similarly, Bennett et al.'s study found frequency of pet presence contributed to reduced anxiety levels in dog owners. Silva et al.'s study demonstrated significant findings for both primary and secondary outcomes. Dog owners with high levels of human social support had significantly lower levels of anxiety, and on further analysis, those who intentionally patted or stroked their dog as a coping mechanism for pain reported lower levels of anxiety.

We further examined the anxiety study results based on study populations. The studies that included community dwelling adults (n = 4) demonstrated nonsignificant findings (Fraser et al., 2020; Martin et al., 2021; Mueller et al., 2021; Powell et al., 2019), while the studies that included specific populations (n = 4) such as older adults (Bennett et al., 2015), individuals with fibromyalgia (Silva et al., 2021) and chronic pain (Bradley &

Bennett, 2015), and individuals experiencing homelessness (Scanlon et al., 2021) all demonstrated positive findings.

Mechanisms. No anxiety-specific mechanisms were discussed in the reviewed literature.

Posttraumatic Stress Disorder Studies

PTSD is a clinically diagnosed mental disorder that can occur following exposure to an event of extreme or life-threatening stress (APA, 2022), such as experiences associated with ICU-related care. PTSD involves sustained dysregulation of emotional and neurophysiological responses. Symptoms are grouped in four classes: intrusive and disturbing memories; avoidance of people, places, and activities; changes in cognition and persistently negative mood; and changes in arousal, attention, and activity level (APA, 2022). PTSD is frequently comorbid with depression and anxiety disorders (Armenta et al., 2019; Spinhoven et al., 2014).

Study Characteristics. Five studies examined the use of companion dogs to address PTSD or its symptoms. Studies were conducted with military veterans with PTSD (n = 3), military veterans without a PTSD diagnosis (n = 1), and people working in high-stressor occupations (n = 1). In their quasi-experimental studies, Bergen-Cico et al. (2018) measured the effects of a dog adoption and training program (Dogs2Vets) on posttraumatic stress symptoms in military veterans, and Ortmeyer and Robey (2019) assessed the feasibility of a foster dog program on physical and mental health indicators, including heart rate and HRV. Of the three cross-sectional studies, Anderson (2017) examined associations between dog ownership, demographic characteristics, and military pay grade; Stern et al. (2013) surveyed veterans about changes they perceived in their PTSD symptoms since becoming dog owners;

and Lass-Hennemann et al. (2020) measured associations between dog owners and non–dog owners with PTSD.

To assess PTSD symptoms, researchers used four different psychometrically tested self-report measures (Table 2.1). Stern et al. also administered an author-designed Dog Relationship Questionnaire in which respondents rated their level of agreement with 18 statements pairing having a companion dog with improvements in specific PTSD-associated symptoms.

Impact of Companion Dogs on PTSD. Effects of companion dogs on trauma and stress were mostly positive, with variable impact. Bergen-Cico et al. found veterans in the Dogs2Vets program had significant improvement in PTSD symptoms and perceived stress at 12-month follow-up compared to controls. In open-ended responses, the Dog2Vets participants described having better PTSD symptom management since beginning the program. While all participants in Ortmeyer and Robey's study demonstrated improvement in perceived stress after companion dog adoption, the one participant with PTSD at baseline demonstrated the most improvement in outcome measures and was the only participant to experience improved HRV. Stern et al.'s respondents reported that since acquiring a dog, they were calmer, less lonely, less worried, less depressed, had better feelings about self, were less angry/irritable, enjoyed nature more, and got more exercise. At the same time, respondents reported no improvements in the burden of nightmares, memories/flashbacks, or being with people. Anderson's and Lass-Hennemann et al.'s surveys found no significant correlation between dog ownership and PTSD.

As with the depression and anxiety studies, we further examined the PTSD study results based on study populations. All five studies included populations that had a diagnosis

of PTSD or were at risk for developing PTSD. Findings conflicted when results for individuals at risk for PTSD (Lass-Hennemann et al., 2020; Ortmeyer & Robey, 2019) were compared to those who had a diagnosis of PTSD (Anderson, 2017; Bergen-Cico et al., 2018; Stern et al., 2013). Additionally, all but one PTSD study (Lass-Hennemann et al., 2020) focused on military veterans, a finding that suggests companion dogs may be beneficial for this population.

Mechanisms. Four articles discussed or tested mechanisms to explain how companion dogs might improve symptoms of PTSD (Anderson, 2017; Bergen-Cico et al., 2018; Lass-Hennemann et al., 2020; Stern et al., 2013). Mechanisms included social factors, self-effects, opportunity for emotional disclosure, and enhanced sense of safety and coherence. For veterans with PTSD, researchers in two studies hypothesized improved PTSD symptoms occurred because owning and walking a dog facilitated social reintegration by increasing social connectedness (Bergen-Cico et al., 2018; Stern et al., 2013). The process of training a dog was argued to have potential self-effects leading to improved symptoms, since training tapped into a sense of responsibility and self-efficacy, giving participants a chance to apply military-based skills and track their own progress (Bergen-Cico et al., 2018). Bergen-Cico et al. found the human–animal bond in dog ownership influenced self-compassion, which they argued protects against PTSD symptoms through reduced self-judgment and rumination. Stern et al. proposed that, due to a perception that dogs are nonjudgmental, owners may be willing to confide in their dog, thus enabling emotional disclosure. Additionally, Stern et al. suggested that, by requiring a consistent schedule and enhancing a sense of security and safety, companion dogs may alleviate PTSD symptoms by improving sleep. Lass-Hennemann et al. did not find support for their hypothesis that companion dogs

might be protective during stressful and traumatic events for people with PTSD by improving the sense of coherence.

Discussion

What and How: Outcomes and Mechanisms

In the growing body of literature focused on the impact of human–companion dog relationships on depression, anxiety, and PTSD, depression was disproportionately the most common mental health outcome examined, followed by anxiety and then PTSD. Study outcomes were notably inconsistent across the depression and anxiety literature, and mostly positive within the PTSD literature. This finding contrasted with the results in Hughes et al.'s (2019) systematic review that found companion animals had a mostly positive effect on mental health in older adults. The discrepancy may be due to differences in design, since Hughes et al. did not differentiate between pet species, focused on older adults, and included animal-assisted interventions (AAI) and therapies (AAT). Benefits of AAI and AAT on human psychological health have been supported across the literature (Huber et al., 2022; Shen et al., 2018; Villafaina-Dominguez et al., 2020). Unlike companion dogs, which lack defined roles and responsibilities, AAI and AAT are goal-directed activities that include intentional engagement with an animal (Howell et al., 2022). Notably, we saw the greatest effects of companion dogs on mental health symptoms in the PTSD, and to a lesser extent anxiety studies, which is also where we saw more work that evaluated intentional activities and engagement with companion dogs (e.g., petting a dog, dog training, frequency of pet presence).

In all three mental health domains, most prominently in the depression studies, we found most measured associations between dog ownership and mental health outcomes were

not statistically significant. In the studies demonstrating positive effects, authors not only examined intentional engagement and activities with a companion dog, but also specific aspects of the human–companion dog relationship (e.g., ability to care for a dog, attitude toward pet) and/or specific populations. We saw the most inconsistent results across the depression literature, which is where researchers predominantly focused on samples of the general population. Half of the anxiety studies included samples from the general population and the other half from specific populations. The anxiety studies that focused on specific populations, rather than samples of the general population, had positive results. Finally, the PTSD studies, which demonstrated mostly positive results, included the most specific populations; all studies included populations diagnosed with or at risk for PTSD. To identify the populations who may benefit most, researchers should inquire beyond owning/not-owning a dog.

Across the sample, we found companion dogs may not benefit all individuals equally, a finding consistent with systematic reviews exploring mental health outcomes in owners of various types of pets (Brooks et al., 2018; Hughes et al., 2019). For example, in the depression studies we saw marital status, employment status, attitude, and the ability to care for a dog may influence the effect of companion dogs; in the anxiety studies we found attitude, ability to care for a dog, and health status may influence a companion dog's effect; and in the PTSD studies we found military veterans and individuals with/at high risk for PTSD likely to benefit from companion dogs. These findings further suggest the *what* (effect) is contingent on the *who* (is involved) and *how* (what the involvement involves). This work indicates a need for research to identify and examine relevant and influential elements of human–companion dog relationships. Barcelos et al.'s (2020) framework of 58 human–

companion dog activities and how they relate to human well-being provides an example of work that can advance our understanding and provide a steppingstone for future analysis of the influential factors in human–companion dog relationships. Additional work is necessary to consider how owner culture and context might also factor into companion dog effects.

Another notable finding that emerged from the depression and anxiety studies was that greater mental health effects were found when companion dog owners had moderate to high levels of human social support. This contrasts with research finding companion dogs benefit human health more when human social support is lacking (Oliva & Johnston, 2021; Pruchno et al., 2018). Our findings suggest human social support remains an important and beneficial element in the psychological health of companion dog owners and that companion dogs may not be sufficient as independent forms of social support but may be most beneficial when they are combined with human social support.

While PTSD, anxiety, and depression are often comorbid, differences in symptoms exist. Our review suggests companion dogs have the potential to improve symptoms in all three mental health domains, yet understanding the unique mechanisms behind these potential benefits remains unclear. Most mechanisms in the reviewed literature were general, addressing how companion dogs influenced health and well-being overall. As previously noted, researchers found the greatest effects of companion dogs on symptoms in the PTSD studies, which is also where authors identified condition-specific mechanisms. These at times echoed types of PTSD treatment (e.g., emotional disclosure). It seems reasonable to speculate that the positive results in PTSD studies may be related to a focus on the unique needs of the population. In contrast, mechanisms specific to anxiety were not discussed in the reviewed articles, and most of the proposed mechanisms for depression remained broad. To better

understand how companion dogs influence patient recovery or well-being and to determine how human–companion dog relationships can be facilitated to be most therapeutic, researchers should continue to explore and test mechanisms associated with condition-specific outcomes. Similarly, we identified limited use of theory throughout the reviewed literature. Theory-driven investigation can help focus analysis on determinant pathways and lend coherence to a disjointed field. Both would help guide researchers' understanding and eventually facilitation of companion dogs as a means of improving human health.

Implications for Future Research

Our scoping review illuminates the range and diversity of the current literature focusing on companion dogs and depression, anxiety, and PTSD. Future research should incorporate longitudinal and experimental designs, seek homogeneity in measurement, and continue to leverage the diverse perspectives of multidisciplinary research teams. We found an abundance of cross-sectional designs and no randomized controlled trials (RCTs). RCTs could help address the absence of defined mechanisms and relationships linking companion dogs and human health. While HAI researchers have argued RCTs would be difficult to conduct in human–companion animal research due to challenges of randomization and masking (Brooks et al., 2018; Krause-Parello et al., 2019), these proposed challenges should not deter future intervention research. By conducting pilot studies, researchers can test and identify ways to overcome such challenges and explore the feasibility of RCTs involving companion dogs.

Another area of weakness in the field was the large number of instruments used to quantify mental health symptoms. Inconsistency of measures can complicate comparisons between studies and contribute to the inconsistency of results across the literature. Research

to comparatively test or develop field consensus of preferred measures for human–companion animal research outcomes would facilitate greater consistency in the collection, reporting, and interpretation of results and ultimately their usability.

We highlight the multidisciplinary teams used to conduct the reviewed research. The diverse disciplinary makeup of scientific teams aligns with the aims of One Health, an international approach that promotes HAI research, policy, and health initiatives (Centers for Disease Control and Prevention [CDC], 2023). One Health was founded on the interconnection of humans, animals, and the environment and the need for holistic strategies to optimize health and well-being in all three domains (CDC, 2023). We found the use of multidisciplinary teams a fitting and promising indication of the field's readiness to acknowledge the complexities of the human–companion dog relationship and pursue future interventional innovation.

Limitations of this review included exclusive reliance on published studies and studies published in English. To compensate, we used a systematic, comprehensive search strategy and three reviewers, but we may have still missed sources with valuable findings. We also did not consult with a HAI expert, an optional step in Arksey and O'Malley's framework that might have brought an informative perspective (Levac et al., 2010).

Companion Dogs and ICU Survivors

Our results indicate companion dogs have the potential to facilitate the unique needs of ICU survivors. ICU survivors have described critical illness as an evolving, complex struggle of mental, emotional, and physical recovery (Ewens et al., 2018; Kang & Jeong, 2018). To successfully cope and recover, ICU survivors benefit from holistic recovery strategies (Geense et al., 2019) that facilitate physical health, meaningful recovery (Kang &

Jeong, 2018), a sense of normalcy (Hanifa et al., 2018; Kang & Jeong, 2018), and social connection (Khan & Jeong, 2018; Langerud et al., 2018). The reviewed literature suggests companion dogs facilitate a meaningful recovery by instilling a sense of responsibility, purpose, and identity; a sense of normalcy by supporting routines and consistency; and enhanced social support, especially for those with higher levels of human social support. For those with limited human social support, companion dogs may facilitate connections to other people, building the potential for meaningful human relationships. Additionally, multiple mechanisms may work together to facilitate human well-being, thereby providing a holistic approach to recovery, where physical, social, and mental health benefits can occur simultaneously. Future research should include ICU survivor samples along with measuring all three mental health domains simultaneously.

Implications for Health Care Practice

Supportive relationships are important in the recovery of ICU survivors, and our findings demonstrate companion dogs could play a key role in developing such support. Our results also indicated that sharing intentional activities with companion dogs may be necessary to optimize their mental health benefit. Such activities can vary in physical demand from minimal (petting, talking, snuggling, presence) to moderate (grooming) to more vigorous (throwing a ball and walking/running). Nurses and other health care professionals can assess for and encourage physically appropriate activities that facilitate engagement with a companion dog while holistically promoting social connection and mental well-being. Such activities could be integrated into a patient's personalized health and recovery plan. For individuals limited in their ability to care for their companion dog after discharge, health care professionals should be knowledgeable about community resources available to assist with

temporary and long-term pet care. Developing and testing assessment guidelines, training, and supportive programs to encourage companion dogs, where appropriate and desired, could provide a low-cost, easily implemented, and effective means of improving health outcomes in ICU survivors and other populations with complex health needs. Nurses and health care professionals are in an optimal position to assess supportive relationships that facilitate recovery, including companion dogs. In inquiring about dog ownership, health care professionals seize an opportunity to discuss and optimize a special relationship in their patient's lives.

Conclusions

Companion dogs have the potential to facilitate better mental health in ICU survivors by meeting their unique needs: providing a holistic approach, a meaningful recovery, a sense of normalcy, improved physical health, and enhanced social connectedness and support. Additional multidisciplinary research using ICU survivor samples, longitudinal and experimental designs, and more consistent measurement across studies is needed. To advance the science, researchers should prioritize the identification and testing of specific mechanisms of the human–companion dog relationship as they relate to human mental and other health. Nurses and health care professionals are in an optimal position to incorporate such research into their practice. Our scoping review suggests that encouraging social connection and intentional, physically appropriate activities with companion dogs is an underdeveloped but very promising potential avenue for optimizing mental health benefits in a group with complex needs. Companion dogs may be a refreshing countercurrent in a time of shrinking mental health resources and AI-mediated health care.

Funding

No funding was received for this project.

Acknowledgments

We would like to thank our consulting librarian, Marie Thompson, for assistance in the search strategy and process.

CHAPTER 3

THEORETICAL FRAMEWORK AND METHODOLOGY

Theoretical Framework

The theoretical framework that guided this study was based on Engel's biopsychosocial (BPS) model, attachment theory, and the cross-stressor adaptation hypothesis. The BPS model provided the central concepts and ideas that guided the intervention. Attachment theory and the cross-stressor adaptation hypothesis provided the theoretical basis that explained the mechanisms behind each component of the intervention.

The BPS model stems from general systems theory and posits biological, psychological, and social processes are interrelated and must be considered in every healthcare task including understanding and treating illness (Engel, 1977; Engel 1980). Any imbalance within or among the elements of health can manifest in poor health (Engel, 1980). The Society of Critical Care Medicine (SCCM) referred to PICS as a public health concern requiring holistic approaches (Elliot et al., 2014). In alignment with SCCM's call and Engel's BPS model, the companion dog-walking intervention took a holistic approach that aimed to address biological, social, and psychological components of ICU survivor health, and thus QOL.

The first component of the intervention was the companion dog. The companion dog served as the social element of Engel's model. The mechanisms underlying how animals benefit human health are not clearly understood, yet one mechanism discussed frequently in the human-animal interaction literature is attachment (Fine & Beck, 2019; Krause-Parello, 2012; Nelson et al., 2024), a concept that stems from attachment theory. Attachment theory, first developed by John Bowlby and expanded by Mary Ainsworth, focused on infant

relationships with a caregiver (Gillath et al., 2016), and was later extended to include relationships across the lifespan, including relationships in adulthood (Ainsworth et al., 1978; Barthalomew & Horowtiz, 1991; Hazan & Shaver, 1978). Attachment theory contends humans have a natural predisposition to seek emotionally and physically close relationships for psychological and physical security throughout their lives (Ainsworth, 1989; Gillath et al., 2016). Those who experience positive relationships that fulfill this innate need have a heightened sense of self-worth and trust, and respect others (Barthalomew & Horowtiz, 1991; Hazan & Shaver, 1978). Such relationships facilitate psychological wellbeing (e.g., confidence, resilience, coping, self-efficacy). Lacking positive social relationships is associated with stress, anxiety, loneliness (Ainsworth, 1989; Bowlby, 1988), and depression (Jinyao et al., 2012).

Meehan et al. (2017) and Keefer et al. (2014) propose the concepts of attachment theory can be applied to the human-animal relationship because pets can function as attachment figures. Ainsworth (1989) describes attachment as an enduring affectional bond that includes the following characteristics: a base for comfort, security, and safety; the confidence to explore and be independent; and a need to maintain proximity, distress with separation, and grief when a loss occurs. Additionally, attachment figures can never be fully replaced by another (Ainsworth, 1989). These defining characteristics of attachment have been reported by dog owners from various populations. Dog owners have reported that their companion dog makes them feel physically (Rhoades et al., 2015) and psychologically safe and protected. For example, dog owners have described their dogs as providing comfort because they provide unconditional love (Brkljačić et al., 2020), are non-judgmental (Ingram & Cohen-Filipic, 2019), and are able to sense emotions and respond in a comforting way

(Compitus, 2019; Ortmeyer & Robey, 2019). Other dog owners have expressed their companion dog helped them grow as a person and facilitated confidence and strength in themselves (Bergen-Cico et al., 2018; Bennett et al., 2015; Compitus, 2019). Study results indicate it is often the time spent with the dog during daily routines that may be the most important and influential for owners (Barcelos et al., 2020; Bennett et al., 2015; Ingram & Cohen-Filipic, 2019), such as being in close proximity to their dog and sharing tactile interaction such as snuggling (Barcelos et al., 2020). Grief is often experienced by owners when a dog dies (Rémillard et al., 2017; Spain et al., 2019) which can occur as low levels of grief or overwhelming levels of grief leading to depression (Compitus et al., 2019) and feelings of distress, loneliness, and guilt (Cowling et al., 2020; Kemp et al., 2016).

Additionally, Hazan and Shaver (1987) describe attachment in adults as a reciprocal relationship that provides comfort and security to both partners. (Hazan & Shaver, 1987). Dog owners often report sharing a relationship of interdependence and mutual benefit with their dog; the dog relies on their owner for food, water, walks, and attention, and the dog-owner relies on their dog for comfort, enjoyment, and safety (Ingram & Cohen-Filipic, 2019; Ortmeyer & Robey, 2019). For example, pet owners who walk their dogs have reported satisfaction and fulfillment not just because of the comforts their dog provides them, but also due to meeting their dog's needs (Campbell et al., 2016; Lim & Rhodes, 2016). Just as dog owners have expressed the importance of being near their dog, they have also explained that their dog likes to remain close as well (Bradley & Bennett, 2015; Ingram & Cohen-Filipic, 2019). The nature of the human-animal bond has the potential to facilitate a mutually beneficial relationship and the benefits of enduring attachment. Therefore, including companion dogs in an intervention targeting individuals who are at risk for social isolation

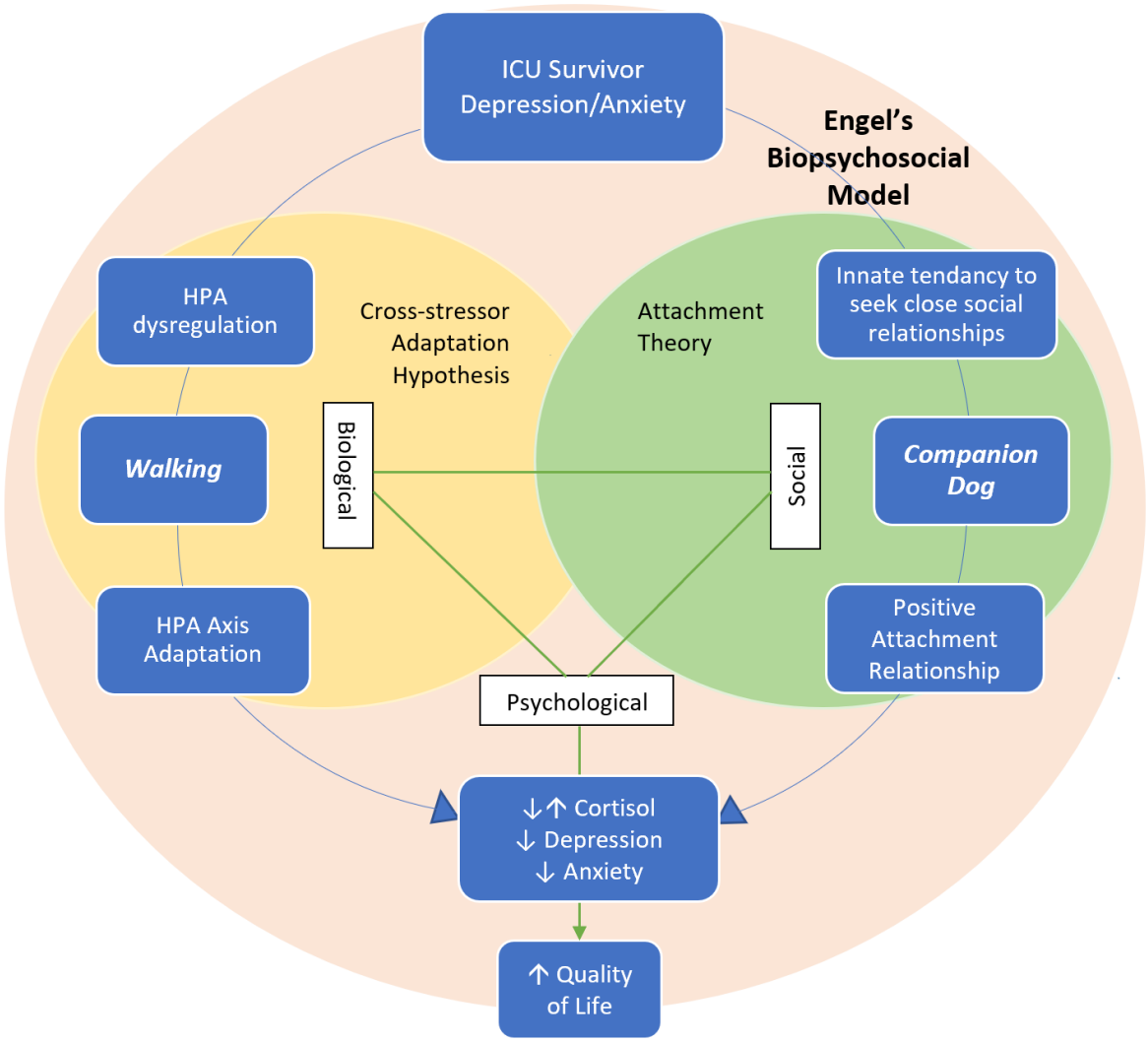
could facilitate a positive attachment relationship which in turn could support coping and recovery and prevent and improve depression and anxiety.

The second component of the intervention was walking. Walking acted as the biological element of Engel's model. Sothman's (2006) cross-stressor adaptation hypothesis stems from the fields of biochemistry and exercise science and posits biological adaptations occur with regular exercise, including decreased physiological responses to both physical and psychological stressors. Such physiological improvements are often seen with improvements in cortisol regulation and release. Depression and anxiety can lead to hypothalamus-pituitary-adrenal (HPA) axis dysregulation, leading to hyper or hypo secretion of cortisol (Cowen, 2010; Mikkelsen, 2017). Therefore, walking served as a form of physical activity aimed to regulate biological activity in the way of HPA axis regulation and cortisol release.

The social and biological elements of Engel's model came together to form companion dog walking. Based on attachment theory and the cross-stressor adaptation hypothesis, companion dog walking works to improve the third element of Engel's model, psychological health. When all aspects of a person's health are addressed, improved wellbeing is anticipated (Engel, 1977; Engel 1980). Outcome measures of a study represent operational definitions of the concepts (Wells & McEwen, 2019). The outcome measures of this study addressed Engel's concept of psychological health by measuring depression, anxiety, and serum cortisol. The overarching concept of wellbeing that occurs when biological, psychological, and social health are supported was measured through QOL. Figure 3.1 provides a visual of the theoretical framework.

Figure 3.1

Theoretical Framework



The final theory that guided a single element of this study was the theoretical framework of acceptability (TFA) (Sekhon et al., 2017). Acceptability is important to consider in the development and implementation of health-related interventions (Sekhon et al., 2017). When an intervention is acceptable to study participants, there is an increased chance of intervention adherence during trials and increases the likelihood of following and maintaining health recommendations (Borrelli et al., 2005). According to the TFA,

acceptability is a construct reflecting the degree to which people involved with an intervention perceive it to be satisfactory due to experienced or anticipated emotional and cognitive factors (Sekhon et al., 2017). The constructs that should be measured to evaluate acceptability include burden, affective attitude, ethicality, intervention coherence, perceived effectiveness, opportunity costs, and self-efficacy (Sekhon et al., 2017). An acceptability survey was designed in alignment with the TFA and the questions that addressed intervention acceptability reflected each of the seven constructs (Appendix B).

Methodology

Design

An eight-week, prospective, single-masked (participant), two-arm RCT was conducted. Adult ICU survivors were recruited from two Colorado hospitals using consecutive sampling. Potential participants were contacted, consented, and screened for inclusion and exclusion criteria prior to being discharged home from the hospital. Due to five months of low recruitment, the institutional review board (IRB) application was amended to initiate an additional recruitment strategy. The second recruitment strategy took place simultaneously and included displaying recruitment flyers in out-patient clinics (see Appendix C); potential participants used the contact information on the flyer to communicate interest. Those meeting inclusion criteria were enrolled, masked, and randomly assigned to a companion dog-walking intervention (independent variable) or an attention control education intervention (control) that began two to four weeks post hospital discharge. The dependent variables of depression, anxiety, serum cortisol, and QOL were assessed at baseline, the end of week four, and at the end of the eight-week intervention. Study feasibility and acceptability were assessed at the end of the eight-week study. The study was registered with

ClinicalTrials.gov (Identifier: NCT05820308). As the student researcher and principal investigator (PI), I conducted all aspects of the study (i.e. electronic health record (EHR) review, screening, consent, and the intervention) unless otherwise noted.

Subjects and Setting

Recruitment sites included two acute care hospitals located in Southern Colorado. The first site was a 268-bed hospital, with 36 general ICU beds, providing care to adult trauma, cardiovascular, medical, surgical, and neurological patient populations. The second site was a 195-bed hospital with a 14-bed general ICU providing care to cardiovascular, medical, and surgical patient populations. Both hospitals serve the Southern Colorado region which is comprised of the following demographics: 78% ≥ 18 years old, 51% male, 49% female, 64% white, 23% Hispanic/Latino, 4% black/African American, 2.4% Asian/Pacific Islander, and 1% American Indian and Alaska Native (Colorado Department of Local Affairs, 2020; United States Census Bureau, 2019). Given the hospitals' annual inpatient discharges (Colorado Hospitals Association, 2020), Colorado's ICU utilization trends (U.S. Department of Health and Human Services, 2021), and a national mortality rate of 20% for ICU patients (SCCM, 2021), 240 total adult ICU patients were estimated to be discharged between the two sites every month (180 and 60 respectively).

Four outpatient specialty clinics were added as additional recruitment sites. The specialty areas included pulmonology, cardiology, and neurology/neurosurgery. Recruitment flyers were displayed in the clinic waiting areas. Outpatient clinics were used to expose more potential participants to the study and because most ICU survivors are scheduled for a follow-up appointment two weeks after discharge. Access to the sample was acquired by obtaining IRB approval from both the University of Missouri Kansas City (UMKC) and the health system CommonSpirit Health.

For in-patient hospital recruitment, electronic health records (EHR) were used to identify and screen potential participants. Intensive care unit patients' EHRs were used to track their progress throughout their hospital stay to identify potential eligibility. Potential participants were adult (≥18 years) ICU survivors who spent ≥24 hours in the ICU with plans to be discharged home. The patients' charts were screened for age, length of time in the ICU, and physician notes and case management notes were reviewed for discharge status and disposition. Potential participants were able to speak, read, and understand English, which was determined by reviewing the patient's documented "preferred language." Potential participants also needed to be physically capable of dog walking. Physical therapy, occupational therapy, and nursing documentation were reviewed for functional status and ability. Provider orders were reviewed to identify any activity limitations and requirements. Potential participants were considered eligible for further screening if they were able to walk in the halls without assistance and without a mobility aid, had been cleared by physical therapy if physical therapy was on the care team, and if they did not have weight bearing restrictions. Standard care required all patients admitted to the hospital be assessed for suicidal ideation by the healthcare team using the Columbia Suicide Severity Rating Scale-Screen Version (Posner et al., 2011). Anyone scoring moderate or high risk (answers 'yes' on any questions 3-6) while in the hospital was referred to the mental health team for further evaluation and administration of appropriate resources and treatment. Those deemed high risk for suicide based on the screening tool and the mental health team (mental health provider notes were reviewed) were excluded from the study.

When eligibility criteria were met, a member of the nursing team was notified. The nurse made initial contact, provided a recruitment flyer with study information to the

potential participant (see Appendix C), and asked if the potential participant would like to learn more about the study. Initially, patients interested in learning more could reach out directly using the contact information on the recruitment flyer or could communicate interest through their nurse by completing a permission form that included their name and room number. Those who communicated interested were then visited while in the hospital to obtain study consent and screen for additional inclusion and exclusion criteria. However, less than two months into recruitment, an interested patient was discharged prior to being visited and there was no means to follow up. As a result, the IRB application was amended to include a section on the permission form that allowed potential participants to volunteer a phone number that could be used if they were discharged from the hospital prior to being visited. When a potential participant reached out directly but was no longer in the hospital (including those who received the recruitment flyer in the hospital but were since discharged and those who saw the flyer in an out-patient clinic), a meeting time was arranged to discuss the study, obtain consent, and screen for additional inclusion and exclusion criteria.

Potential participants were screened for depression and anxiety using the PROMIS Depression Short Form (SF) 6a and the PROMIS Anxiety SF 6a (Cella et al., 2019; Pilkonis et al., 2011). Individuals were also screened for dog ownership and dog-walking habits. Individuals who had symptoms of depression and/or anxiety (a score ≥ 12 as measured by the PROMIS Depression SF6a or the PROMIS Anxiety SF6a) (Clover et al., 2018; Clover et al., 2022; Kroenke et al., 2020), owned a companion dog, and walked their dog <10 minutes/week met inclusion criteria. Intensive care unit survivors are at risk for developing cognitive impairment (Honarmand et al., 2020), and therefore permission was obtained for use of the University of California San Diego Brief Assessment of Capacity to Consent

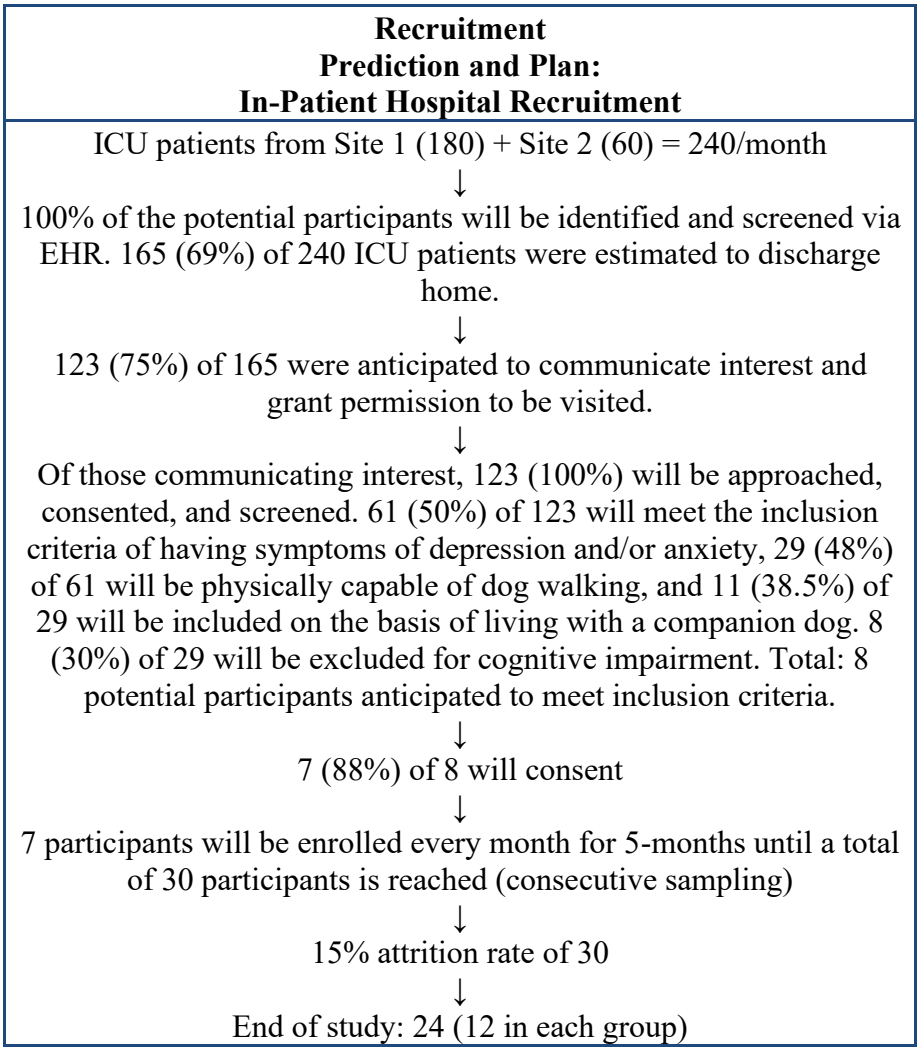
(UBACC) tool to screen for decisional capacity; those scoring <14.5 were excluded (Jeste et al., 2007). Screening questions developed by animal behaviorists and adopted with permission from Ng et al. (2021) were used to evaluate and exclude participants if dog walking was unsafe with and for the dog (those answering "yes" to any questions were excluded). Based on the wide variety of diagnoses and conditions that require critical care, participants were asked questions about their physical health. If indicated, provider authorization was required prior to participation. Due to practical limitations, participants were initially excluded if they lived outside a 30-mile radius of the hospital. Due to low enrollment, the IRB application was amended twice to extend the geographic range; after five months of recruitment, the final geographic radius was set at 45 miles. Due to the period between discharge and study initiation (2-4 weeks), participants were asked to complete the Timed Up and Go (TUG) test (Podsiadlo & Richardson, 1991) during their initial home visit to verify if the participant remained physically capable of dog walking. Participants scoring ≤ 20 seconds on the TUG test remained eligible to participate in the study (Christopher et al., 2021; Podsiadlo & Richardson, 1991).

Individuals recruited through the out-patient clinic flyers were screened for suicide risk using the same screening tool used by nurses in the hospital settings (the Columbia Suicide Severity Rating Scale-Screen Version). Those deemed moderate or high risk for suicide were excluded from the study and provided with mental health resources. Individuals with moderate risk were referred to their primary care provider to seek a behavioral health referral and/or local behavioral health services through Colorado Wellness Recovery for full assessment. Those considered high risk were immediately referred to Colorado Crisis Services and the local emergency department. Screening tools can be found in Appendix D.

Feasibility and acceptability studies evaluate study processes and acceptability rather than outcomes and therefore do not necessitate a fully powered sample size (Arain et al., 2010; Eldridge et al., 2016; Hertzog, 2008). Based on suggestions by Julious (2005) regarding feasibility studies, a goal sample size of 24 (12 per group) was set for this study. The ICU survivors were recruited using consecutive sampling. Anticipated recruitment for the study is outlined below and in Figure 3.2. Of the 240 available ICU patients, 100% were anticipated to be screened. An estimated 69% were anticipated to be discharged directly home from their hospital admission (Stelfox et al., 2018). Of the ICU patients discharged home, 75% were anticipated to communicate interest directly or grant permission to the nurse (Denehy et al., 2013; Wolters et al., 2016). Of those communicating interest, it was anticipated that 100% would be approached, consented, and screened. An estimated, 50% would meet the inclusion criteria of having symptoms of depression and/or anxiety (Choi et al., 2016; Hatch et al., 2018; Garcez-Leme & Avelino-Silva, 2022), 48% would be physically capable of dog walking (Colbenson et al., 2019), and 38.5% would be included based on living with a companion dog (American Veterinary Medical Association, 2018). Approximately, 30% were anticipated to be excluded for cognitive impairment (Colbenson et al, 2019). In alignment with similar dog walking trials, 88% of invited participants were expected to agree and consent (Morrison et al., 2013; Richards et al., 2015). Consequently, it was anticipated seven ICU survivors would be enrolled every month, and recruitment would take place for five months to obtain the necessary sample size of 30 participants. A 15% attrition rate was consistent with other dog walking trials (Morrison et al., 2013; Richards et al., 2015) and therefore an estimated 24 ICU survivors were anticipated to complete the study.

Figure 3.2

Recruitment Prediction and Plan



Once participants were enrolled, they were randomly assigned to either the companion dog-walking intervention group or the attention control education group using a 1:1 block design (blocks of 4). Block randomization facilitates random assignment of participants to groups in a way that produces an equal number of participants in each group; a randomization strategy that is beneficial for small sample sizes and when participants are recruited and enrolled at different times (Broglio, 2018).

The POOCH Study aimed to recruit a representative sample of ICU survivors within the United States (U.S.). Reporting of racial and ethnic demographics in studies focused on ICU survivors is limited, but large-scale U.S. studies have demonstrated 10-22% of ICU survivors are non-white (Jackson et al., 2014; Rydingsward et al., 2016). Additionally, large-scale studies in various locations across the U.S. found approximately 50-70% of ICU survivors are male (Castillo et al., 2016; Jackson et al., 2014; Rydingsward et al, 2016). These demographics established the recruitment goals of the study and minority recruitment was evaluated as part of the feasibility assessment to determine if additional measures were needed to recruit a representative sample in future studies (Stewart et al., 2020).

Instruments

Demographic data were collected from all eligible participants (Appendix E). If eligible participants chose not to enroll in the study, they were given the opportunity to consent to the use of their demographic data only to determine if there were demographic differences between those who consented and those who declined to participate. Participant's age, biological sex, ethnicity, education level, and marital status, along with baseline ICU data (i.e., reason for admission, length of stay, time on ventilator) were obtained from participants. These demographics have been found to be potential predictors for depression and anxiety.

The outcome measures evaluated were depression, anxiety, QOL, and serum cortisol. Participants completed assessments at baseline, end of four weeks, and again at the completion of the study (eight weeks). The Center for Epidemiologic Studies Depression Scale (CES-D) is a 20-item self-report tool that assesses intensity of depression using a 4-point Likert scale and takes 5 minutes to complete (Radloff, 1977). Lower scores indicate milder levels of depression while higher scores indicate more severe depression (range 0-60). The scores can be used to differentiate mild (0-16), moderate (16-23), and severe (24-60) depression (Radloff, 1977). Clinically meaningful depression is represented by a score of 16 or greater (Radloff, 1977). The CES-D has been applied in various adult populations, including the ICU survivor population (Boyle et al., 2004; Chelluri et al., 2004; Weinert & Meller, 2006). Weinert and Meller (2006) compared CES-D scores to clinician diagnosis in ICU survivors and found similar results. The CES-D has demonstrated adequate test-retest reliability (r=0.40-0.70) (Radloff, 1977), strong internal consistency in general and clinical populations (α =0.85- 0.90) (Cosco et al., 2017; Radloff, 1977), high concurrent validity with other depression scales such as the Symptom Checklist-90 (r=0.83) (Radloff, 1977) and the Becks Depression Inventory II (r > 0.66-0.86) (Beck et al., 1996), and strong construct validity (Cosco et al., 2017; Naughton & Wiklund, 1993; Radloff, 1977).

The Spielberger State Trait Anxiety Inventory (STAI-AD) is a 40-item (20-items per subscale) self-report assessment tool using a 4-point Likert scale that assesses both trait (general feelings) and state (current feelings) anxiety and takes 10 minutes to complete (Spielberger et al., 1983). The higher a participant's score the higher the level of anxiety (range 20-80). Scores can further be described as no/low anxiety (20-37 points), moderate anxiety (38-44 points), and high anxiety (45-80 points), with a cut-off point of 39 indicating

clinically significant symptoms of anxiety (Kavikcioglu et al., 2017; Ruffinengo et al., 2009; Spielberger, et al., 1983). The STAI-AD has demonstrated strong psychometric properties with strong internal consistency in diverse populations (α =0.86-95) (Bergua et al., 2012; Spielberger et al., 1983), and high test-retest reliability over two months (α =0.65-.0.75) for trait anxiety (Spielberger et al., 1983). Moderate test-retest reliability has been demonstrated for state anxiety (α =0.33) which aligns with the variability of state anxiety based on current context (Spielberger et al., 1983). Additionally, the STAI-AD demonstrates strong concurrent validity with other anxiety scales such as the Anxiety Scale Questionnaire (r=0.73) (Spielberger & Sydeman, 1994), and construct validity has also been established for the trait scale when comparing psychiatric patients to healthy individuals and the state scale when comparing scores in non-stressful situations to stressful situations (Spielberger et al., 1983; Spielberger & Sydeman, 1994). Permission was obtained, and fees were paid for the use of the STAI-AD.

The RAND 36-Item Health Survey, also known as the Short Form 36 (SF-36), is a 36-item self-report questionnaire using various ranking questions to measure health related quality of life (HRQOL) (Brazier et al., 1992). The SF-36 examines eight dimensions of HRQOL (physical functioning, physical and emotional limitations, social functioning, bodily pain, general health, energy/fatigue, and mental health) and takes 5-10 minutes to complete (Brazier et al., 1992). The higher the score (100) the better the health and wellbeing, the lower the score (0) the poorer the health and wellbeing. Chrispin et al. (1997) examined the psychometric properties of the SF-36 in general ICU patients (n=166) and found strong internal consistency (α >0.85) in all dimensions except mental health (α >0.77). Reliability coefficients were also high (r > 0.75). Brazier et al. (1992) examined the SF-36 in the

primary care setting and found strong levels of internal consistency ($\alpha > 0.85$) and reliability ($r > 0.75$) in all dimensions except social functioning ($\alpha > 0.73$, $r > 0.74$), and strong test-retest reliability at 2 weeks ($r = 0.60$-0.80). Construct validity was determined to be adequate in both studies when comparing results between age ($p < 0.01$) and sex ($p < 0.01$) (Brazier et al., 1992; Chrispin et al., 1997).

Cortisol is a frequently used biomarker that evaluates the physiological stress response and provides insight into HPA axis activity (Kudielka et al., 2012; Smyth et al., 2013). The body's HPA axis response can become dysregulated in anxiety and depression, affecting the release of cortisol (Cowen, 2010; Mikkelson et al., 2017). Serum cortisol measures total cortisol through serum sample and is more sensitive to lower levels compared to salivary samples (Vieira-Correa et al., 2019). Research has found serum cortisol levels can distinguish between those with depression and those without depression (Jia et al., 2019). Serum cortisol samples were collected from participants during home visits and delivered to a local lab center for assessment. Cortisol release aligns with the body's circadian rhythm and cortisol levels are highest in the morning upon awakening and decline throughout the day (Dziurkowska & Wesolowski, 2021; Mohd Azmi et al., 2021). The collection of morning cortisol levels is the best predictor of endocrine function and HPA axis regulation when conducting single point testing (El-Farhan et al., 2017; Montes-Villarreal et al., 2020; Mohd Azmi et al., 2021). Yet when monitoring for mental disorders such as depression, single point testing can also be done in the afternoon when levels are more constant (Dziurkowska & Wesolowski, 2021). Cortisol collection times were established with each participant based on their availability and then took place at the same time of day across all data collection time points (baseline, four weeks, and eight weeks). Normal morning serum cortisol levels range

from 6.2−19.4 μg/dL and afternoon serum cortisol levels range from 2.3-11.9 μg/dL (Laboratory Corporations of America, 2022).

Procedure

Companion Dog-Walking Intervention

Those assigned to the intervention group took part in a home-based companion dog-walking intervention. The participants in the companion dog-walking group received verbal and written instructions (Appendix F). Participants were also given information on dog walking safety tips and the benefits of dog walking prior to starting the intervention (Zeltzman & Johnson, 2011). Given the varying levels of exercise tolerance anticipated for ICU survivors (Gandotra et al., 2021; Mackney et al., 2022) and that lower dosages of recommended exercise have demonstrated higher intervention adherence without compromising outcomes (Trivedi et al., 2011), participants were asked to walk their dog in the locations of their choice at least three times per week for ≥30 minutes per day. Consistent with public health activity recommendations, participants were given the choice to complete all 30 minutes of dog-walking at once, or in bouts ≥10 minutes (Haskell et al., 2007; U.S. Department of Health and Human Services, 2018). Participants were given a Fitbit accelerometer and diary log (Appendix G). To monitor intervention adherence, participants were asked to wear the accelerometer during waking hours during the eight-week study and were asked to record walking times (start and end) in the diary log throughout the eight-week study. Using both diary logs and activity monitors enhances physical activity adherence monitoring (Sylvia et al., 2014) and is recommended to identify periods of interest from the collected accelerometer data (Edwardson et al., 2017). Participants were called after the first week and asked if they had started and what specifically they had been doing to ensure the intervention had been initiated and implemented appropriately. During weeks two and three,

participants were called to promote adherence, ask about dog walking, and answer any questions. At the end of week four, home visits were conducted to promote adherence; questions were answered; and the first half of the diary log, serum cortisol, and questionnaires were collected. Accelerometer and diary data from the first four weeks were evaluated for consistency and intervention adherence. If inconsistencies existed or participants were not adhering to the intervention, they were called and given additional education. During weeks five, six, and seven participants were called to promote adherence, ask about dog walking, and answer any questions. A final home visit was conducted at the end of week eight where the diary log, accelerometer, serum cortisol, questionnaires, and acceptability exit survey were collected.

Attention-Control Education Intervention

Those assigned to the control group received a home-based attention control education intervention. Participants received verbal and written instructions (See Appendix H) and were given a folder with educational brochures that were assigned every week. The brochures were purchased from the National Humane Education Society (NHES) (2022), the Pet Health Network (2021), and the Humane Society of the United States (2022) and included topics related to health and healthy living for dogs. The weekly topics were as follows: (1) winter and summer care tips; (2) preventative care; (3) dog bite prevention; (4) keeping pets safe; (5) canine leptospirosis, canine parvovirus, and other parasites; (6) reasons and response to itching in dogs; (7) traveling with pets; and (8) pet first aid. None of the educational materials included information about dog walking or the benefits of dog walking. Participants were provided with a Fitbit accelerometer and diary log. Participants were asked to wear the accelerometer during waking hours throughout the eight-week study and were

asked to record reading times (start and end) in the diary log throughout the eight-week study. Participants were called after the first week and were asked if they had started and for a description of what they had been doing to assess appropriate initiation and execution of the attention control education intervention. During weeks two and three, participants were called to promote adherence, ask about the educational materials, and answer any questions. At the end of week four, home visits were conducted to promote adherence; questions were answered; and the first half of the diary log, serum cortisol, and questionnaires were collected. Diary and accelerometer data from the first four weeks were evaluated for intervention adherence. If participants were not adhering to the attention control intervention (i.e. completing the assigned readings), they were called and given additional education. During weeks five, six, and seven participants continued to be called to promote adherence, ask about the education resources, and answer any questions. A final home visit was conducted at the end of week eight where the diary log, accelerometer, serum cortisol, questionnaires, and acceptability exit survey were collected.

Participants in both groups completed the CES-D, STAI-AD, and SF-36, along with collecting serum cortisol samples at baseline, at the end of week 4, and again at study completion (end of week 8). The Center for Health Insight of UMKC was used for data documentation and management using the software Research Electronic Data Capture (REDCap) (Harris et al., 2009). Steps were taken to enhance and evaluate intervention fidelity throughout the study and within both groups. A written protocol was developed, a participant's understanding of their assigned intervention was evaluated through verbal discussion after week one, and participant intervention fidelity was monitored through accelerometers and self-report diary logs.

The Fitbit Charge 4 Device is a triaxial wrist-worn accelerometer that captures and reports step count, step speed, distance, sedentary time, and moderate to vigorous physical activity (MVPA). The Fitbit Charge has not been assessed in the ICU survivor population but demonstrates adequate concurrent validity with gold standard research grade accelerometers in adults in free living environments (r=0.862) (Brewer et al., 2017). The Fitbit Charge has also demonstrated adequate intra-rater reliability with research grade accelerometers or manual counts in adults with motor impairments such as knee osteoarthritis (ICC=0.62) (Collins et al., 2019) and Huntington's Disease (ICC=0.81), along with community dwelling older adults (ICC=0.86-0.89) (Farina & Lowry, 2018; Tedesco et al., 2019). While walking a dog on a leash may cause inconsistent wrist movements, the wrist worn Fitbit Charge has been shown to be a reliable measure of step counts in individuals with Huntington's Disease- a disease that often includes motor symptoms such as involuntary jerking, tremors, and/or muscular rigidity (Mann et al., 2022). Mann et al. found the Fitbit's average counts were not influenced by the severity of motor symptoms. Additionally, Leung et al., (2022) conducted a meta-analysis and found, for adults in free living environments, hip versus wrist worn devices did not significantly influence validity data, and Floegel et al. (2017) compared ankle, hip, and wrist worn devices in older adults with varying physical abilities/activity limitations and found although ankle devices were most accurate, all locations were acceptable. Overall, the Fitbit Charge was determined to be an appropriate tool to monitor and measure objective physical activity data and changes due to research interventions (Collins et al., 2019).

Data Collection

Institutional review board (IRB) approval was obtained by both UMKC and CommonSpirit Health. For in-patient hospital recruitment, unit nurse managers and staff nurses were collaborators in the recruitment process. After being informed of a potential participant, the nurse made initial contact by providing a recruitment flyer with basic study information. When a potential participant communicated interest in the study, the completed permission form was verified, and the potential participant was visited in the hospital for an introductory visit. For out-patient recruitment, potential participants reached out directly, and an introductory visit was arranged. During the introductory visits information was provided about the study, risks and benefits were reviewed, informed study consent was obtained, and the screening tools for inclusion criteria were administered (demographic survey, PROMIS 6-item depression short form, PROMIS 6-item anxiety short form, TUG tool, UBACC, along with dog ownership status, dog-walking habits, and health and behavior of the dog, and the Columbia Suicide Severity Rating Scale-Screen Version if applicable). Those meeting inclusion criteria were enrolled, assigned a study number, and randomly assigned to the companion dog-walking intervention group or attention control education group using 1:1 block randomization. After being discharged home, an initial home visit was conducted and participants were provided with information about the interventions, questions were addressed, and baseline assessments were collected (CES-D, STAI-AD, SF-36, and serum cortisol samples).

After the initial visit, participants were contacted weekly by phone and then in-person during weeks four and eight to answer any participant questions. Total time involved for those in the companion-dog walking group was estimated to be 120-155 minutes per week,

and a total of 18 hours over the course of the eight-week study. Total time involved for participants in the attention control education group was estimated to be 50-95 minutes per week and a total of 10-hours over the course of the study. To increase participant retention and engagement, participants were contacted weekly and thanked with a $20 gift card after completing the assessments during week four and a $30 gift card, along with a bandana for the dog(s), at the end of the eight-week study after completing the final assessments and exit survey.

Limitations and Potential Hazards

Procedural limitations included the potential for participant protocol nonadherence, required time commitment of the participants, and the inability to visualize and directly monitor participant adherence to the interventions. In response to these limitations participants were contacted weekly and given progressive gift cards to encourage continued participation, and the use of accelerometers and diary logs were used to monitor participant protocol adherence and intervention fidelity.

Orientation Plan for Data Collector

Given this study was conducted with a single researcher/data collector, a written protocol, script, and checklist were developed to facilitate intervention fidelity. An experienced researcher with expertise in fidelity monitoring also assisted by observing protocol fidelity with practice participants to ensure the protocol was followed consistently.

Data Analysis

Data was managed and stored securely in REDCap, a Health Insurance Portability and Accountability Act (HIPAA) compliant data storage and research manager (Harris et al., 2009). Data from REDCap were downloaded into the data analysis software SPSS Statistics-

Version 29 which was used to facilitate data analysis. The biostatistician assisting with the study reviewed the data analysis process. The exploratory aims of the study were to test the differences between and within the two groups, and therefore the initial plan was to analyze significant differences using non-parametric statistical tests and an alpha level of 0.05 (Corder & Foreman, 2014; Kellar & Kelvin, 2013). However, due to the small sample size and reduced intervention fidelity by participants, significance testing was not done to avoid erroneous conclusions (Curtis et al., 2015). Alternatively, trends were examined using data visualization and trend analysis (Cramer e al., 2016; Kumar et al., 2020; Yau, 2011). Consequently, all results were interpreted with caution.

Descriptive Statistics

Demographic data were cleaned, missing data were noted, and data were analyzed and described. Nominal level variables (biological sex, ethnicity, marital status, education level, reason for admission, and ventilator use) were analyzed and reported as frequency percentages. Ratio level variables (age, length of ICU stay, and time on ventilator) were reported using mean, standard deviation, and range.

Primary Research Questions

Feasibility. The first primary research question asked, what is the feasibility of conducting an RCT comparing a companion dog-walking intervention to an attention control education intervention on depression, anxiety, serum cortisol, and QOL in adult ICU survivors? Feasibility was evaluated based on the following questions and data collection:

1. To what extent did the recruitment procedure produce study participants?
    - Number of ICU patients screened.
    - Number of ICU patients meeting eligibility based on EHR data.

- Number of participants enrolled.
- Total time of recruitment.
- Number of potential participants agreed to screening process and visit/Number of patients approached.
- Number of participants enrolled in the study/Number of ICU patients approached.
- Number of participants consented and enrolled/Total number of potential participants identified.
- To what extent were minority goals achieved?
- To what extent were there demographic differences between eligible participants and those declining to participate?

2. How many participants met inclusion and exclusion criteria?
    - Number of potential participants who met all criteria for enrollment/Total number of potential participants screened
3. What were the obstacles to recruitment?
    - If recruitment goals were not achieved, reasons were documented and assessed.
4. What was the attrition rate of participants?
    - Number completing the study/Number consented and enrolled
    - Number of participants crossing over from assigned group
    - If participants withdrew, the week they withdrew was documented to calculate dose of the intervention
5. To what extent were participants masked to their assigned group?

- Number of participants successfully masked/Total number of participants

6. To what extent was fidelity of the intervention maintained by participants?
    - Accelerometer (stepping time) and diary log data were reviewed to identify if dog walking frequency and time requirements were completed.
7. To what extent were measurements completed?
    - Total number of measures completed per participant/Total number assigned to each participant
    - Total number of measures completed by all participants/Total number assigned to all participants
    - Measures were reviewed for frequently missed questions
    - Frequently missed tools were reviewed along with timing of measurement completion
    - If goals for serum cortisol samples were not achieved, reasons were documented and assessed.
8. What was the extent and patterns of missing data?
    - Number of participants with missing data points
    - Number of total missing data points
    - Missing data points/Total potential data points (including data obtained from measurement tools and demographic data)

Acceptability. The second primary research question asked, for adult ICU survivors, what is the acceptability of participating in an RCT comparing a companion dog-walking intervention to an attention control education intervention on depression, anxiety, serum cortisol, and QOL? Participants completed an acceptability exit-survey at the end of the study

and acceptability was analyzed by evaluating survey answers and trends. Items were reported as descriptive statistics using frequency percentages. Questions that were addressed to evaluate acceptability were: (1) What was the acceptability of the time spent in the study and per session, (2) what was the acceptability of completing the measurement tools, (3) what was the acceptability of the intervention (corresponding questions developed in alignment with the TFA (Sekhon et al., 2017), (4) to what extent do study participants intend to continue the intervention after the end of the study, (5) what suggestions for improvement do participants have, and (6) what were reasons for participation?

Exploratory Outcomes. The exploratory questions were: What were the differences in depression, anxiety, serum cortisol, and QOL between a companion dog-walking intervention compared to an attention control education intervention; and what were the differences in depression, anxiety, serum cortisol, and QOL within the companion-dog walking intervention group and the attention control education intervention group? The dependent variables of depression, anxiety, and QOL produce composite scores which were used as the basis for trend analysis to analyze and interpret results. Trend analysis focused on the movement of composite scores over the eight-week study identifying net change and upward or downward trends. Individual tracking of participants took place, followed by a comparison within their assigned group, and then between groups. Visualization of trends took place by charting scores on a line graph to visualize trends over time within and between groups; line graphs are one of the best ways to compare and demonstrate change in a dependent variable (Kumar et al., 2020). Identified trends were then compared to the current literature to understand results and potential treatment effect (Cramer et al., 2016). Finally, contextual factors were considered to gain a better understanding of results. Graphical and

narrative visualization are essential to understanding data trends (Kumar et al., 2020; Yau, 2011).

Limitations

Limitations related to data collection and analysis were single masking, self-report instruments used to measure anxiety and depression, and sample size. As part of a dissertation research where all aspects of the study must be performed, only masking of participants was possible. To address this limitation and limit potential bias and/or influence on the participants and outcomes, strict protocol adherence was maintained (Chan et al., 2013). The measurement tools chosen also limited potential researcher bias because they did not require subjective interpretation (Kahan et al., 2014). Additionally, the STAI-AD, SF-36, and CES-D are self-report measures that may influence internal validity due to self-report bias (Althubaiti, 2016; Howard et al., 1979). In response to this limitation, serum cortisol was measured to provide an objective measure of psychological health. Finally, due to the small sample size, the exploratory outcomes were evaluated as data trends only and were not used to draw decisive conclusions about intervention effect (Arain et al., 2010; Orsmond & Cohn, 2017; Thabane et al., 2010).

Human Subjects Protection

Current certification in human subjects' protection was maintained, and IRB approval was obtained prior to study initiation. Informed consent (Appendix I) was also obtained from all participants, which included the potential risks and benefits of participation. For participants in the dog walking group, there was a risk for injury during dog walking, such as falls (Cosco & Storey, 2017; Stevens et al., 2010), and a risk that the dog may break away from their owner or become aggressive towards other dogs or people. To lessen these risks,

potential participants were screened for physical ability and health using the electronic health record and TUG test, and healthcare provider approval was required if indicated by the healthcare provider authorization screening tool. Dog health and behavior was also screened prior to beginning the study using a screening tool designed for companion dog interventions and developed by animal behavioral experts (Ng et al., 2021). If the dog or potential participant did not meet the requirements, they were unable to participate in the study. Participants in the dog-walking intervention were also given education on safe-dog walking habits prior to initiating the intervention; the education included safety considerations for both the person and dog (Zeltzman & Johnson, 2011).

This was a home-based study where participants completed the interventions independently. If the participant sustained a fall or injury, they were to seek care with their healthcare provider as usual. If an injury was sustained, the participants were responsible for the treatment and associated costs. If the participant's dog was injured, the participant was to seek care from a veterinarian as usual. If the participant's dog injured another person or dog, the participant was responsible for any treatment and associated costs.

Those with severe depression and anxiety were excluded from the study and were referred for immediate treatment and given information about the local mental health organization, Colorado Wellness Recovery. All patients admitted to the hospital were assessed for suicidal ideation by their healthcare team and were referred to appropriate resources. If there was a concern that a participant had become suicidal while in the study, the Columbia-Suicide Severity Rating Scale-Screen Version was used to assess suicide severity. If a participant was assessed to have a high risk of suicide (answers "yes" on questions 4 or 5 and "yes, past three months" on question 6) they were unenrolled from the

study and immediately referred to Colorado Crisis Services and the local emergency department. If a participant scored moderate risk (answers "yes" on question 3 or "yes, lifetime" on question 6), the participant would be referred to their primary care provider to seek a behavioral health referral and/or local behavioral health services through Colorado Wellness Recovery for full assessment. Based on findings from this assessment, the participant would be unenrolled if mental health treatment was initiated.

Risks related to blood drawn from the arm included some pain with needle insertion and a slight risk of bruising and/or infection at that site. Some people get lightheaded, nauseous, or faint with blood sample collection. Accordingly, participants were informed that drinking at least 2 glasses of water and having a snack before the blood draw may lessen these risks. Guidelines for safe and clean blood sample collection were followed.

The activity monitor could have caused slight skin irritation for participants. To reduce the risk and occurrence of skin irritation, participants received education on proper placement, application, and maintenance of the monitor.

There were also risks that a participant and their information could be identified. Participants were assigned an enrollment number, information was de-identified, digital information was stored on a password-protected laptop computer in REDCap, any hard copies were stored in a locked filing cabinet, and all items were stored in a locked office. Access to participants' individually identifiable data was restricted. As a dissertation research study, various experts (dissertation committee, biostatistician, experienced researcher with expertise in intervention fidelity) supported the process. However, these individuals were not directly involved in conducting the research and did not have access to any identifiable participant data. Participants were informed that participation was voluntary, they had the

right to refuse participation or to discontinue participation at any time without consequence and assured that such a decision would not affect medical care in any way.

Participants were informed of potential benefits of the intervention which could include improvement in depression and anxiety symptoms and improved quality of life. Participants could also benefit from knowing that they were contributing to medical knowledge. The information learned from this study could benefit other ICU survivors in the future, and benefits to science and/or society could include better understanding of how pet dogs can help ICU survivors.

Monitoring, Documentation, and Reporting Adverse Events. Expected and unexpected adverse events were monitored via weekly communication. Participants were asked to report any concerns they had during those weekly communications. Outside the weekly communications, participants were informed they could reach out at any time during the study via phone or email. In the informed consent, participants were instructed to share any adverse events that occurred. Per chain of command, the dissertation chair would also be informed of any adverse events. If a participant appeared to have experienced an expected or unexpected serious adverse event related to participating in the study they would be withdrawn immediately from the study and the IRB would be notified.

CHAPTER 4

RESULTS

Chapter 4 contains the results of the study as they relate to the primary and exploratory research questions. The chapter includes demographic results, results for feasibility and acceptability, and results for the exploratory research questions.

Demographic Data

A total of 10 participants enrolled in the study. Two participants were lost to follow-up prior to baseline data collection and three participants withdrew from the study due to declining health status at the following time points: prior to baseline data collection (*n*=1), after baseline data collection but prior to participating in their assigned intervention (*n*=1), and after completing four weeks of the assigned intervention and the four-week outcome measures (*n*=1). In total, six participants completed the first four weeks of the intervention, and five participants completed the full eight-week study. Please see the CONSORT Flow Diagram in Figure 4.1 for a summary of participant recruitment and the flow of participants through the study. Demographic data comparisons between groups can be found in Table 4.1.

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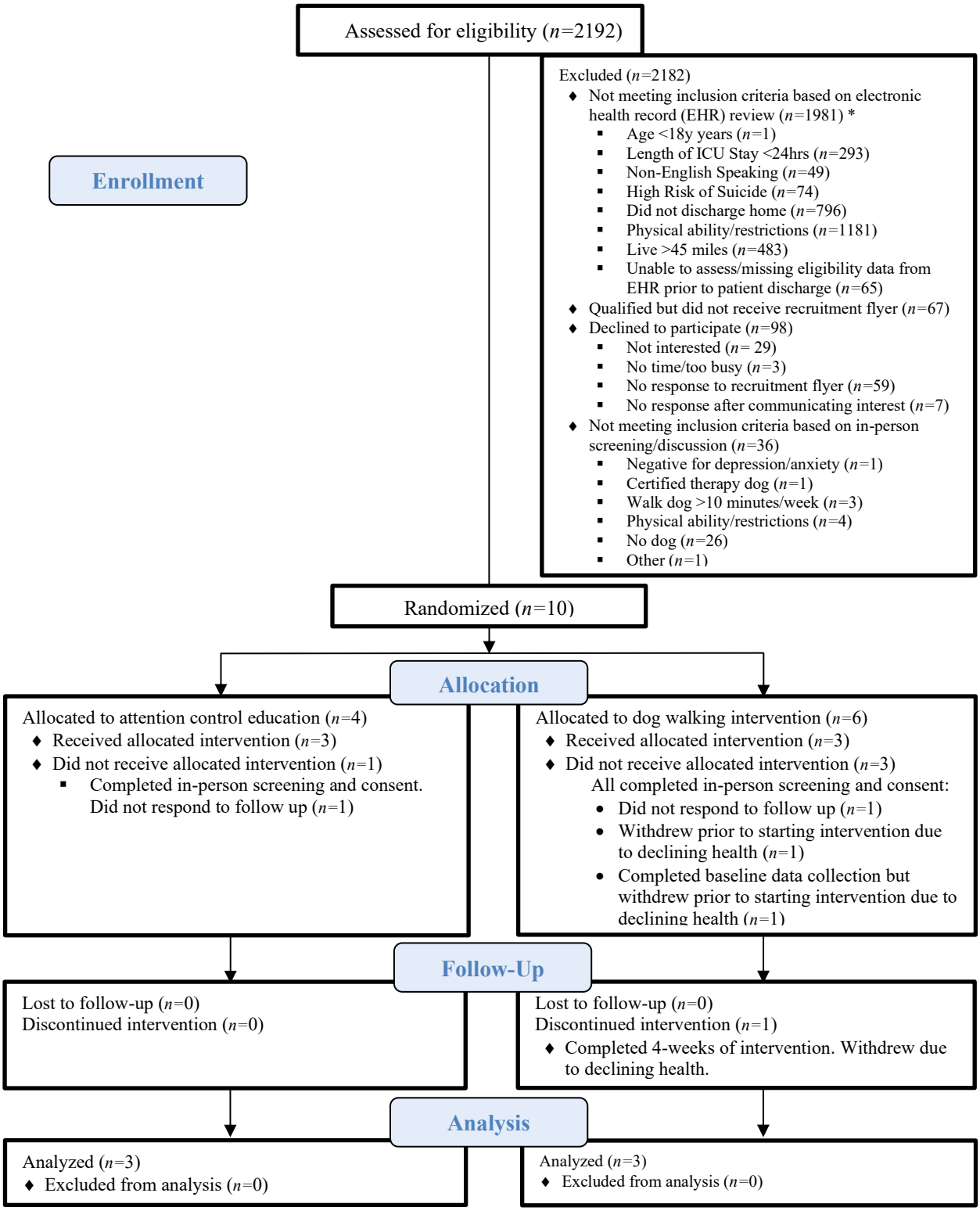
Figure 4.1

CONSORT Flow Diagram: Participant Recruitment and Flow through the Study



Note: *ICU patients could be excluded for more than one reason

Table 4.1

Demographic Group Comparisons

Characteristics	Group		
	Withdrew* *n=4*	Attention Control *n*=3	Dog-Walking Intervention *n*=3
Individual Characteristics			
Age			
Age, Range	25-60	49-71	48-76
Age, Mean (SD)	48.8 (16.2)	61 (11.1)	60.3 (14.3)
Ethnicity (No. [%])			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Black or African American	0	0	0
Hispanic or Latino	2 (50%)	0	0
Native Hawaiian/Other Pacific Islander	0	0	0
White	2 (50%)	3 (100%)	3 (100%)
Marital Status (No. [%])			
Unmarried (Single, separated, divorced, widowed)	2 (50%)	2 (50%)	1 (33.3%)
Married/Long Term Partner	2 (50%)	1 (33.3%)	2 (66.7%)
Highest Achieved Education Level (No. [%])			
High school Diploma/Post-secondary non-degree award/Some college no degree	2 (50%)	1 (33.3%)	0
Associate /Bachelor's/Graduate Degree	2 (50%)	2 (66.7%)	3 (100%)
ICU admission characteristics			
Reason for Admission (No. [%])			
Medical	2 (50%)	3 (100%)	1 (33.3%)
Surgical	0	0	0
Neurological/Trauma	0	0	2 (66.7%)
Other	2 (50%)	0	0
Length of ICU Stay (days)			
Length of Stay, Range	1-3	2-7	1-7
Length of Stay, Mean (SD)	2.3 (0.95)	3.8 (2.8)	3.3 (3.2)
Time on a Ventilator (days)	0	1.5	1.25

Note: Due to the small sample size demographic details were combined or removed to protect the identity of participants

*Enrolled in the study but withdrew prior to participating.

Feasibility

The first primary research question was, what is the feasibility of conducting an RCT comparing a companion dog walking intervention to an attention control education intervention on depression, anxiety, serum cortisol, and QOL in adult ICU survivors? Results addressing feasibility are presented below.

To What Extent Did the Recruitment Procedure Produce Study Participants?

In-patient hospital recruitment took place over 10 months (May 2023-March 2024). During that time, 2,191 ICU patients were identified and screened through the EHR, 210 met eligibility criteria, 143 eligible participants were approached with a recruitment flyer, and 10 participants enrolled. Of the 143 eligible participants approached, 17.5% (*n*=25) communicated interest in the study by returning the permission form to their nurse (*n*=22) or reaching out directly using the contact information on the recruitment flyer (*n*=3); 10.5% (*n*=15) agreed to the full screening process; and 7% (*n*=10) were enrolled.

Recruitment flyers were also displayed in the waiting rooms of four specialty out-patient clinics for six months (October 2023-March 2024). During that time, two potential participants responded directly to the flyers and communicated interest in the study. The first potential participant was screened but did not qualify based on eligibility criteria. The second potential participant communicated interest via email but did not respond to follow-up attempts and therefore was not screened for eligibility. In total, 2,192 ICU survivors were screened from both recruitment methods, and 10 enrolled (7%).

Minority Recruitment

The goal was to determine to what extent the recruitment strategy enrolled a sample population reflecting the demographics of ICU survivors within the United States. According

to large scale studies, 50-70% of ICU survivors are male (Castillo et al., 2016; Jackson et al., 2014; Rydingsward et al, 2016) and 10-22% of ICU survivors are non-white (Jackson et al., 2014; Rydingsward et al., 2016). Of the 10 participants enrolled, two (20%) identified as Hispanic/Latino, eight (80%) identified as white, four (40%) were males, and six (60%) were females. A total of 49 potential participants were excluded during EHR review because they did not read/speak English. Overall, compared to the demographics of ICU survivors in the United States, the recruitment strategy produced a comparable number of minority participants but more females than males.

Demographic Differences Between Eligible Participants and Those Declining to Participate

There were no potential participants who agreed to the screening process, qualified, and then declined to participate. Of the ten participants who enrolled, two were lost to follow up because they did not respond to follow-up communication efforts.

How Many Participants Met Inclusion and Exclusion Criteria?

Of the 2,191 patients screened via the EHR, 210 (9.6%) met initial inclusion criteria and 143 (6.5%) received a recruitment flyer (67 eligible participants did not receive a recruitment flyer due to researcher and hospital-based limitations). Of the 143 potential participants who were approached with a recruitment flyer, 15 (10.5%) agreed to the full screening process. After full screening, five (33%) potential participants were excluded based on eligibility criteria, and a total of 10 (66%) participants met inclusion criteria and were enrolled. Only one patient from the out-patient clinic sites was screened and they did not meet inclusion criteria.

Many of the ICU patients screened were excluded for more than one reason (See Figure 4.1). The most common reason for exclusion was related to physical ability/restrictions (*n*=1,181, 54%). More specifically, 233 (10.6%) ICU patients were not cleared by physical therapy and/or occupational therapy, suggesting they required additional support to safely complete physical activity and/or activities of daily living; 221 (10.1%) were unable to walk in the halls independently; 343 (15.7%) had activity restrictions related to recent surgeries or injuries; and 384 (17.5%) used mobility aids such as canes, walkers, or crutches. The second most common reason for exclusion was being discharged some place other than home (*n*=796, 36.3%), such as another acute care hospital, a long-term care center, a rehabilitation center, hospice, and anyone deceased. Of the ICU patients excluded, 483 (22%) exceeded the distance limit of 45 miles, 293 (13.4%) spent less than 24 hours in the ICU, 74 (3.4%) were at a high risk of suicide, 49 (2.2%) did not read/speak/understand English, and one (0.05%) patient was less than 18-years-old. Finally, a total of 65 charts could not be fully assessed because eligibility data were missing from the EHR (*n*=53), or researcher availability prevented EHR access prior to a patient's discharge (*n*=12).

Of the 143 patients who received recruitment flyers, 31 patients informed the nurse they did not qualify because they did not own a dog (*n*=25), they had physical limitations preventing them from walking their dog (*n*=2), they walked their dog on a regular basis (*n*=2), they recently moved and lived >45 miles from the recruitment site (*n*=1), and they did not have time to participate (*n*=1).

There were 16 patients who agreed to the full screening process; 15 patients came from in-patient hospital recruitment, while one patient was from the out-patient clinics. Everyone who met inclusion criteria enrolled in the study (*n*=10), while six were excluded

because they had physical restrictions (*n*=2), did not have a dog (*n*=1), walked their dog at baseline (*n*=1), and were negative for symptoms of anxiety and depression (*n*=1). The patient who was from an out-patient clinic was excluded because their dog was a certified therapy dog.

What Were the Obstacles to Recruitment?

The initial recruitment goal was a sample of 30 participants, with an anticipated attrition rate of 15%, estimating a final sample size of 24. The final results included a total of 10 enrolled participants with an attrition rate of 50%, resulting in five participants who completed the full study. Due to low recruitment, a second recruitment strategy was initiated. Obstacles to recruitment are detailed for both recruitment strategies: in-patient hospital recruitment and out-patient clinic recruitment.

In-Patient Hospital Recruitment

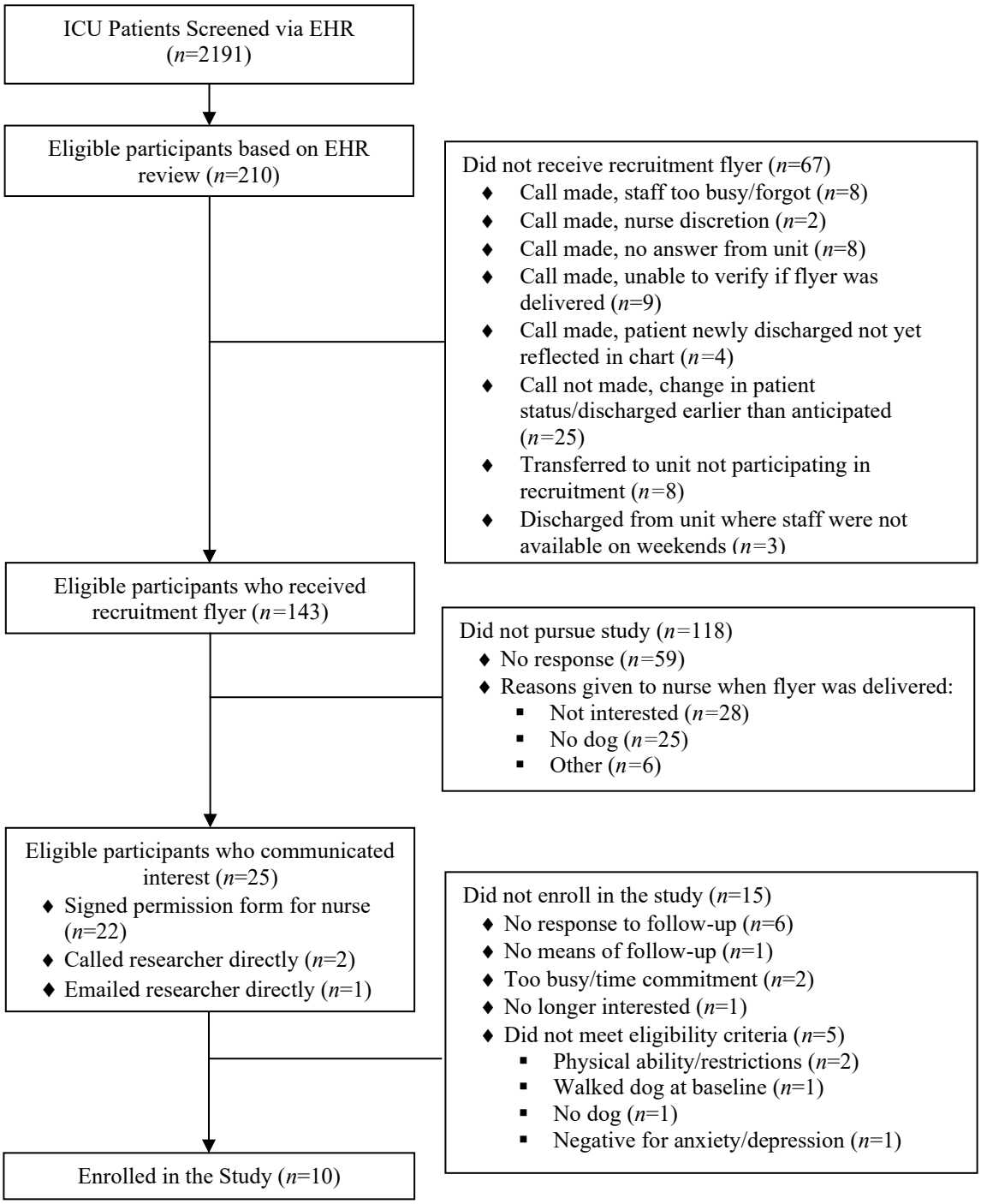
Obstacles to recruitment included patient turnover rate, researcher limitations, and hospital/staff constraints. Please see Figure 4.2 for a summary of the hospital recruitment process and results.

Patient Turnover Rate. Patient progression from admission to discharge typically included ICU admission, transfer to a lower acuity care unit, and then discharge from the hospital. Patients moved quickly through the hospital and were discharged as soon as medically cleared. The fast-paced nature of a patient's admission, movement between units, and a high turnover rate of patients resulted in recruiting obstacles. Of the 210 ICU patients who met initial eligibility criteria, only 143 (68%) received a recruitment flyer. Of the 67 eligible patients who did not receive a recruitment flyer, 25 (37%) did not receive a flyer due to the rate of patient progression. In 17 instances, the patient was discharged sooner than expected and therefore the recruitment flyer was not delivered. In eight instances, the

recruitment flyer was not delivered due to the short time between a patient meeting eligibility criteria and then being discharged.

Figure 4.2

Flowsheet of Hospital Recruitment Process and Result



Researcher Limitations.

EHR Review. The EHR offered a lot of valuable information, but there were limitations on what was reported in the chart and when the chart was updated, which created obstacles to both screening and recruitment. During EHR screening, of the 2,191 ICU patients screened, 65 (3%) charts could not be fully assessed. In most of these cases (*n*=53), the charts could not be screened for all eligibility criteria because some eligibility criteria were not recorded in the record. During recruitment, of the 67 eligible patients who did not receive a recruitment flyer, there were two (3%) instances where a patient qualified based on EHR review, but the nurse deemed the patient inappropriate to receive a flyer due to concerns not noted in the EHR.

Another obstacle related to EHR review was the timing of when charts were updated. Charting is not always completed by staff in real time and consequently there was a delay in determining patient status. With the shortened time between hospital admission and discharge, any delay could hinder screening and the successful delivery of recruitment flyers. There were four instances where the EHR indicated an eligible participant was still an in-patient, however when the unit nurse was called to request the delivery of a recruitment flyer, the nurse reported the patient had been discharged.

Inclusion/Exclusion Criteria. The study included a large number of inclusion and exclusion criteria, most of which were essential given the population of interest and ensuring the safety of participants and their dogs. However, participants were excluded if they lived >45 miles of the hospital due to practical limitations of the researcher. Of the 2,192 participants screened, 484 (22%) were excluded based on living location. The initial inclusion standard was those living within a 30-mile radius of the recruitment site. Request to

extend the travel distance was amended twice in the IRB application; from 30 to 35 miles and from 35 to 45 miles. Due to this change in inclusion criteria, 278 potential participants who would have been previously excluded remained eligible based on living location, and one participant who would have previously been excluded was enrolled.

Schedule. Due to the wide range of times patients were discharged throughout the day, the timing of charting, and the patient discharge rate, EHR screening often required accessing and assessing charts multiple times per day. Due to schedule constraints, there were circumstances where a patient's record was not fully assessed for eligibility criteria before a patient was discharged (n=12).

Hospital/Staff Constraints.

Workload. Of the 67 eligible participants who did not receive a recruitment flyer, 33 (49.2%) did not receive a flyer because of nurse workload and patient care. In eight cases, the nurse was called to request the delivery of a recruitment flyer, however the recruitment flyer was not delivered because the nurse reported being "too busy" or getting "caught in an emergency." In another eight cases, a call was made to the unit but there was no answer. In nine cases, a call was made to request the delivery of a recruitment flyer, but delivery of the flyer was not verifiable.

Between both hospital sites, there were a total of 13 in-patient units. All but one unit manager agreed to participate prior to study initiation. The manager who declined to participate reported concerns about workload for themselves and for their staff. After ongoing communication, another manager, whose staff collaborated closely with the unit, volunteered to lead recruitment. Five months after study recruitment began, all 13 units were

participating. During those five months, eight eligible participants did not receive a flyer because they were transferred to the unit not participating in recruitment.

Schedules. Two managers who agreed to facilitate recruitment could not support recruitment efforts on weekends. Due to this restriction, three eligible participants did not receive recruitment flyers because they were discharged on Saturday or Sunday.

Changes in Leadership. Recruitment site two had consistent unit managers throughout the study period and supported the recruitment process from the beginning. At site two, 79.4% (54/68) of eligible patients received a recruitment flyer. Recruitment site one experienced high manager turnover during the study period; site one had nine units participating in recruitment and there were six new managers during the study period. At site one, 62.7% (89/142) of eligible participants received a recruitment flyer.

System Level Changes. During the study period, there was a change in organizational ownership; the healthcare system the two hospitals belonged to was bought out by another healthcare system. This change required a 12-day pause in recruitment because of the time necessary to complete additional administrative requirements. This change in hospital ownership was cited often by staff as a cause of added stress.

Out-Patient Clinic Recruitment

The out-patient clinic recruitment strategy, initiated five months into the study, yielded two interested potential participants. One of these potential participants was screened and did not qualify based on eligibility criteria; the other did not respond to follow-up communications. The primary obstacle to recruitment was likely the lack of personal engagement. The recruitment flyers were visible in the clinics, but clinic staff did not engage with the recruitment process; the clinic staff did not promote or bring attention to the flyers.

Potential participants were required to take the initiative to engage with the flyers independently. The exception was one clinic manager encouraged their staff to bring attention to the flyers when working with patients they felt may be interested. The interested individual who was determined to be ineligible, reported seeing the flyer in this clinic.

A QR code was added to the recruitment flyers so potential participants could learn more about the study and make a more informed decision about participating. Based on QR code analytics, during the six months the QR code was present on the flyers, the code was scanned 26 times by seven different users. Whether the QR code was scanned by someone in the hospital or an out-patient clinic could not be determined, but overall engagement with the QR code was low.

What Was the Attrition Rate of Participants?

Of the 10 participants enrolled, five completed the study, resulting in an attrition rate of 50% (*n*=5). Four participants withdrew from the study prior to starting the intervention and one withdrew after completing the first four weeks of the dog walking intervention. Three of the participants who withdrew reported declining health status and all were assigned to the dog walking intervention. No participants crossed over from their assigned group.

To What Extent Were Participants Masked to their Group Assignment?

Participants were asked what treatment group they were assigned to after study completion. Three participants reported being *"unsure"* and one reported being in the treatment group when they were in the control group. One participant correctly identified themselves as being assigned to the control group, and one participant correctly identified themselves as being assigned to the treatment group. Overall, 66.7% of participants were successfully masked to their group assignment.

To What Extent Was Fidelity of the Intervention Maintained by Participants?

Intervention fidelity was monitored using diary logs and accelerometers. For those in the attention control education group, self-report diary logs were used to determine if the assigned weekly readings were completed. For any participant who reported *dog walking* on their diary log, accelerometer data were used to verify the reported activity. Accelerometer data were also used to determine if dog walking frequency and time requirements were completed for those in the dog walking intervention group. First, accelerometer data were analyzed to determine if the accelerometer data aligned with dog walking reported on the diary log (see Table 4.2). Next, intervention fidelity by participants was analyzed. Dog walks that could be verified by the accelerometer were used to determine intervention fidelity.

Table 4.2

Comparison Between Diary Logs and Accelerometer Data

Walks Recorded in Diaries [Range]	Walks Verified with Accelerometer [Range]	Reason(s)	Walks Accounted for with Accelerometer but not Reported in Diary	Reason(s)
Dog Walking Group				
179 [10-157]	133 (74%) [12-109]	Unable to verify walks: Participant recorded not wearing Fitbit; Participant estimated time of walks (ex: "afternoon" time)	2	Matched the pattern of previously recorded walks (steps/min, length, and time of day). Verified with participant.
Attention Control Education Group				
14 [1-9]	--	Unable to verify walks: Time of walks not recorded. Longest stretch of steps on days with recorded walks: 6-25 minutes.	--	--

Dog Walking Group

Participants in the dog walking intervention group were asked to report the start and end time of every walk they took with their dog during the study. Diary log reports were compared to accelerometer data. See Table 4.3 for intervention fidelity by participants in the dog walking intervention group.

Table 4.3

Intervention Fidelity by Participants: Dog Walking Group

Dog Walking Intervention	Participants Assigned	Dog Walks Assigned (minimum)	Dog Walks Completed	Dog Walks Meeting Time Requirement (30 min/walk)
Week 1	3	9	9 (100%)	3 (33.3%)
Week 2	3	9	7 (77.8%)	5 (55.6%)
Week 3	3	9	5 (55.6%)	4 (44.4%)
Week 4	3	9	7 (77.8%)	5 (55.6%)
Week 5	2	6	4 (66.7%)	4 (66.7%)
Week 6	2	6	6 (100%)	5 (83.3%)
Week 7	2	6	4 (66.7%)	4 (66.7%)
Week 8	2	6	4 (66.7%)	4 (66.7%)

Overall, participants completed the diary logs accurately and in detail. One participant demonstrated 100% congruence between their accelerometer data and diary log recordings. Another participant recorded more walks than what could be verified by the accelerometer data but also recorded rationale for each of the discrepancies; the participant accounted for all unverified walks in their diary log by reporting every instance they were not wearing their Fitbit, and/or noted time estimates (ex: “noonish”) when they forgot to record specific times for their dog walks. The exception was a participant who did not document all

their dog walks in their diary log. There were two instances where the accelerometer data were consistent with the participant's dog walking patterns (same step count/minute and same time of day as pervious walks) but were not recorded in the diary log. When asked, the participant shared they forgot to record the walks in their diary log.

Participants in the dog walking intervention group were asked to complete a minimum of three days of walking per week for at least 30 minutes each day of walking. While all participants increased their dog walking from baseline, two participants did not adhere to *both* elements of the intervention in any given week, and one participant not only fully adhered to but surpassed the minimum requirements for dog walking. Participants who did not complete all elements of the assigned dog walking intervention contributed their non-adherence to traveling during the study, "working up to it," inclement weather, needing to find a new walking route, and declining health.

More specifically, one participant had 14 verified days of walking, with three days of walking for two weeks, two days of walking for two weeks, and one day of walking for four weeks. Each walk recorded by the participant took place on a different day. Of the 14 dog walks accounted for, seven were noted to be 30 minutes or more. Overall, the participant walked an average of 1.75 days per week, completed 58% (n=14) of the assigned dog walks, and walked the 30-minute minimum 29% (n=7) of the time. The remaining walks were close at 28-minutes, and one dog walk was 15-minutes in length.

Another participant completed 109 verified dog walks. They walked three to seven days per week, (resulting in an average of 19.6 walks per week and 5.4 days of walking per week), approximately three walks per day (ranging from 10-40 minutes each walk), and 30-75 minutes each day of walking. Of the 109 verified dog walks, 47 dog walks were clearly

verified and differentiated from other activities of daily living due to higher and more consistent step count/minute, while 62 recorded dog walks were verified with accelerometer data but could not be clearly differentiated from other activities. These walks were typically of shorter duration (10-15 minutes), while the walks that were easier to differentiate were typically 20 minutes or longer.

The other participant in the dog walking group recorded ten walks over nine days of walking during the four weeks they participated. All dog walks were verified with the accelerometer data. They successfully completed three days of dog walking for one week, two days of dog walking for two weeks, and one day of dog walking for one week. In total, the participant walked an average of 2.25 days per week, completed 75% (n=9) of the assigned dog walks, and walked the 30-minute minimum 11% (n=1) of the time. The remaining walks were 15-24-minutes.

Control Group

All participants in the control group recorded at least one dog walk over the course of eight weeks. Those in the control group did not report the time of day their walks took place and therefore, the longest stretch of time with consistent step counts was used to estimate the maximum dog walking time. In alignment with study protocol, potential participants were eligible to participate if they did not walk their dog at baseline (<10 minutes per week).

Based on data from the accelerometer, the single walk recorded by one participant was at most six-minutes long. Another participant recorded four dog walks, of which two were less than 10 minutes and the other two were a maximum of 11 and 13 minutes, indicating the participant may have had two weeks where they exceeded 10 minutes of dog walking (19 and 22 minutes per week). The other participant in the control group recorded

nine dog walks; accelerometer data showed the maximum amount of time per walk ranged from 8-25 minutes and that they may have had four weeks where they exceeded 10 minutes of dog walking (14, 24, 23, and 79 minutes per week). The participant who increased their dog walking the most from baseline reported they adopted a new dog four-weeks into the intervention which prompted the increase in dog walking.

All participants in the attention control education group recorded that they completed all required readings within the week they were assigned. See Table 4.4 for intervention fidelity by the control group.

Table 4.4

Intervention Fidelity by Participants: Attention Control Education Group

Attention Control Education	Participants Assigned	Assigned Readings	Readings Completed
Week 1	3	3	3 (100%)
Week 2	3	3	3 (100%)
Week 3	3	3	3 (100%)
Week 4	3	3	3 (100%)
Week 5	3	3	3 (100%)
Week 6	3	3	3 (100%)
Week 7	3	3	3 (100%)
Week 8	3	3	3 (100%)

To What Extent Were Measurements Completed?

Participants completed all self-report measures and there were no missed questions within those measures. The five participants who enrolled and completed the study completed all 11 assigned measures. The participant who completed the first four weeks of

the study was assigned eight measures and completed all eight measures. In total, 63 measures were assigned to the six participants and 63 were completed.

A total of 17 serum cortisol samples were assigned to be collected on the six participants. All 17 cortisol samples were obtained and submitted to the lab. Sixteen samples resulted in a serum cortisol level, but one sample was not analyzed due to a labeling error. Immediate communication with the lab regarding the error and ways to avoid another occurrence resolved future concerns for missing cortisol levels. All subsequent lab samples resulted in reported cortisol levels.

What was the extent of missing data?

There were 1,889 potential data points collected during the study. Of the six participants, one had a single missing data point (serum cortisol), resulting in one missing data point for the study. Therefore, the percentage of missing data was 0.05%.

Acceptability

The second primary research question asked, for adult ICU survivors, what is the acceptability of participating in an RCT comparing a companion dog-walking intervention to an attention control education intervention on depression, anxiety, serum cortisol, and QOL? Results addressing acceptability are discussed.

Six participants completed the acceptability exit survey. Results of the acceptability survey are summarized in Table 4.5.

Table 4.5

Acceptability Survey Results

Acceptability Questions	Group	
	Attention Control (*n*=3)	Intervention (*n*=3)
Acceptability of time spent		
Do you feel the total time spent in the study was?		
Too Long	0	0
Just Right	2 (66.7%)	3 (100%)
Too Short	1 (33.3%)	0
Do you feel the time spent per session (including assigned intervention and completing the diary log) was?		
Too Long	0	0
Just Right	1 (33.3%)	3 (100%)
Too Short	2 (66.7%)	0
Acceptability of measurement tools		
Do you feel the time it took to complete the measurements (surveys and cortisol sampling) was?		
Too Long	0	0
Just Right	2 (66.7%)	3 (100%)
Too Short	1 (33.3%)	0
Do you feel the number of measurements (surveys and cortisol sampling) were too many?		
Yes	0	0
No	3 (100%)	3 (100%)
Do you feel the measurements (surveys and cortisol sampling) were easy to complete?		
Yes	3 (100%)	3 (100%)
No	0	0
Do you feel the activity monitor was easy to use and wear?	3 (100%)	3 (100%)
Yes	0	0
No		
Do you feel the diary log was easy to complete?		
Yes	3 (100%)	3 (100%)
No	0	0
Studies that test new treatments often have a second group to compare the treatment with (control group). Were you in the treatment group or the control group?		
Treatment Group	1 (33.3%)	1 (33.3%)
Control Group	1 (33.3%)	0
Unsure	1 (33.3%)	2 (66.7%)

Acceptability Questions	Group	
	Attention Control (*n*=3)	Intervention (*n*=3)
Acceptability of intervention		
I enjoyed participating in the weekly [assigned intervention].		
Strongly Disagree	0	0
Disagree	0	0
Undecided	0	0
Agree	2 (66.7%)	1 (33.3%)
Strongly Agree	1 (33.3%	2 (66.7%)
*I understand the dog walking routine I was asked to participate in and how it might improve my symptoms.		
Strongly Disagree		0
Disagree		0
Undecided		0
Agree		2 (66.7%)
Strongly Agree		1 (33.3%)
The [assigned intervention] forced me to give up other things that were important to me.		
Strongly Disagree	3 (100%)	1 (33.3%)
Disagree	0	2 (66.7%)
Undecided	0	0
Agree	0	0
Strongly Agree	0	0
I was confident in my ability to participate in [assigned intervention].		
Strongly Disagree	0	0
Disagree	0	0
Undecided	0	0
Agree	1 (33.3%)	2 (66.7%)
Strongly Agree	2 (66.7%)	1 (33.3%)
The [assigned intervention] fits well with my values.		
Strongly Disagree	0	0
Disagree	0	0
Undecided	1 (33.3%)	0
Agree	0	2 (66.7%)
Strongly Agree	2 (66.7%)	1 (33.3%)

Acceptability Questions	Group	
	Attention Control (*n*=3)	Intervention (*n*=3)
Acceptability of Intervention		
Participating in [assigned intervention] took a lot of effort.	1 (33.3%)	0
Strongly Disagree	2 (66.7%)	1 (33.3%)
Disagree	0	1 (33.3%)
Undecided	0	1 (33.3%)
Agree	0	0
Strongly Agree		
Participating in [assigned intervention] has made me feel better.		
Strongly Disagree	0	0
Disagree	0	0
Undecided	0	1 (33.3%)
Agree	2 (66.7%)	1 (33.3%)
Strongly Agree	1 (33.3%)	1 (33.3%)
Intention to continue intervention		
I intend to continue [assigned intervention] on a weekly basis?		
Strongly Disagree	0	0
Disagree	0	0
Undecided	1 (33.3%)	1 (33.3%)
Agree	1 (33.3%)	1 (33.3%)
Strongly Agree	1 (33.3%)	1 (33.3%)
Other exit survey questions		
Did you access your Fitbit data on your phone or computer during the study?		
Yes	3 (100%)	2 (66.7%)
No	0	1 (33.3%)
If so, how much did looking at your Fitbit data impact your motivation to participate in physical activity?		
Not at all motivating	1 (33.3%)	0
Slightly motivating	0	2 (100%)
Somewhat motivating	0	0
Moderately motivating	2 (66.7%)	0
Extremely motivating	0	0

Note: Two different acceptability surveys were used for each group with verbiage specific to the assigned activity. [assigned intervention] refers to 'dog walking' for those in the intervention group and 'weekly educational materials' for those in the control group.

*Measures intervention coherence (the relationship between one's perceived illness and how the intervention works to improve that illness [Sekhon et al., 2017]). This question was asked of the dog walking group only and was not applicable for the control group.

Acceptability of Time Spent

All participants in the dog walking intervention reported total time in the study and time spent per session (including dog walking and completing the diary log) was *just right.* Those in the control group felt total time spent in the study was *just right* (*n*=2) or *too short* (*n*=1) and time per session (including reading the educational materials and completing the diary log) was *just right* (*n*=1) or *too short* (*n*=2). No participants reported the study or weekly sessions were *too long.*

Acceptability of the Measurement Tools

Five participants felt the time it took to complete the measurements (including surveys and cortisol sampling) was *just right* while one participant in the control group felt it was *too short.* All participants (*n*=6), regardless of assigned group, reported that the measures were easy to complete, there were not too many measures, the Fitbit activity monitor was easy to use and wear, and the diary log was easy to complete.

Acceptability of the Intervention

According to Sekhon et al.'s (2017) TFA, the acceptability of a healthcare intervention should be based on the following emotional and cognitive responses experienced by participants: affective attitude, burden, ethicality, intervention coherence, opportunity cost, self-efficacy, and perceived effectiveness.

Affective Attitude

Affective attitude was assessed by asking participants about the enjoyment they experienced participating in their assigned intervention. Participants were asked to report their level of agreement with the statement, "I enjoyed participating in the weekly intervention." Regardless of group, all participants *agreed* (*n*=3) or *strongly agreed* (*n*=3).

One participant in the control group *strongly agreed*, and two participants in the dog walking intervention group *strongly agreed*.

Burden

Burden was assessed by asking participants if participating in their assigned intervention took a lot of effort. Those in the control group *disagreed* (*n*=2) or *strongly disagreed* (*n*=1) that the weekly educational readings took a lot of effort. Responses varied for those in the dog walking group. One participant *disagreed,* another participant was *undecided,* and one participant *agreed* that weekly dog walking took a lot of effort.

Ethicality

To assess ethicality, participants were asked if their assigned intervention aligned with their values. Those in the control group were *undecided* (*n*=1) or *strongly agreed* (*n*=2) that reading education materials about their dog fit well with their values. Participants in the dog walking group either *agreed* (*n*=2) or *strongly agreed* (*n*=1) that dog walking aligned with their values.

Intervention Coherence

Intervention coherence is the relationship between one's perceived illness and understanding of how the intervention works to improve that illness (Sekhon et al., 2017). As a control group, the educational materials were not intended to improve symptoms and therefore this question was only asked of the dog walking intervention group. Participants either *agreed* (*n*=2) or *strongly agreed* (*n*=1) that they understood the dog walking routine and how it might improve their symptoms.

Opportunity Cost

Opportunity cost was assessed by asking participants if they felt their assigned intervention forced them to give up other things that were important to them. All participants in the control group (*n*=3) *strongly disagreed* with the statement. Participants in the dog walking group either *disagreed* (*n*=2) or *strongly disagreed* (*n*=1) that dog walking forced them to give up other things that were important to them.

Self-Efficacy

To assess self-efficacy, participants were asked if they were confident in their ability to participate in their assigned intervention. Participants in the control group *agreed* (*n*=1) or *strongly agreed* (*n*=2) that they were confident in their ability to participate in weekly educational readings. Participants in the dog walking intervention group responded similarly. Two participants *agreed* while one participant *strongly agreed* that they were confident in their ability to participate in weekly dog walking.

Perceived Effectiveness

Perceived effectiveness was assessed by asking participants if they thought their assigned intervention made them feel better. The control group *agreed* (*n*=2) and *strongly agreed* (*n*=1) that reading weekly education material about their dog made them feel better. When asked to agree with the statement, *participating in weekly dog walking has made me feel better,* those in the intervention group *agreed* (*n*=1), *strongly agreed* (*n*=1), and one participant was *undecided.*

Intention to Continue Intervention After Study Completion

When participants were asked to report their level of agreement with the statement, "I intend to continue the assigned intervention on a weekly basis," responses varied but were

the same for each group. One participant from each group reported being *undecided,* one participant from each group *agreed* with the statement, and one participant from each group *strongly agreed.*

Suggestions for Improvement and Additional Comments

Each participant was given the opportunity to suggest improvements for the study and to share any additional comments. Within the control group, two participants shared that they would like to see more and/or longer reading materials, and one wanted to see larger print. Within the dog walking group, one participant suggested the study not be done in the winter months because the weather can make dog walking difficult. One participant in the control group left an additional comment that they enjoyed learning more about their dog. Two participants in the dog walking group shared additional remarks as well. One participant shared they enjoyed being in the study and appreciated the convenience of the home visits. Another participant shared they too enjoyed being in the study and explained "but it turned out because of health issues I wasn't physically able to finish the study."

Reasons for Participation

Every enrolled participant was asked during the screening process, "what makes you want to consider participating in the study?" Eight participants shared their dog was one of the reasons they wanted to participate. One participant shared, "I want to do right by my dog," another shared, "I love my dog, I like to do anything I can with them," and two participants wanted to "learn more about my dog." Four participants shared that they wanted to participate to help other ICU survivors. One participant explained, "being in the ICU was one of the worst things I've had to do and if this helps others in the future then I want to do it." Participants also mentioned wanting to participate for personal reasons such as their

mental health, walking, learning more about themselves, their "personal goals," and "[my wife] wants the bandana." Finally, one participant stated they wanted to help because it was a nursing student's dissertation research, and another stated they wanted to participate "just for the heck of it."

Gift cards were provided as participant incentives. When gift cards were explained to participants, all but one participant stated explicitly during the enrollment process, although they appreciated the gift cards, they were not participating for the money. One participant declined the gift cards entirely and requested the money be used elsewhere for the study. One participant stated the gift cards were important because they were unemployed until their health improved.

Exploratory Research Questions

The exploratory research questions asked, what are the differences in depression, anxiety, quality of life, and serum cortisol between and within a companion dog walking intervention compared to an attention control education intervention for ICU survivors. Due to the small sample size and inconsistent intervention fidelity by participants, exploratory outcomes were assessed looking at trends between and within groups along with contextual factors.

Outcome Trends

Outcome measures were plotted to allow visualization of trends between and within groups (Figures 4.3-4.9). Please see Table 4.6 for a summary of all outcomes results.

Table 4.6

Outcome Measures Results

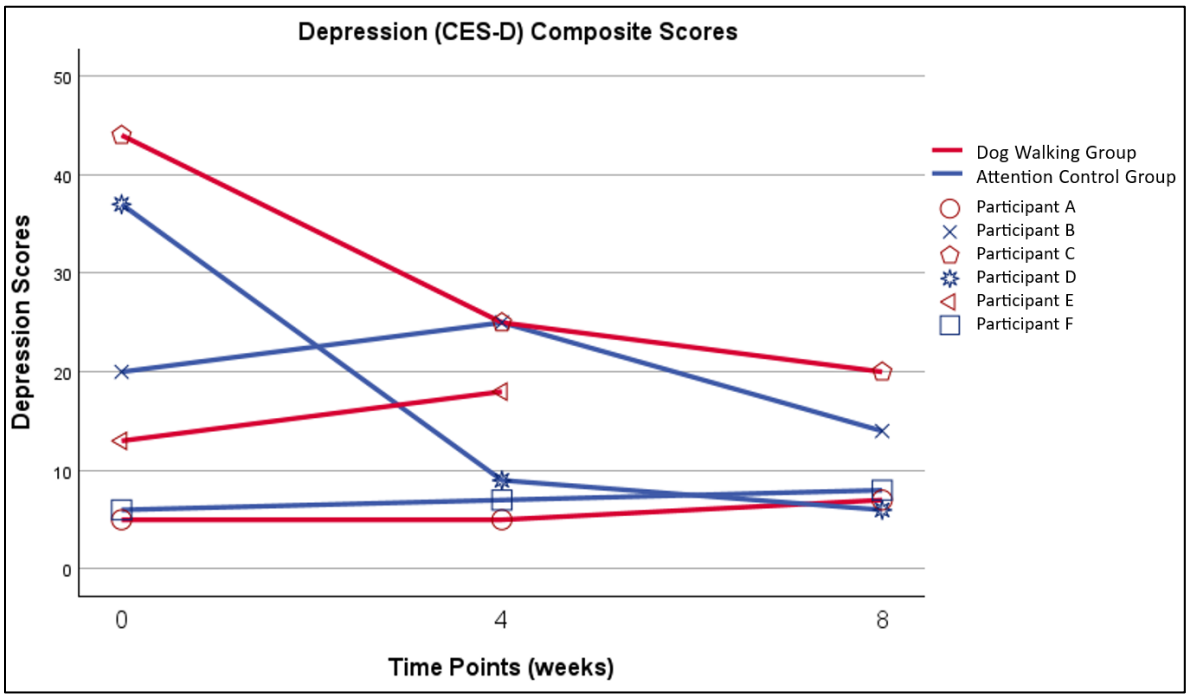
Outcome Measure	Depression				Anxiety-Trait				Anxiety-State				QOL-MCS				QOL-PCS				Serum Cortisol (ug/dL)			
Collection time (weeks)	0	4	8	Net Δ	0	4	8	Net Δ	0	4	8	Net Δ	0	4	8	Net Δ	0	4	8	Net Δ	0	4	8	Net Δ
Participant	Results																							
A	5	5	7	+2	34	32	25	-9	22	25	25	+3	81.8	68.1	79.1	-2.7	55	70.6	81.9	+26.9	-	7.2	5.6	-1.6
B	20	25	14	-6	38	51	42	+4	28	29	28	0	50.8	45.5	56.8	+6	60.6	54.4	44.4	-16.2	9.9	10.5	7.5	-2.4
C	44	25	20	-24	64	48	30	-34	66	36	27	-39	14.1	53.2	68.8	+54.7	34.4	85	62.5	+28.1	3.2	5.8	8.8	+5.6
D	37	9	6	-31	28	46	41	+13	46	36	43	-3	13.3	45.3	55.8	+42.5	33.8	38.1	38.1	+4.3	8.4	12.3	9.4	+1.0
E	13	18	-	+5	29	38	-	+9	23	35	-	+12	55	53.2	-	-1.8	38.1	28.8	-	-9.3	15.8	19.5	-	+3.7
F	6	7	8	+2	47	47	47	0	45	39	39	-6	56	57.5	65.8	+9.8	40	60	50	+10	13.3	9.7	13.2	-0.1

Depression

Depression was measured with the CES-D; higher scores indicate greater levels of depression (range 0-60) and a score of 16 or greater indicate clinically meaningful depression (Radloff, 1977). The scores can also be indicative of mild (0-16), moderate (16-23), and severe (24-60) depression (Radloff, 1977). Three participants began with a depression score >16 and two participants ended the study with a score >16. See Figure 4.3 for Depression Score Trends.

Figure 4.3

Outcome Trends: Depression



Within the dog walking intervention group, two participants had an increase in their depression scores; one had an increase of 2-points over eight weeks and the other had an increase of 5-points over four weeks. One participant demonstrated improved depression

with a 24-point decrease over eight weeks. All participants experienced either consistent decline or consistent improvement between baseline, four weeks, and eight weeks.

Within the control group, one participant experienced a 2-point increase in depression over eight weeks, and two participants experienced overall decreased depression over eight weeks. One experienced an increase of depression at four weeks (5-point increase) and then a decrease in depression at eight weeks (11-point decrease) for a net decrease in depression of 6-points. The other had a consistent decrease in their depression score over eight weeks; they experienced a 31-point decrease.

Each group had one participant with substantial improvement in depression, while the other participants had more subtle changes in depression. The CES-D scores within and between groups demonstrate no clear trends in depression.

State Anxiety

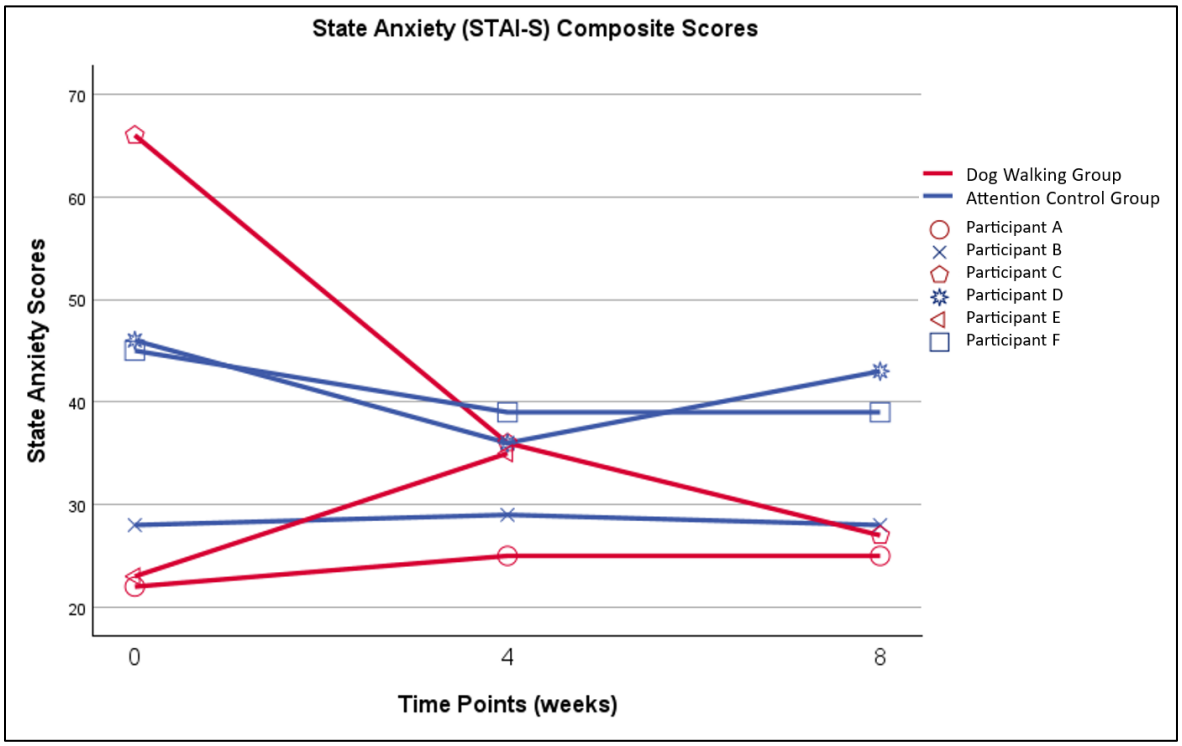
The STAI-S measures the level of anxiety at a given moment, with higher scores (range 20-80) indicating more severe anxiety and a score of 39 or greater indicating clinically relevant anxiety (Spielberger et al., 1983). The scores can be further delineated as low (20-37), moderate (38-44), and high (45-80) levels of anxiety (Kavikcioglu et al., 2017; Ruffinengo et al., 2009). Three participants had scores >39 at baseline, and two participants had scores >39 at eight weeks. See Figure 4.4 for State Anxiety Trends.

Within the dog walking group, two participants had an increase in state anxiety, and one had a decrease in state anxiety. The change scores for those experiencing an increase in anxiety were 3-points and 12-points. The participant experiencing improvement had a decrease in state anxiety of 39-points. Changes within the dog walking group consistently

increased or consistently decreased over the course of the study. There were no notable trends in state anxiety scores within the dog walking group.

Figure 4.4

Outcome Trends: State Anxiety



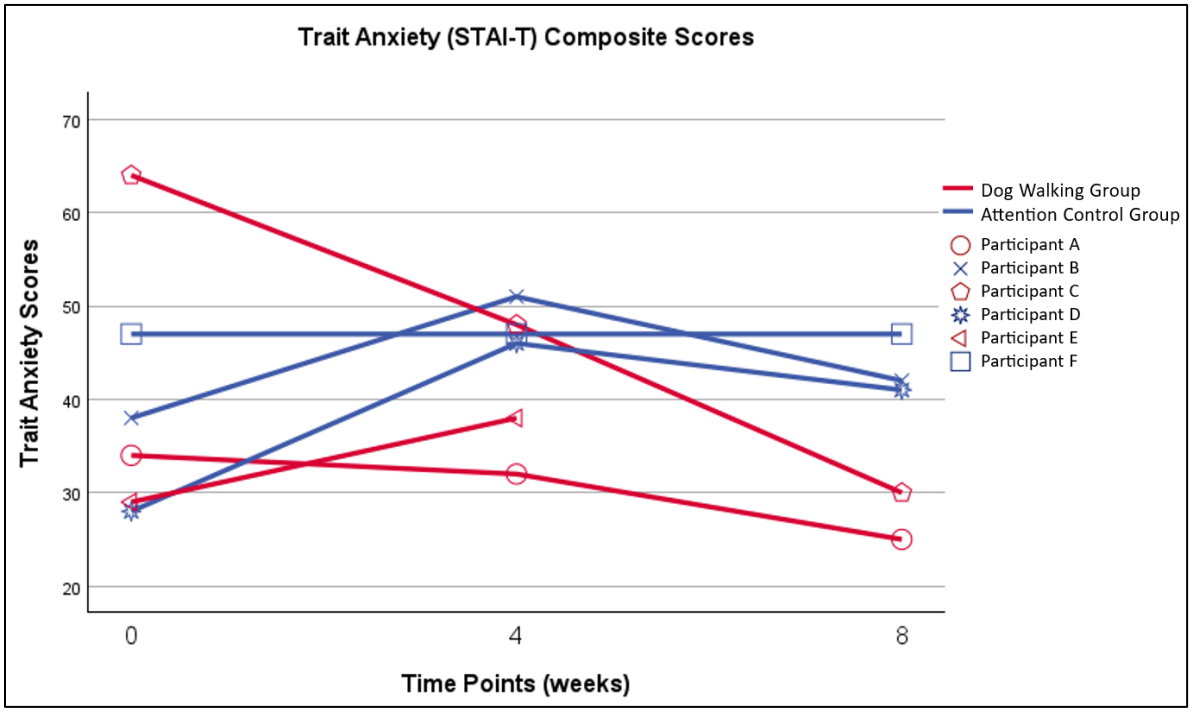
Within the control group, state anxiety scores remained relatively stable. One participant experienced a 6-point decrease in state anxiety scores at the four-week data collection and remained the same at week eight. One participant's state anxiety fluctuated by 1-point, but they experienced no net change in state anxiety scores. The other participant also had fluctuating state anxiety scores (10-point decrease at week four and 7-point increase at week eight) with a net decrease of 3-points.

Trait Anxiety

The STAI-T measures trait anxiety. Trait anxiety is a tendency to experience negative emotions in response to different situations and is considered to be a stable part of one's personality. Higher scores (range 20-80) indicate more severe trait anxiety and a score of 39 or greater indicates clinically relevant trait anxiety (Spielberger et al., 1983). Two participants had scores >39 at baseline, four participants had clinically significant trait anxiety at week four, and two participants had scores >39 at eight weeks. See Figure 4.5 for Trait Anxiety Trends.

Figure 4.5

Outcome Trends: Trait Anxiety



Within the dog walking group, the two participants who completed the study experienced a consistent decrease in trait anxiety over the study duration. One of whom experienced a 9-point decrease and the other who experienced a 34-point decrease in their

trait anxiety score. The other participant experienced a 12-point increase over the four weeks they participated.

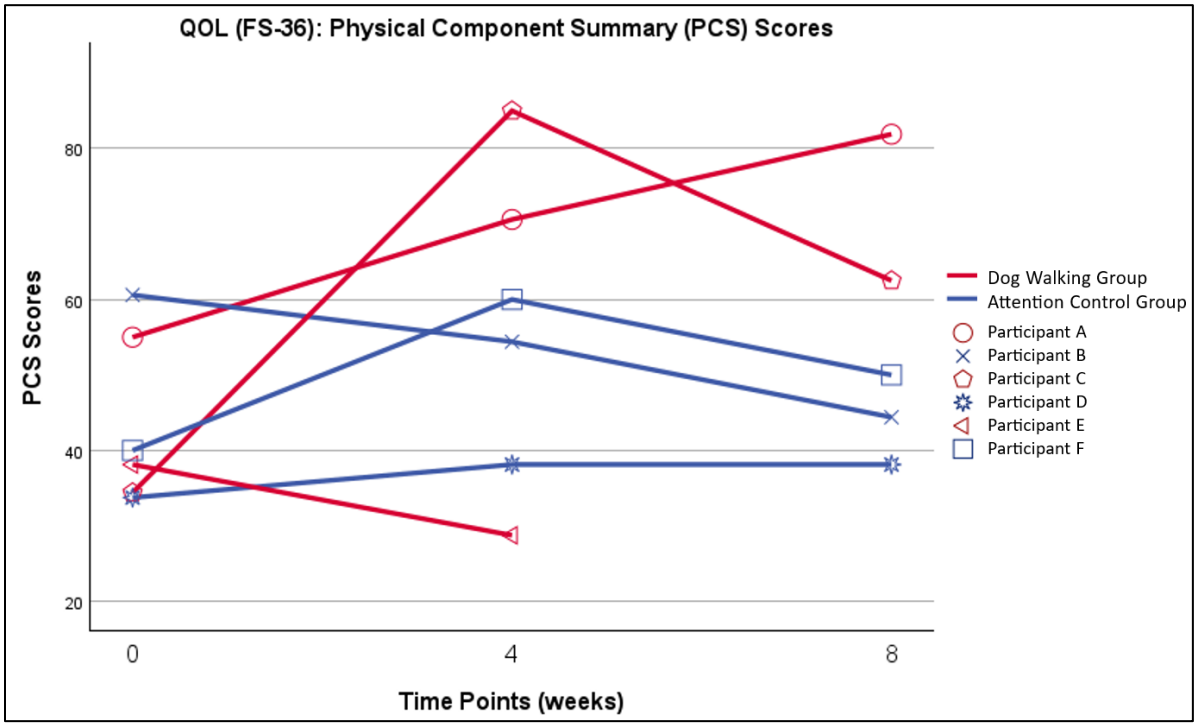
The trait anxiety scores for those in the control group either remained the same or increased. One participant had the same score at all data collection time points. The other two participants experienced an increase in trait anxiety at four weeks, followed by a decrease at eight weeks, with an overall net increase in trait anxiety. Their net increases were 4-points and 13-points. In general, those in the control group experienced consistently higher trait anxiety scores than those in the dog walking group at eight weeks. Overall, the only participants to experience a decrease in trait anxiety were the two who completed eight weeks of dog walking.

Quality of Life: Physical Component Summary

The SF-36 measures eight dimensions of health. The physical component score (PCS) encompasses indicators of physical health including the four dimensions of physical functioning, bodily pain, role limitation related to physical health, and general health. Scores range from 0-100, with higher scores indicating higher quality of life related to physical wellbeing. See Figure 4.6 for QOL-PCS Trends.

Figure 4.6

Outcome Trends: Quality of Life-Physical Component Summary



Regardless of group, all but one participant who completed the full study demonstrated a net increase in PCS scores. The two participants who completed eight weeks of dog walking demonstrated the largest increase in PCS scores with net increases of 26.9-points and 28.1-points. The two participants in the control group who experienced a net increase in PCS saw increases of 10-points and 4.3-points. The participant who experienced a decrease in PCS was in the control group and had a decrease of 16-points. The participant who completed four weeks of the dog walking intervention and withdrew due to declining health experienced a decrease of 9.3-points.

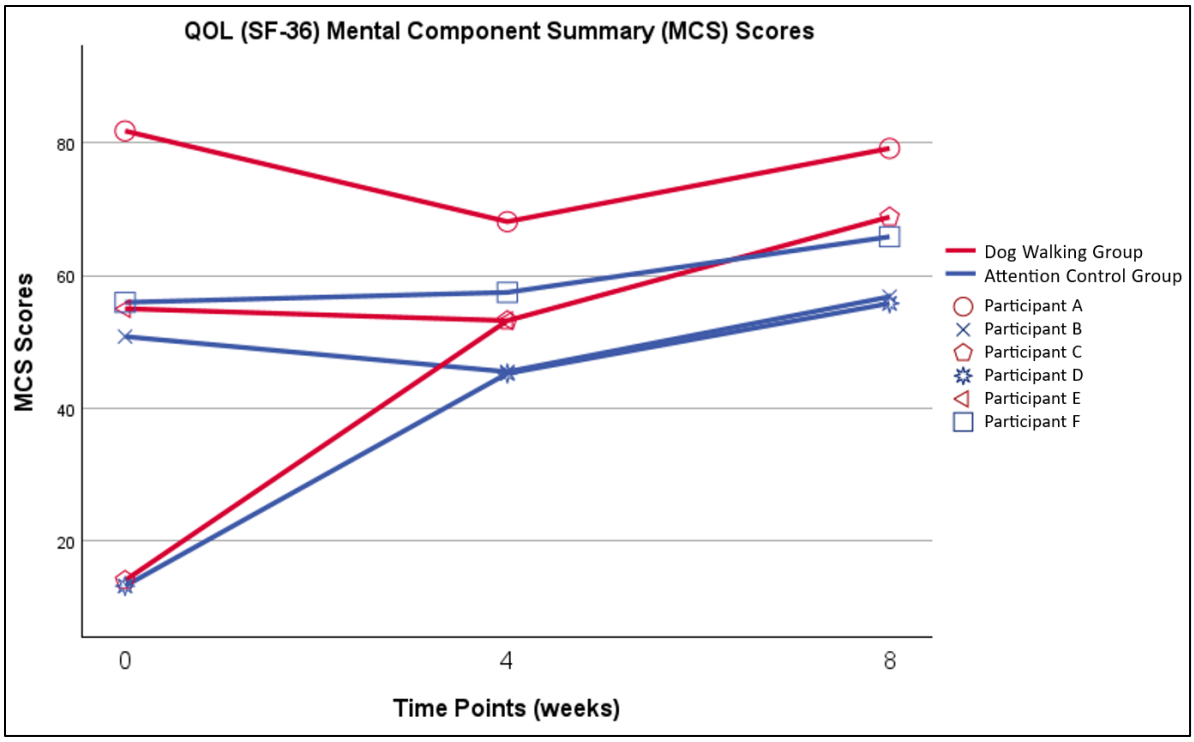
Quality of Life: Mental Component Summary

The mental component summary (MCS) comprises of four dimensions of health measured by the SF-36 (social functioning, energy/fatigue, emotional wellbeing, and role

limitation related to emotional health). Scores range from 0-100, with higher scores indicating higher levels of quality of life related to mental wellbeing. See Figure 4.7 for QOL-MCS Trends.

Figure 4.7

Outcome Trends: Quality of Life-Mental Component Summary



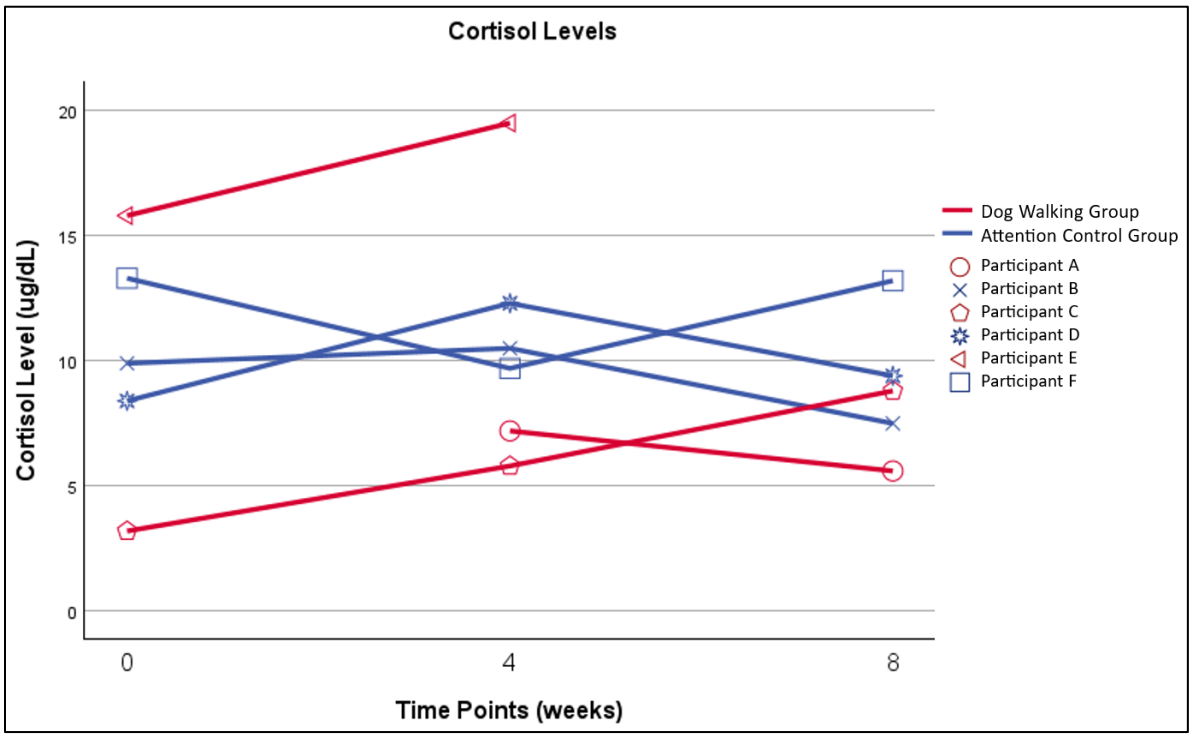
All but one participant who completed the eight-week study experienced a net increase in their MCS score. Within the attention control group, all participants experienced a net increase in their MCS scores (6-points, 9.8-points, and 42.5-points). Within the dog walking group, one participant had a net increase of 54.7. The other had a net decrease of 2.7-points, but also had the highest MCS score at baseline and throughout the study. The final participant in the dog walking group experienced a decrease in their MCS score during the four weeks they participated.

Cortisol

Cortisol is a biomarker that acts as an objective measure of anxiety and depression. Four participants had serum cortisol levels drawn between 8:00am-10:00am and two participants had serum cortisol levels drawn between 12:00pm-2:00pm. Due to the varying collection times across participants and the wide range of values that can be seen from one individual to the next, trends are a better indicator than specific values, and must be evaluated within the context of psychological health. See Figure 4.8 for serum cortisol trends.

Figure 4.8

Outcome Trends: Serum Cortisol



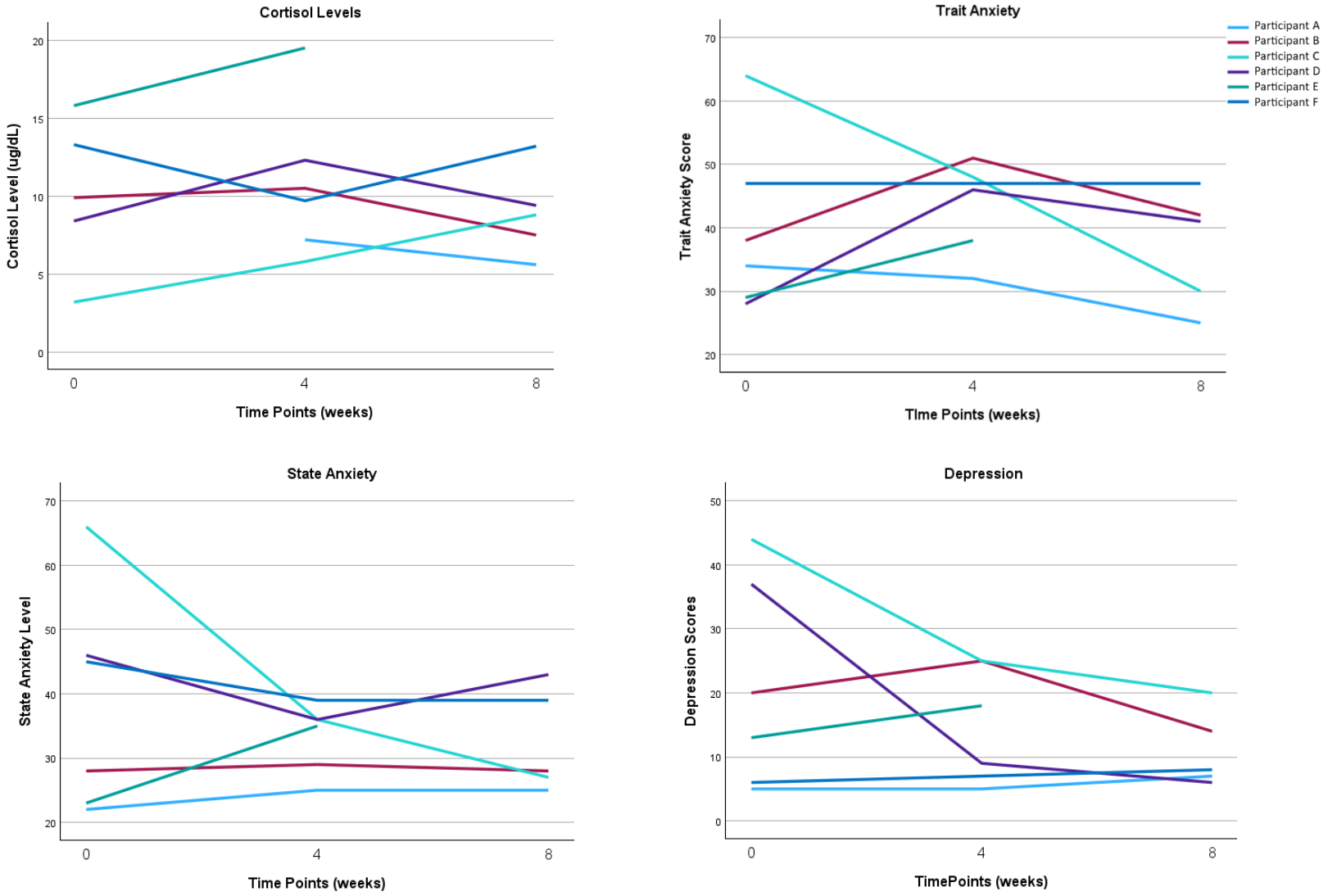
Within the dog walking group, only one participant had serum cortisol levels for all three data collection points. The serum cortisol levels that were available did not indicate any trends within the intervention group. Cortisol levels within the control group fluctuated at each collection time and varied within the group. For example, one participant had a net

decrease of 2.4 ug/dL, one had a net increase of 1 ug/dL, and one remained relatively the same with a net change of 0.1 ug/dL.

As a biomarker of psychological health, cortisol levels were compared to the outcomes of depression, trait anxiety, and state anxiety (see Figure 4.9). Cortisol did not demonstrate a clear or consistent relationship with depression or state anxiety but had a similar trajectory as trait anxiety for all but one participant. For the participant who did not follow the same trajectory, as their trait anxiety decreased, cortisol levels increased.

Figure 4.9

Comparison Between Psychological Outcomes and Serum Cortisol Levels



Contextual Factors

To better understand the data, contextual factors were considered. A summary of contextual factors is discussed below and can be found in Table 4.7.

Dog Walking Group

Participants in the dog walking group included both females and males, ranged in age from 48-76 years old, were either married or unmarried, and all had degrees (associate, bachelor's, or graduate). The participants spent a range of one to seven days in the ICU. Two participants in the dog walking group communicated interest in the study by signing the permission form and were visited while in the hospital where they were screened, consented, and enrolled. The other participant communicated interest in the study after being discharged by responding to the recruitment flyer directly; a subsequent meeting was arranged where the participant was screened, consented, and enrolled. During the screening process, all participants screened positive for anxiety, while one also screened positive for depression. Two participants in the dog walking group were required to obtain medical provider approval to participate in the study. All participants began the intervention two weeks after being discharged from the hospital and took part in either the summer, fall, or winter months. Participants in the dog walking group owned up to three dogs of various ages and sizes.

Two participants in the dog walking group did not completely adhere to the dog walking requirements. Contextual factors such declining health, weather, and travel contributed to their non-adherence.

Table 4.7

Contextual Factors

Contextual Factors	Group	
	Attention Control	Dog-Walking Intervention
Participant Factors	Participants (*n*=3)	Participants (*n*=3)
Means of Communicating Interest in Study		
Hospital Permission Form	1 (33.3%)	2 (66.7%)
Direct Contact with Researcher	2 (66.7%)	1 (33.3%)
Mental Health Screening Results		
Anxiety	0	2 (66.7%)
Depression	0	0
Both	3 (100%)	1 (33.3%)
Permission Required from Medical Provider		
Yes	2 (66.7%)	2 (66.7%)
No	1 (33.3%)	1 (33.3%)
Started Intervention (post-hospital discharge)		
2-weeks	1 (33.3%)	3 (100%)
3-weeks	0	0
4-weeks	2 (66.7%)	0
Participated (time of year)		
Spring/Summer	2(33.3%)	1 (33.3%)
Fall/Winter	1 (33.3%)	2 (33.3%)
Number of Dogs Owned		
1-2	3 (100%)	2 (66.7%)
≥3	0	1 (33.3%)
Dog Demographics	Dogs (*n*=4)	Dogs (*n*=5)
Age		
Age, Range	0.20-9	0.25-11
Age, Mean (SD)	4.8 (3.6)	4.45 (4.09)
Age (years)		
<1	1 (25%)	1 (20%)
1-3	0	1 (20%)
4-6	2 (50%)	2 (40%)
7-10	1 (25%)	0
>10	0	1 (20%)
Size		
Small	2 (50%)	1 (20%)
Medium	1 (25%)	1 (20%)
Large	1 (25%)	3 (60%)

Overall, participants in the dog walking group reported mostly positive responses on the acceptability survey and were consistent in their responses. For example, one participant chose positive responses, but never chose the most extreme answer; rather, they always "agreed" or "disagreed." The only answer that did not reflect a positive response, was when asked if going on dog walks took a lot of effort; in this case the participant reported "undecided." Another participant chose the most positive responses on almost all acceptability survey questions. The only question where they chose "disagree" rather than "strongly disagree" was when asked if dog walking took a lot of effort. Finally, one participant had mixed responses, but also the only negative responses regarding the intervention; this was the same participant who withdrew due to declining health status. They felt the time and measurements were appropriate and "strongly agreed" when asked if they enjoyed participating in dog walking. However, they "agreed" that dog walking took a lot of effort and was "undecided" if dog walking made them feel better and if they wanted to continue to walk their dog weekly in the future.

As for the exploratory outcomes, one participant in the dog walking group had the overall lowest levels of psychological symptoms on the outcome measures compared to all other participants and experienced small levels of change on most outcome measures, except PCS which saw substantial improvement. The participant who withdrew from the study after four weeks due to declining health status experienced a decline in all outcome measures. Finally, the single participant in the companion dog walking group to demonstrate full intervention adherence was also the only participant in the study to experience notable improvement on all self-report measures.

Attention Control Education Group

Participants in the attention control education group included both females and males, ranged in age from 49-71 years old, were either married or unmarried, and all had 14-years of education or less. The participants spent a range of two to seven days in the ICU. Two participants in the attention control education group communicated interest in the study by responding to the recruitment flyer directly, and one participant communicated interest in the study by signing the permission form for their nurse. During the screening process, all participants screened positive for both anxiety and depression. Two participants in the attention control education group were required to obtain medical provider approval to participate in the study. All participants began the intervention either two or four weeks after being discharged from the hospital and took part in either the spring, summer, or fall months. Participants also owned one or two dogs of various ages and sizes.

Participants in the attention control education group demonstrated 100% intervention fidelity to their assigned educational readings. However, two participants may have also increased their dog walking beyond baseline (defined as <10 minutes per week) during the eight-week study period. One participant attributed this increase to adopting another dog.

Participants reported overall positive responses on the acceptability survey. The common trend among participants in the control group was the desire to engage in the study more; for some they felt the study as a whole was too short, for others they wanted the measurement tools to be longer, and most of the participants wanted more educational materials to read.

In general, the results of the exploratory outcomes for those in the attention control group remained relatively stable or demonstrated small changes (n=2). The participant who

demonstrated the greatest improvement in outcome measures was the same participant who engaged in the most dog walking within the control group.

CHAPTER 5

DISCUSSION

Chapter 5 contains the results of The POOCH Study in the context of current literature and discusses limitations and implications for future research. Chapter 5 includes results of feasibility, acceptability, exploratory outcomes, and ends with a conclusion.

Demographics

Research has shown that ICU survivors tend to be middle-aged with 50%-70% being male (Casitillo et al., 2016; Jackson et al., 2014; Righy et al., 2021; Rydingsward et al, 2016). The study enrolled a generally representative sample of middle-aged and older adult participants, with 70% being middle aged (40-65 years-old) and 20% being classified as older adults (≥65 years-old). The enrolled sample contained 40% males. Although lower than the reported ICU survivor demographic in the United States, enrollment was consistent with the human-companion dog literature in that studies focused on companion dogs predominately report more female enrollment than male enrollment (Barcelos et al., 2020; Bennet et al., 2015; Blouin, 2013; Bradley & Bennet, 2015; Campbell et al., 2016).

Large scale studies across the United States examining ICU survivors have reported median years of education as 12, and an interquartile range from 12-14 years (Haddad et al., 2020b; Jackson et al., 2014; Marra et al., 2018; Mart et al. 2022). In comparison, participants enrolled in The POOCH Study had a generally higher level of education, with only one participant reporting 12 years of education and the remaining participants reporting more than 12 years; 80% of participants had an associate degree or higher. While the small sample size of The POOCH Study limits the ability to obtain a truly representative sample, a more representative sample including a greater distribution of males, minority populations, and

individuals with fewer years of education would be desirable to improve external validity and generalizability.

Feasibility

Feasibility research is conducted to assess study processes to identify necessary protocol refinement for large scale studies and implications for future research. Accordingly, recruitment results and obstacles, attrition, masking of participants, intervention fidelity, and missing data are discussed below.

Recruitment Results and Overcoming Obstacles

Recruitment results suggest protocol refinements are necessary to increase recruitment and enrollment. Suggested refinements are discussed for in-patient hospital recruitment, out-patient clinic recruitment, and additional recruitment strategies and considerations.

In-Patient Hospital Recruitment

While the in-patient hospital recruitment strategy produced 10 enrolled participants, recruitment goals were not met. Recruitment challenges are common with ICU patients and in the ICU setting (Chlan et al., 2009; Paddock et al, 2021). The primary recruitment obstacles for this study included limitations related to EHR screening, exclusion criteria, and the number of eligible participants who did not receive a recruitment flyer. To overcome these obstacles, suggestions for protocol refinement include the development of a multi-person research team and the establishment of strong internal connections between the research team and hospital staff.

A single researcher conducted this study. During the screening process, limitations of a single researcher included the inability to fully assess eligibility criteria before a patient

was discharged due to scheduling constraints and the exclusion of participants due to time and travel limitations for data collection and home visits. During the recruitment process, the single researcher was not always able to visit individuals in-person prior to being discharged. This was a notable obstacle because 80% of the enrolled participants were visited by the researcher prior to discharge, the remaining 20% contacted the researcher directly after discharge, and no interested patients whose first point of contact was a telephone call after discharge were enrolled. This finding suggests personal contact and connection with the researcher was important for participants and aligns with other researchers who found the same (Adams et al., 2015; Forsat et al., 2020; George et al., 2014). Accordingly, a multi-person research team is suggested to overcome obstacles associated with a single researcher. A multi-person team would allow for greater flexibility in schedules, be better equipped to meet the demands of the recruitment process, and be able to cover a greater distance of travel for data collection and home visits, increasing the pool of eligible participants. A large research team could also facilitate the inclusion of multiple sites across multiple states.

Other obstacles to recruitment included fast turnover rates of patients, delayed and missing charting, organizational restructuring, and at times unsuccessful collaboration with nursing staff. These obstacles limited the ability to adequately identify and recruit patients in a timely manner that matched the fast-paced patient progression and limited the number of eligible patients who received a flyer. To overcome these obstacles, future studies may benefit from selecting internal care team staff to champion in-hospital recruitment (Chlan et al., 2009).

Previous ICU survivor recruitment strategies have varied. Khan et al. (2024) found success in a similar strategy as The POOCH Study with the study team screening the EHR

twice daily for inclusion criteria and approaching potential participants within 48 hours of anticipated discharge. Vranceanu et al. (2020)'s and Snell et al.'s (2020) approach differed in that the nursing team screened and identified eligible participants. An internal champion would provide consistency in recruitment and would be better equipped to meet the need for real-time screening, recruitment flyer delivery, and in-person meetings with participants prior to discharge. Chlan et al. (2009) reflected on their experiences recruiting patients in the ICU for clinical trials and encouraged researchers to individualize recruitment strategies to align with each unit's culture and capability.

Healthcare staffing shortages and organizational restructuring are prevalent right now with no immediate solution (Chervoni-Knapp, 2022; McMillan & Perron, 2020). These system-based barriers can substantially hinder recruitment efforts (Adams et al., 2015). Researchers should anticipate such obstacles when recruiting within a healthcare setting yet attempt to mitigate these challenges in their recruitment plan. Once again, the establishment of a close collaborative relationship with invested internal care team members who take an active role in recruitment may enhance recruitment efforts.

Out-Patient Clinic Recruitment

Hanging flyers in out-patient clinics was an ineffective recruitment strategy for this study, producing only two individuals who communicated interest and no enrollments. However, recruitment flyers in clinics indicate to potential participants that the research is supported and encouraged by their providers, which can facilitate trust in the research and subsequently promote participation (George et al., 2014). Protocol refinement for out-patient clinic recruitment includes the addition of other clinic sites to increase exposure to the study. Establishing a personal connection to potential participants is also important in establishing

trust and interest (George et al., 2014). Accordingly, further collaboration and engagement with clinic staff is recommended. Staff involvement may differ based on a clinic's capacity and interest. At a minimum, clinic staff could emphasize the research opportunity when participants enter the clinic. Preferably, providers would be engaged in the recruitment process, helping to identify eligible participants, providing the recruitment flyers directly, and referring them to the research team.

Additional Recruitment Strategies and Considerations

Researchers with experience in recruiting challenging populations have encouraged other researchers to try multiple, new, creative, and overlooked strategies (Chlan et al., 2009; Forsat et al., 2020; Kim et al., 2021). Haines et al. (2024) recruited ICU survivors for an RCT that required participation shortly after discharge by mailing out invitation letters 2-4-weeks after discharge (Haines et al., 2024). ICU survivors have been found to significantly increase their physical activity once discharged home from the hospital (Chrisman et al., 2024; Gandotra et al., 2021). Therefore, screening physical activity through the EHR or at the time of hospitalization may cause potential participants to be excluded when they may be physically capable and thus eligible to participate shortly after discharge (and prior to the 30-day deadline in which the dog walking intervention must begin). As a result, another suggested protocol refinement to facilitate recruitment includes mailing invitation letters to ICU survivors after discharge.

The POOCH Study has the potential to be conducted remotely by mailing study supplies, emailing self-report measurement tools, and having participants collect their own cortisol samples through salivary sampling. However, the convenience of home visits and the personal interaction was appreciated by the participants and has been identified as especially

important for minority recruitment and retention (George et al., 2014). Additionally, in-person data collection likely aided in the thorough and timely completion of measurement tools (Tiersma et al., 2022). Therefore, maintaining in-person data collection for The POOCH Study is recommended. Once more, the development of a multi-person research team could help maintain in-person interaction with participants throughout the study.

Effective Strategies

The reported reasons that participants were interested in The POOCH Study highlight some of the effective recruitment strategies that should be maintained. First, participants reported helping others was a key reason for their interest in the study. Altruism has been identified as a significant motive in research participation (Carrera et al., 2018; George et al., 2014). Participants reported a desire to help other ICU survivors, their dogs, and the student researcher. Although gift cards were provided as incentive, participants overwhelmingly shared they were not participating because of the money. Simultaneously, there were participants who reported they were interested in the study because of the incentives such as the gift cards and dog bandana. This aligns with other research that has shown research incentives to be effective in recruitment and retention (Abdelazeem et al, 2022).

Other strategies used to enhance interest in the study included highlighting personal connections and establishing credibility through the recruitment flyers. Personal connection and institutional trust are important to participants and play an important role in recruitment (George et al., 2014; Guillemin et al., 2018). To highlight personal connection, the recruitment flyer included a statement linking the research to the local region. To establish credibility, the recruitment flyers included both the University logo and the hospital logo. Reasons for participation, incentives, and institutional affiliation were all included on the

recruitment flyers and further expanded on during the consent process. These strategies should be maintained in the protocol.

Minority Recruitment and Retention

Twenty percent of enrolled participants identified as non-white which is comparable to the reported ethnicity of ICU survivors across the United States (Jackson et al., 2014; Rydingsward et al., 2016). However, the only minority ethnicity represented in this study was Hispanic/Latino and the two participants who identified as Hispanic/Latino could not be reached for follow up after enrollment and therefore did not participate. Additionally, 2% of the ICU patients screened were excluded because they did not read and/or speak English. A larger sample of racial-ethnic minorities would be warranted in a future large-scale study.

The inclusion of socially diverse groups, including females and ethnic/racial minorities, is a research standard (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979; National Institutes of Health, 2017; U.S. Code, 2012) and, if not upheld, can limit generalizability and perpetuate social inequities and health disparities (Langer et al., 2021; Rojo et al., 2024). Research shows that to enhance minority recruitment and retention, studies should include diverse research teams with multilingual team members and study materials (George et al., 2014; Langer et al., 2021). Additionally, while African Americans, Pacific Islanders, and Asians have identified collaboration with community-based partnerships as key to enhancing research participation (George et al., 2014), collaborating with trusted community partners has been an essential recruitment and retention strategy for Hispanics/Latinos (Langer et al., 2021; Rojo et al., 2024).

Based on results, suggestions for protocol refinement include the formation of a diverse multi-person research team and multilingual staff who can provide participants with

culturally and linguistically aligned interactions and communication. Multilingual study materials should also be included. With Hispanics being the largest minority population in the United States and Spanish being the second most common language after English (Deitrich & Hernandez, 2022), at a minimum, study materials should also be available in Spanish. Consents and educational materials would be translated and back-translated in Spanish and the CES-D (McCabe et al., 2011; Roberts et al., 1989) , STAI-AD (Spielberger et al., 1983), and SF-36 (Vilagut et al., 2005) measurement tools have been psychometrically tested in the Spanish language and within the Hispanic culture and are available in Spanish for administration. Another protocol refinement includes collaborating with local organizations to enhance recruitment and facilitate minority recruitment. For example, collaborating with local community outreach organizations and recruiting in-person within the community, such as at churches or local fairs, festivals, and events to promote trust and participation for minority populations (George et al., 2014; Rojo et al., 2024).

Attrition

Participant attrition for The POOCH Study was high at 50% compared to other dog walking trials that saw an attrition rate of 15% (Morrison et al., 2013; Richards et al., 2015). Of those who withdrew from this study, 60% withdrew due to declining health status. One notable difference between this study and the studies conducted by Richards et al. and Morrison et al. is that their studies included populations of community dwelling healthy adults and families (adult parents and their children). Due to the severity of illnesses and injuries requiring ICU level care, ICU survivors are at an increased risk of persistent fatigue (Bench et al., 2021), hospital readmission (Hirshberg et al., 2019), challenges in physical function, and mortality (Wieske et al., 2015). The physical ability of ICU survivors must be

considered when planning and conducting physical activity-based interventions. Researchers may benefit from anticipating higher levels of attrition and proactively increasing their recruitment goals at study onset.

Other RCTs involving ICU survivors have had attrition rates between 24%-35% (Haines et al., 2024; Khan et al., 2024; Vranceanu, et al., 2020), yet again, these interventions did not incorporate physical activity requirements. Denehy et al.'s (2013) RCT examining an exercise rehabilitation program for ICU survivors after discharge had a more comparable attrition rate of 45%. Researchers may consider incorporating other less physically demanding activities for ICU survivors to share with their companion dogs. Activities with a dog such as grooming, massaging, playing, and walking have been found to produce positive psychophysiological responses in people by activating parts of the brain responsible for decreased stress, increased relaxation, and emotional stability (Yoo et al., 2024). Additionally, walking and playing with a dog may improve memory, and massaging and grooming a dog may improve concentration (Yoo et al., 2024). While dog walking may be beneficial for some ICU survivors, it may not be physically appropriate for others. Future research should incorporate and evaluate alternative activities to share with a dog. Not only may this improve attrition but would allow for more individualized care of ICU survivors. Future researchers may even consider using these various dog activities as the basis for an individualized adaptive intervention.

Masking of Participants

There are few RCTs within the companion dog literature (Brooks et al., 2018; Nelson et al., 2024), and HAI researchers have argued RCTs would be challenging due to an inability to mask participants (Brooks et al., 2018; Krause-Parello et al., 2019). The POOCH

Study suggests researchers may have the ability to successfully mask participants of HAI research under the right circumstances and with the use of an attention control group. Four of the six participants (66.7%) (n=4) were successfully masked to their group allocation. Successful masking of participants taking part in companion animal research would facilitate the completion of high-quality intervention research and begin to address unanswered questions within the companion dog literature related to causal relationships, theoretical foundations, mechanisms, intervention effectiveness, and inevitably a better understanding of how the human-companion dog relationship may be optimized to support wellbeing.

Throughout the companion dog literature, outcomes remain inconsistent across studies and populations (Brooks et al., 2018; Nelson et al., 2024). However, consistent across the companion dog literature is that owners generally perceive their dogs as having a positive effect on their health and wellbeing (Brooks et al., 2018; Campbell et al., 2016; Nelson et al., 2024). Additionally, mainstream media frequently reports on the health benefits of dogs and/or shares "endearing" anecdotal stories about dogs. For example, ABC News (2024), CBS News (2024), People Magazine (2024), and Time Magazine (2024) have news sections devoted solely to stories about dogs and pets. Such reporting by mass media can further mold public opinion that dogs positively influence human health (Hu & Zhu, 2017). Consequently, when working with populations of companion dog owners, masking participants is important to reduce expectation bias. Expectation bias is when one's expectations can influence their experience, interpretation, perceptions, and behaviors, and subsequently the study results (Sheffield et al., 2021).

A systematic review conducted by Hróbjartsson et al. (2014) compared clinical trials evaluating complementary medical interventions that masked participants to those that did

not mask participants and found effects sizes to be an average of 0.56 greater in studies that did not mask participants. Additionally, risk for bias is high when a study incorporates self-report measures related to perceived symptoms (such as depression, anxiety, and QOL) and participant masking is an essential strategy to minimize such bias (Christian et al., 2020). Future intervention research involving companion dogs and their owners should attempt to mask study participants and continue to analyze the feasibility of successful masking. From a pragmatic standpoint, masking participants can also decrease attrition (Hróbjartsson et al., 2014).

The POOCH Study was a single masked study with the aim of identifying the feasibility of masking participants. However, refining the protocol to support a double masked large-scale study is also recommended. By taking a multi-team approach, those collecting data from participants should be masked to group allocation to minimize performance bias and those participating in data analysis and outcome assessment should be masked to group allocation to minimize detection bias (Christian et al., 2020; Higgins et al., 2011; Hróbjartsson et al., 2014). A double masked study would facilitate internal validity.

Intervention Fidelity

Comparing Diary Logs and Accelerometer Data

Overall, the use of diary logs and accelerometers to track activities in both groups was feasible and effective. This aligns with research that posits wearable physical activity monitors are a feasible strategy for activity tracking in the ICU survivor population (Chrisman et al., 2024). All participants completed their diary logs daily, and accelerometer data verified the information reported on the diary log. This contrasts with studies that have found inconsistencies between self-report physical activity and accelerometer data (Berglind

et al., 2016; Colley et al., 2018; Limb et al, 2019; Welch et al., 2021). Challenges with using diary logs and accelerometers included participants forgetting to report dog walks on the diary log, estimating the time of a walk because they could not remember the exact time they walked, and forgetting to wear the accelerometer. ICU survivors are at risk for long term cognitive impairment which can cause challenges with memory (Lasiter et al., 2021). To facilitate complete documentation of dog walking, technology-based physical activity logs using smart phones would encourage real time reporting rather than retrospective reporting as seen with using paper diary logs (Welch et al., 2021). Additionally, text message reminders have been effective in improving adherence to medical interventions and behavior change (Schwebel & Larimer, 2018). Participants were already required to own a smart phone to use the Fitbit devices, therefore transitioning the diary log to a phone-based log and implementing text reminders may be a beneficial strategy to facilitate intervention adherence in a population at risk for memory impairments.

Another consideration when reviewing accelerometer data was that for some participants it was challenging to distinguish between dog walking and other activities of daily living. This is congruent with findings that dog walking intensity varies from person-to-person and from walk-to-walk; dog walking can range from sedentary and light to moderate and intense, with most dog walking being classified as light and moderate intensity (Richards et al., 2014). Slower speeds and shorter distances were more challenging to discern from other activities of daily living and therefore the diary log was needed to verify accelerometer data. Researchers comparing self-report diary logs and accelerometers argue using both diary logs and accelerometers is best because they provide complimentary data (Berglind et al., 2016; Colley et al., 2018; Limb et al, 2019; Welch et al., 2021). Accordingly, the continued

use of both diary logs and accelerometers should be maintained in the protocol until/unless a more valid and reliable strategy is developed.

Intervention Fidelity: Dog Walking Group

Participant adherence for those in the dog walking group was inconsistent. The single participant who was complaint with the minimum dose of dog walking every week (3 days/week of walking; 30 minutes/day of walking) also far exceeded the minimum requirements. The other two participants did not walk the minimum dose requirements for dog walking which were assigned based on current public health activity guidelines. This finding aligns with the ICU survivor literature examining physical activity after discharge home (Christman et al., 2024). For example, Denehy et al. (2012) found most ICU survivors did not meet the international guidelines for physical activity two months after discharge and Gandotra et al. (2021) reported ICU survivors' daily step counts were significantly lower than the recommended amount. Even when ICU survivors who received a physical rehabilitation intervention were compared to those receiving usual care, both groups continued to function below population norms (Denehy et al., 2013).

Given the physical limitations and challenges facing ICU survivors, it is reasonable to speculate general population guidelines may not be appropriate for the ICU survivor population immediately post-discharge. The companion dog walking literature suggests intentional engaging activities between owner and dog are necessary to optimize the mental health benefits of the human-companion dog relationship (Nelson et al., 2024). Therefore, one may posit, perhaps it is not the distance walked or steps attained, rather it is the shared experience between dog and owner that provides the most benefit. Yet, the mental health benefits of physical activity should not be ignored and aligns with The POOCH Study's

theoretical framework that suggests the interconnection between physical activity and the human-companion dog relationship work together to optimize mental health.

For the ICU survivor population, it may be best to develop a personalized physical activity goal for each participant based on physical ability. It is also notable to mention that the participant who exceeded the minimum dose requirement for dog walking was also the only participant to consistently take part in more than one walk per day. The researcher should emphasize to participants during enrollment and throughout the study, that they can take part in multiple walks per day (as short as 10 minutes, which also aligns with public health activity guidelines) to achieve their daily dog walking goal. Finally, future studies should investigate the dose effect of dog walking on outcome measures to determine optimal standards to improve outcomes in ICU survivors.

Intervention Fidelity: Attention Control Group

The attention control group fully adhered to the assigned education materials. However, all three participants reported walking their dog during the study, and accelerometer data indicated two participants may have increased dog walking beyond their baseline of <10 minutes/week. When participants in the control group engage in the same activities as the intervention group, unwanted crossover effects can occur, compromising internal validity, introducing confounding variables, and limiting the ability to determine the effect of companion dog walking on the outcome measures. When enrolling participants into the control group, it is essential to emphasize that they must maintain their current dog routines and habits. Additionally, the protocol should be revised to include a section on the diary log for participants in the control group to record start and end time of any physical activity they took part in during the day to allow for validation of reported dog walks with accelerometer data.

There are concerns that the act of measuring physical activity prompts behavior change and increases activity levels, a phenomenon referred to as the mere-measurement effect (Freene et al., 2020). However, the majority of research has reported no significant change in the physical activity of control groups wearing activity monitors (Freene et al., 2020). Similarly, the motivating effect of the Fitbit in this study did not seem to influence dog walking for those in the control group; those who participated in increased dog walking and those who reported that their Fitbit data motivated them to participate in physical activity did not consistently align. To avoid any motivating effects of the Fitbit monitor, the Fitbit device settings were adjusted so that participants did not receive reminders, updates, or prompts related to their health or physical activity, a practice that should be maintained in future studies unless desired for research purposes. Participants should also be informed about and reminded to adhere to the Fitbit protocol.

Measurements and Missing Data

The current protocol for data collection was successful. Data collection was conducted in-person with the participants which allowed for the verification of completed measures and data points. The single missing data point of cortisol reinforced the necessity to maintain thorough and consistent communication with study partners.

Acceptability

Overall, survey results indicate The POOCH Study was acceptable to participants. This finding is not remarkable given all participants were dog owners and dog owners are likely to look at their dog in a positive light (Brooks et al., 2018; Campbell et al., 2016; Nelson et al., 2024). Most participants also reported their dog as a primary reason for participating in the study.

Dog Walking Group

The notable trend to emerge from survey responses of the dog walking participants was the range of responses when asked if participating in weekly dog walking took a lot of effort. This question received the only *negative* response from the survey across both groups, with one participant reporting they *agreed* it took a lot of effort. For participants to find an intervention acceptable, the intervention cannot be perceived as too burdensome (Sekhon et al., 2017). While the perception of effort is not always negative, too much perceived effort may interfere with participation, retention, and long-term continuation of the activity (Baumel & Muench, 2021; Sekhon et al., 2017). Incorporating regular dog walking into one's routine and life is a behavior change. Behavior changes can be challenging to maintain and can be perceived as a burden (Baumel & Muench, 2021). Understanding the benefits of a behavior can counteract perceived effort (Baumel & Muench, 2021). Rhodes et al. (2012) conducted a pilot RCT examining dog walking as a physical activity and found providing educational materials about how dog walking benefits the dog significantly increased dog walking in dog-owners. To improve intervention adherence and to decrease perceived effort, those in the dog walking group should receive education on the benefits of dog walking for both the owner and the dog. Given the participant who withdrew due to declining health was the same to report dog walking took a lot of effort, it is reasonable to infer that the amount of required activity did not align with their physical capability. As previously mentioned, this study may be improved by developing personalized dog walking goals with participants based on physical ability.

Attention Control Group

For attention control groups to be successful, they also need to be acceptable to participants (Aycock et al., 2017). Based on results from the acceptability survey, and in

alignment with Sekhon et al.'s (2017) theoretical framework of acceptability, reading weekly educational materials about dog health is an acceptable attention control intervention for participants. A distinguished trend for those in the control group was the desire for more reading materials. However, the number and length of readings should remain the same in the future. All participants in the control group were retained, and the attention control intervention was deemed acceptable by participants. These findings suggest the readings were adequate to meet the purpose of the control group. Reading over a 30-minute time-period has been shown to significantly reduce stress (Rizzolo et al., 2009) and therefore extended readings should not be introduced to the control group to avoid unintended treatment effects.

Exploratory Outcomes

Overall, notable trends were lacking throughout the exploratory outcomes and results were often comparable to health trajectories of ICU survivors and/or aligned with current literature and contextual factors. However, results did suggest companion dog walking may have an impact on QOL-PCS and trait anxiety, and a relationship may exist between cortisol and trait anxiety. It must be emphasized again that results and inferences should be interpreted with caution due to the small sample size.

Depression

Research has found depression in ICU survivors decreases significantly from discharge to three and four-months post-discharge (Castillo et al., 2016; Choi et al., 2016; Wunsch et al., 2014) and depressive symptoms were lower in those discharged home than those discharged elsewhere (Choi et al., 2016). Additionally, Boede et al. (2021) conducted an observation cohort study of ICU survivors (n=244) one-year after discharge and found trajectories of depression in ICU survivors vary within the population and highlighted three

primary trajectories: those with mild depression initially who recovered gradually, those with severe depression initially who recovered gradually, and those with severe and persistent depression. The natural progression of ICU survivor depression over time aligns with the results of this study. Participants varied in their depression levels, two participants with high levels of depressive symptoms experienced substantial improvement over the eight-week study, one participant with moderate depressive symptoms experienced gradual improvement, and two participants with very low depressive scores remained relatively stable. The single participant who did not follow this trajectory and had an increase in depressive symptoms was the same participant who experienced a decline in health status and withdrew from the study. ICU survivors who have greater care needs and physical limitations experience higher levels of depression (Choi et al., 2016; Estrup et al., 2020). Based on result trends, there is no current indicator that the dog walking intervention influenced depression scores.

State and Trait Anxiety

The relationship between trait and state anxiety remains unclear (Saviola et al., 2020). In the context of ICU survivors, trait anxiety has been found to correlate with long term outcomes of depression and anxiety, while state anxiety has not (Castillo et al., 2016). Results from The POOCH Study do not reveal notable trends between trait anxiety, state anxiety, or depression. State anxiety is transient and situational, and can vary at any given time, limiting its use in the interpretation of long term change scores and intervention effect; conversely, due to the more stable nature of trait anxiety and its positive association with anxiety disorders, (Dong et al., 2022; Saviola et al., 2020), trait anxiety was used as the primary indicator to decipher change and potential intervention effects in the POOCH Study.

Anxiety has been shown to be highest for ICU survivors while in the hospital and two weeks after discharge (Castillo et al., 2016; Choi et al., 2016) and then decrease the first 2-4 months post-discharge (Castillo et al., 2016; Choi et al., 2016; Wunsch et al., 2014). When anxiety was monitored for longer periods, results demonstrate no significant change over time. More specifically, Castillo et al. (2016) found no significant change between 3-6 months post discharge, and a systematic review summarizing 27 articles and 2,880 ICU survivors found no significant change in anxiety between 2 or 3-months and 12-months post-discharge (Nikayin et al., 2016).

Trait anxiety scores in the control group did not share these trajectories. Participants in the control group saw either an increase or no change in trait anxiety, while those who completed eight-weeks of companion dog walking had a decrease in trait anxiety. Unfortunately, studies that report anxiety levels between two-weeks and two-months could not be found, limiting the ability to compare trajectories during this time period. Future studies should measure anxiety more frequently during the initial weeks and months following discharge to fill this gap in the literature and to achieve a comprehensive understanding of the trajectory of anxiety starting at time of discharge and throughout their recovery process. The improvements seen within the intervention group could simply be following the trajectory of anxiety demonstrated in the literature or may be due to the companion dog walking intervention. Evidence shows regular physical activity can improve trait anxiety (Kikkawa et al., 2023).

State anxiety remained relatively stable for the majority of participants in the study regardless of group. This is an unexpected finding considering the transient nature of state anxiety and that ICU survivors have reported recovery as a challenging experience that elicits

worry and fear (Kang & Jeong, 2018). It may be reasonable to speculate that the stability of state anxiety scores over time may be more indicative of an ICU survivor's environment rather than reflective of their general concerns and anxieties. For example, ICU survivors often do not return to work (McPeak et al., 2019), are socially isolated (Kang & Jeong, 2018), and are sedentary (Chrisman et al., 2024), which could create an environment of consistency rather than an environment of diverse unanticipated changes. State anxiety increases when an individual perceives a situation to be an imminent threat (Kikkawa et al., 2023), but consistency in routines may limit the exposure to stress-provoking situations and act as a buffer against stress and anxiety (Hou, Lai et al., 2020; Hou, Liu et al., 2020)

Nikayin et al.'s (2016) systematic review revealed the psychometrically tested Hospital Anxiety and Depression Scale–Anxiety subscale (HADS-A) was the most common measure of anxiety within the ICU survivor literature and the STAI was used far less frequently. To improve consistency of measures and comparison within the ICU survivor literature the HADS-A may be the preferred measurement tool to measure anxiety in future studies.

Quality of Life

In Hofhuis et al.'s (2021) prospective cohort study examining ICU survivors (n=149) and quality of life over 10-years post-discharge, both PCS and MCS increased within the first year after discharge.

QOL-MCS

The MCS scores of Hofhuis et al.'s study showed subtle increase from hospital discharge to six months, the most substantial change occurring between discharge and three months (n=412; mean scores of 46 and 50 respectively) and stabilizing thereafter. These findings align with the results of The POOCH Study, with four participants demonstrating an

increase in MCS scores over the eight-week study. Mean MCS scores at baseline for participants in The POOCH Study were 45 and 65 at study completion (which equates to 2-3 months post-discharge for participants). While the trajectories of MCS scores aligned with Hofhuis et al.'s findings, The POOCH Study found participants demonstrated higher mean MCS scores approximately three months post-discharge. This finding could be due to the participant-researcher interaction that was consistent between the attention control group and intervention group. Social interaction can improve mental health (Kuczynski et al., 2022; Poghosyan et al., 2022; Weziak-Bialowolska et al., 2022) and both social functioning and mental health are considered in the MCS scores.

Of the two participants who experienced a decline in MCS, one experienced a small decrease of 2.7 points but maintained the highest MCS scores throughout the course of the study. The other experienced a decline in both component scores which aligns with the declining health status they experienced and concurrent decline on all measures during their time in the study. Both participants who did not demonstrate an increase in MCS scores were part of the dog walking group. Based on result trends, physical ability of participants in The POOCH Study, and MCS scores based on assigned group, there is no clear indicator that the dog walking intervention impacted MCS scores.

QOL-PCS

The PCS scores in Hofhuis et al.'s study increased from discharge to 12 months with the most substantial increase occurring between discharge and three months (n=412; mean scores of 27 and 37 respectively). In comparison, The POOCH Study demonstrated a similar PCS trajectory with four participants having increased PCS scores over the course of the study. Mean scores on the PCS at discharge and three months for those in The POOCH Study were considerably higher at 44 and 55. This finding could be due to the inclusion criteria of

both studies. Participants in The POOCH Study required higher physical functioning at discharge to be able to participate in dog walking, while physical ability did not restrict participation in Hofhuis et al.'s study. Physical impairment and mental health have an inverse relationship in ICU survivors (Chrisman et al., 2024; Hofhuis et la., 2021).

A notable finding for the QOL-PCS is that both participants who completed the eight-week dog walking intervention (the same participants who completed the most amount of dog walking across groups) experienced substantial increase in their PCS scores (over 25-points). The improvements in the control group were substantially smaller (4.3-points and 10-points) and one participant in the control experienced a decrease in PCS. Given these findings, the companion dog walking intervention may have an impact on PCS scores, however, further study is needed to support this finding.

General Considerations

While other studies have examined QOL trajectories of ICU survivors over time, monitoring usually began 1-6 months post-discharge and often included retrospective preadmission QOL scores as a baseline (Ariyo et al., 2021; Estrup et al., 2022; Kawakami et al., 2021; Rai et al., 2020; Zeggwagh et al., 2020). Understanding QOL as it progresses shortly after discharge is necessary in the interpretation of The POOCH Study results because the first month post-discharge can be filled with many changes. More studies measuring QOL in ICU survivors should obtain QOL measurement shortly after discharge including at discharge and within one-month post-discharge. Another important consideration in the measurement and interpretation of the SF-36 is that the minimal clinically important difference (MCID) for the SF-36 has not been defined in the ICU survivor population. Future research should focus on the identification of SF-36 MCID to better interpret and recognize clinically relevant change for ICU survivors.

Cortisol

Critical illness is associated with HPA-axis alterations, adrenal insufficiency, and poor cortisol breakdown resulting in high levels of cortisol (Boonen et al., 2014; Peeters et al., 2018). However, these alterations typically return to usual function by 28-days post-discharge (Peeters et al., 2018). All participants had cortisol levels within normal range for their collection time at baseline data collection.

The literature suggests cortisol levels may be influenced by both state and trait anxiety (Gao et al., 2024; Hannibal & Bishop, 2014; Pearman et al., 2020; Ritsner et al., 2007; Scholtz et al., 2006) and depression (Jia et al., 2019; Powers et al., 2016). Increased cortisol levels should follow acute stress (state anxiety) and prolonged cortisol release results from persistent negative affect and appraisals (trait anxiety) (Hannibal & Bishop, 2014). Cortisol response in depression varies based on sex and severity (Dziurkowska & Wesolowski, 2021) and a significant positive association has been found between depression and cortisol levels in men (Jia et al., 2019; Powers et al., 2016). In comparison to results from The POOCH Study, no clear trends arose between state anxiety nor depression and cortisol level. Cortisol levels did, however, share a similar trajectory as trait anxiety in all participants except one. The participant with the highest trait anxiety had the lowest cortisol levels. The inverse relationship between trait anxiety and cortisol levels in someone with high levels of trait anxiety is supported by a recent study by Gao et al. (2024). Individuals with high trait anxiety tend to experience more stress and negative emotions resulting in persistent HPA-axis activation which can lead to dysregulation and ultimately decreased HPA-axis reactivity and reduced cortisol (Gao et al., 2024).

One participant in the companion dog walking group had the highest levels of depression and state and trait-anxiety at baseline and had consistent improvement in symptomology throughout the study. Simultaneously, their cortisol levels were the lowest at baseline and demonstrated consistent increase as psychological symptoms improved. The participant's cortisol trends are consistent with HPA-axis dysregulation that can occur in those with mental disorders such as anxiety and depression (Cowen et al., 2010; Mikkelson et al., 2017). A review of meta-analyses by Wegner et al. (2014) found people with anxiety and depression tend to benefit more from physical activity and exercise compared to those with no or low-levels symptoms (Wegner et a., 2014). Wegner et al.'s findings may provide insight into the substantial improvements demonstrated by this participant who was also the only participant to exceed their companion dog walking requirements throughout the study period.

Although the gold standard for single point testing is done in the morning when cortisol levels are at their highest (El-Farhan et al., 2017; Montes-Villarreal et al., 2020; Mohd Azmi et al., 2021), some have argued when assessing cortisol in the context of depression, afternoon single point testing is preferred because cortisol is more constant at that time (Dziurkowska & Wesolowski, 2021). While morning cortisol sampling can be logistically challenging for both the researcher and participant, a consistent reference range for afternoon (12pm-3pm) cortisol levels has not been established, nor is it likely to be, due to the dynamic nature of cortisol secretion and its response to various stressors (Hannibol & Bishop, 2014). Although the collection time remained the same across all time points for each participant, due to logistical constraints, some participants had their cortisol collected in the morning and some had their cortisol collected in the afternoon. This approach allows for

the assessment of individual changes over time but limits the ability to critically analyze cortisol response between participants. To improve comparison between participants, cortisol sampling should be done within the same time period for all participants. Consequently, this may limit eligibility for participants who have scheduling conflicts.

As an alternative, researchers interested in better understanding the complex interplay between depression, anxiety, and cortisol in ICU survivors may consider the use of salivary cortisol sampling which has the benefits of self-collected samples and more frequent sampling (Smyth et al., 2013). For example, salivary sampling at four different time points throughout a given day can be done to evaluate the diurnal pattern of cortisol, or morning sampling on consecutive days can be done to assess the cortisol awakening response (Gao et al., 2024; Smyth et al., 2013). However, salivary samples can be challenging for participants to adhere to collection directions and times (Smyth et al., 2013). Researchers must weigh the benefits and disadvantages with each collection method based on their research aims.

Contextual Considerations

Most of the participants in the dog walking group demonstrated limited intervention fidelity. Contextual factors such as weather, declining health, and travel contributed to their non-adherence. Weather has been found to influence physical activity and exercise participation (Hodgson & Hitchings, 2023; Moran et al., 2014; Wagner et al., 2019). For example, winter weather and inclement weather often deter people from taking part in physical activity (Hodgson & Hitchings, 2023; Moran et al., 2014; Wagner et al., 2019). Therefore, protocol refinement for The POOCH Study may include conducting recruitment and enrollment during the spring, summer, and fall months only. Alternatively, for a future

large-scale multi-site multi-state study, weather and climate should be closely examined to see how these factors may influence companion dog walking.

Results of The POOCH Study indicate dog characteristics may influence companion dog walking in ICU survivors. The two participants in the study with the youngest dogs reported that their dogs required high levels of physical activity. These two participants were also the ones who took part in the most dog walking within their assigned groups and were the ones with the most improvement in outcome measures. This finding contrasts with other research that found the physical activity level of companion dog owners was unrelated to the age, size, or energy level of their dog(s) (Hielscher-Zdzieblik et al., 2022). However, aligns with results that have shown a companion dog's energy level may have a significant influence on dog walking motivation and behavior (Lim & Rhodes, 2016). Accordingly, dog characteristics should be examined in future studies to determine their influence on the intervention and outcome measures.

Another contextual factor that may influence the impact of companion dog walking on ICU survivor health is the human-companion dog relationship. Research shows the human-companion dog relationship is not clearly understood and additional research is needed to identify specific elements of the relationship that may influence human health (Nelson et al., 2024). The Monash Dog Owner Relationship Scale (MDORS) is a psychometrically tested and verified measurement tool that measures specific aspects of the human companion-dog relationship (Dwyer et al., 2006). The tool is unique in that it is species specific to dogs and intended for use with *companion* dogs. The MDORS could contribute valuable insight into the human-companion dog relationships of ICU survivors and the influence of these relationships on companion dog walking and ICU survivor

psychological health. Future protocol refinement may include the addition of the MDORS as an outcome measure.

Conclusion

The POOCH Study was the first RCT to examine the feasibility and acceptability of a companion dog walking intervention on the psychological health of adult ICU survivors. Results suggest the current protocol supports successful masking of participants and collection of measurements and data points, while protocol revisions are necessary to improve recruitment, intervention fidelity by participants, and attrition. Study processes and interventions were acceptable for both those in the attention control education group and companion dog walking intervention group. Analysis and interpretation of exploratory outcomes were limited due to the small sample size. While definitive trends were lacking, results suggest companion dog walking may have the potential to influence aspects of psychological health in adult ICU survivors and future research is warranted.

APPENDIX A

SCOPING REVIEW SEARCH STRATEGY

CINAHL Database Search

#	Query	Limiters/Expanders	Last Run Via
S10	S7 NOT S4	Expanders - Apply equivalent subjects Narrow by Language: - english Narrow by SubjectAge: - all adult Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL
S9	S7 NOT S4	Expanders - Apply equivalent subjects Narrow by SubjectAge: - all adult Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL
S8	S7 NOT S4	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL
S7	S6 NOT animal assisted therapy	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL
S6	S5 NOT S3	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL
S5	S1 AND S2	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL
S4	positron emission tomography	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL
S3	service dog	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL
S2	ptsd OR post traumatic stress disorder OR depression OR anxiety	Limiters - Published Date: 20000101-20221231 Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL
S1	pets OR dog OR dogs OR companion dog OR dog ownership OR companion animal	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL

PsycInfo Database Search

#	Query	Limiters/Expanders	Last Run Via
S8	S5 NOT service animals	Expanders - Apply equivalent subjects Narrow by Language: - English Narrow by SubjectAge: - adulthood (18 yrs & older) Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - APA PsycInfo
S7	S5 NOT service animals	Expanders - Apply equivalent subjects Narrow by SubjectAge: - adulthood (18 yrs & older) Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - APA PsycInfo
S6	S5 NOT service animals	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - APA PsycInfo
S5	S4 NOT positron emission tomography	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - APA PsycInfo
S4	S3 NOT service dogs	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - APA PsycInfo
S3	S1 AND S2	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - APA PsycInfo
S2	DE "pets" OR dog OR companion dog OR dog ownership	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - APA PsycInfo
S1	ptsd OR posttraumatic stress disorder OR depression OR anxiety	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - APA PsycInfo

PubMed Database Search

((dog OR dogs OR companion animal OR companion dog OR pets OR dog ownership) AND (ptsd OR post traumatic stress disorder OR anxiety OR depression)) NOT (positron emission tomography) NOT animal assisted therapy AND (alladult[Filter]) NOT service dog

APPENDIX B

ACCEPTABILITY SURVEY

Acceptability Assessment and Analysis Plan

Research Question 2: For adult ICU survivors, what is the acceptability of participating in an RCT comparing a companion dog-walking intervention to an attention control education intervention on depression, anxiety, salivary cortisol, and QOL?

Acceptability of the study and intervention will be evaluated based on the following acceptability research questions and the associated questions to participants that will be included on the acceptability survey (answers and themes will be evaluated):

1. **What was the acceptability of the time spent in the study and per session?**

Question to Participant: Do you feel the total time spent in the study was?

Too Long	Just Right	Too Short

Dog-walking Group:

Question to Participant: Do you feel the time spent per session (including dog walk and diary writing) was?

Too Long	Just Right	Too Short

Attention Control Group:

Question to Participant: Do you feel the time spent per session (including reading the educational materials and diary writing) was?

Too Long	Just Right	Too Short

2. **What was the acceptability of completing the measurement tools (questionnaires and salivary cortisol)?**

Question to Participant: Do you feel the time it took to complete the measurements (surveys and cortisol sampling) was?

Too Long	Appropriate	Too Short

Question to Participant: Do you feel the number of measurements (surveys and cortisol sampling) were too many?

Yes	No

Question to Participant: Do you feel the measurements (surveys and cortisol sampling) were easy to complete?

Yes	No

Question to Participant: Do you feel the accelerometer was easy to use?

Yes	No

3. What was the acceptability of the masking procedure?

Question to Participant: Studies that test new treatments often have a second group to compare the treatment with (control group). Were you in the treatment group or the control group?

Treatment	Control	Unsure

4. What was the acceptability of the interventions (dog walking and attention control)?

Note: Intervention acceptability questions were developed in alignment with Sekhon et al.'s (2017) theoretical framework of acceptability (TFA).The blue writing indicates which TFA construct is being addressed.

Dog-walking Group:

Question to Participant: I enjoyed participating in weekly dog-walking. (Affective attitude)

Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree

Question to Participant: I understand the dog-walking routine I was asked to participate in and how it might improve my symptoms. (Intervention coherence)

Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree

Question to Participant: Dog-walking forced me to give up other things that were important to me. (Opportunity costs)

Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree

Question to Participant: I was confident in my ability to participate in dog-walking. (Self-efficacy)

Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree

Question to Participant: Dog-walking fits well with my values. (Ethicality)

Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree

Question to Participant: Going on walks with my dog took a lot of effort. (Burden)

Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree

Question to Participant: Walking with my dog has made me feel better. (Perceived effectiveness)

Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree

Attention Control Group:

Question to Participant: I enjoyed receiving and reading weekly educational materials about my dog. (Affective attitude)

Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree

Question to Participant: Reading weekly educational material about my dog forced me to give up other things that were important to me. (Opportunity costs)

Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree

Question to Participant: I was confident in my ability to take part in reading weekly educational material and learning about my dog. (Self-efficacy)

Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree

Question to Participant: Reading weekly educational material about my dog fits well with my values. (Ethicality)

Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree

Question to Participant: Reading the weekly educational material took a lot of effort. (Burden)

Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree

Question to Participant: Reading and learning about my dog on a weekly basis has made me feel better. (Perceived effectiveness)

Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree

5. To what extent do study participants intend to continue the intervention after the end of the study?

Dog-walking Group:

Question to Participant: Do you intend to continue with dog walking on a weekly basis?

Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree

Attention Control Group:

Question to Participant: Do you intend to continue seeking and reading information about your dog on a weekly basis?

Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree

6. What suggestions for improvement do participants have?

Question to Participant: What suggestions do you have to improve this study?

APPENDIX C

RECRUITMENT FLYER

Have you recently received care in the ICU?

If so, consider joining others who are helping researchers in Southern Colorado, in association with the University of Missouri-Kansas City, understand how your pet dog may affect your recovery and wellbeing after hospital discharge.

You May Qualify If:

- You are 18 years of age or older and have a smart phone.
- Within the last month, you received care in the ICU for at least 24 hours.
- You have a pet dog and walk your dog less than 10 minutes per week.
- You are able to walk for at least 10 minutes at a single time.
- You live within a 45-mile radius of Colorado Springs.
- You are willing to participate in the study over an 8-week period.

Why Participate:

- You may experience improvement to your mental health and quality of life.
- You may contribute valuable information that may help future ICU Survivors.
- You will be compensated up to $50.00 in gift cards.
- Your dog will be gifted a bandana with the study logo after study completion.
- You will be supporting a PhD Nursing Student's dissertation research.

If you are interested in participating or learning more, please inform your nurse by completing the attached permission form,
OR contact the researcher Lindsey Nelson, PhD-C, MSN, RN
320-224-6074 or lnr2m@mail.umkc.edu

CommonSpirit [formerly centura]

UMKC UNIVERSITY OF MISSOURI KANSAS CITY

APPENDIX D

SCREENING TOOLS

Screening Questions Built into the Demographic Survey

1. Do you live within a 45-mile radius of Colorado Springs?

   Yes No

2. Do you have any pets in the home? (Please circle the best response)

   Yes No

If you answered 'yes' to question 7, please complete questions 8-9.

3. What type of pet do you have?

   Dog Cat Other

4. Is your pet trained as a service animal or therapy animal?

   Yes No

5. Do you own a smart phone (Apple iOS 15 or higher, or Android 9 or higher)?

   Yes No

6. Are you receiving treatment for anxiety and/or depression?

   Yes No

If you answered 'yes' to question 11, please complete question 12.

a. Please circle the answer that best describes your anxiety and depression treatment.
   i. I recently started a new treatment
   ii. I have an established ongoing routine that I have been taking part in.

Additional screening questions will be added to the demographic form for potential participants being screened outside of the hospital setting:

13. When were you discharged from the hospital?

14. Where did you see the recruitment flyer?

    While in the hospital While at the clinic

If you answered "while at the clinic" proceed to the following questions:

15. How long were you in the ICU?

16. Were you discharged home?

    Yes No

17. Did your doctor give you any activity restrictions?
Yes No

Scoring: Participants will be excluded if they answer in the following ways:

6. No
7. No
8. Cat or Other
9. Yes
10. no
11. n/a
12. a. “I recently started a new treatment”
13. More than 4 weeks ago
15. <24hrs
16. no
17. yes

Dog Safety Tool

Questions

1. Does your dog have any health or medical problems that may prevent them from going for walks?
    a) No (skip to Q2)
    b) Yes- could you please tell me a bit more about this? (e.g., My dog has arthritis and can't walk very far)

2. Does your dog have any behavioral issues that may prevent them from going for walks?
    a) No
    b) Yes
        i. Does your dog display aggressive behavior? (e.g., barking, growling, baring teeth, snapping, lunging, biting or attempting to bite)
            a. No (skip to Q ii)
            b. Yes – could you please tell me a bit more about this? (e.g., My dog doesn't like other dogs when we are walking. He snaps at them.)

        ii. Does your dog show signs of fear or anxiety? (e.g., avoiding eye contact, avoidance of feared object, crouching or cringing with tail lowered, or tucked between the legs, whimpering and whining, freezing, or exaggerated cowering and/or vigorous attempts to escape, retreat or hide from feared object, person or situation)
            a. No (skip to Q iii)
            b. Yes – could you please tell me a bit more about this? (e.g., My dog crouches with its tail low when it meets a new person)

        iii. Does your dog show signs of extreme excitability at the slightest thing? (e.g., barking or yelping hysterically at the slightest disturbance, and is difficult to calm down)
            a. No
            b. Yes, – could you please describe what problems your dog has? (e.g., My dog barks all the time and I find it hard to stop him)

Scoring:

- The dog will be eligible to participate if all questions are answered no.
- If participants answer "yes" on any question they will be asked to expand. If the intervention requirements do not involve scenarios or expectations associated with participants response, participants will be allowed to participate.
    - Example 1: Question 1 asks, "does your dog have any health or medical problems that may prevent them from going for walks?" If the participant answers "Yes, he has developed arthritis and can't do as much. I don't like to do anything with him for more than an hour." This participant could be included because the intervention requires dog walking in 10-30 minute bouts.

- Example 2: Question 2ii asks, “does your dog show signs of fear or anxiety?” If the participant answers “yes” and states, “the only time she gets anxious is when we go the vet,” this participant could participate because the intervention does not involve any veterinary visits.

Adopted and modified with permission.

Ng, M., Wenden, E., Lester, L., Westgarth, C., & Christian, H. (2021). A study protocol for a randomized controlled trial to evaluate the effectiveness of a dog-facilitated physical activity minimal intervention on young children's physical activity, health and development: The PLAYCE PAWS trial. *BMC Public Health, 21*(1), 51-51. https://doi.org/10.1186/s12889-020-10034-7

Provider Authorization

1. Are you able to walk a 1-block distance without assistance and without stopping due to pain, tightness, or pressure in the chest? Yes/No

   If "No", then medical release will be required prior to study randomization.

2. Has your doctor ever said that you have a heart condition? Yes/No

   If "Yes", then medical release will be required prior to study randomization.

3. Do you feel pain in your chest at rest, during your daily activities of living, OR when you do physical activity? Yes/No

   If "Yes", then medical release will be required prior to study randomization.

4. Do you lose balance because of dizziness OR have you lost consciousness in the last 12-months? Yes/No

   If "Yes", then medical release will be required prior to study randomization.

5. Have you ever been diagnosed with another chronic medical condition (other than heart disease or high blood pressure)? Yes/No

   If "Yes", then medical release will be required prior to study randomization..

6. Do you currently have (or have had within the past 12-months) a bone, joint, or soft tissue (muscle, ligament, or tendon) problem that could be made worse by becoming more physically active? Yes/No

   If "Yes", then medical release will be required prior to study randomization.

7. Has your doctor ever said that you should only do medically supervised physical activity? Yes/No

   If "Yes", then medical release will be required prior to study randomization.

Timed Up and Go (TUG) Test

Equipment needed: standard chair, stopwatch, measured distance of 10 feet

Patient Instructions: “You will begin this test when I say, “ready, set, go.” When I say “go,” I want you to stand up from your chair. You may use the arms of the chair to stand up or sit down. Once you are up, I want you to walk as quickly as you can while still feeling comfortable and safe until you reach this piece of tape (or marked area) with both feet. You will then turn around and walk back to the chair. I will stop the clock when you sit down and your back touches the back of the chair. You will complete one practice run, and then two that are counted.”

Researcher Instructions: Start timing on the word “go” and stop timing when the participant is seated in the chair with their back resting on the back of the chair. The participant should wear their normal footwear and cannot be assisted by another person. There is no time limit. They may stop to rest but not to sit down.

Scoring:

≤ 10 seconds = normal
10-20 seconds = good mobility, can go out alone, mobile without gait aid
>20 seconds = mobility problems, cannot go outside alone, requires gait aid

*Those scoring ≤ 20 seconds will be included in the study.

University of California San Diego, Brief Assessment of Capacity to Consent (UBACC)

Question	Score
1. What is the purpose of the study that was just described to you? Response: (2=to study how my dog can help me after my ICU stay)	0 1 2
2. What makes you want to consider participating in the study? Response: (2=help others OR help my anxiety and depression OR help me feel better OR see how my dog can help me)	0 1 2
3. Do you believe this is primarily research or primarily treatment? Response: (2=Research)	0 1 2
4. Do you have to be in this study if you do not want to participate? Response: (2=No)	0 1 2
5. If you withdraw from this study, will you still be able to receive regular treatment? Response: (2=Yes)	0 1 2
6. If you participate in this study, what are some things you will be asked to do? Response: (2=At least 2 study procedures: examples: walk my dog or read about dogs, have my blood drawn, take surveys or answer questions, wear an activity monitor, fill out a diary log	0 1 2
7. Please describe some of the risks or discomforts that people may experience if they participate in this study. Response: (2=At least two of the following: the study may not work for me, injury or fall during dog walking, my dog could become aggressive towards other people or dogs on a walk, my dog may break free from me during a walk, blood draw could be uncomfortable, my information may be accidently shared with others.	0 1 2
8. Please describe some of the possible benefits of this study. Response: (2= might make my depression or anxiety better, might make my quality of life better, might help other ICU survivors, society might learn more about how dogs can help people)	0 1 2
9. Is it certain that this study will benefit you? Response: (2=No)	0 1 2
10. Who will pay for medical care if you, your dog, or another person or dog is injured as a direct result of participating in this study? Response: (2=These costs will be billed to me or my insurance company)	0 1 2

TOTAL SCORE……
_____

Instructions and Scoring:

After reviewing study details and informed consent document, explain that you are going to ask a few brief questions about the study. Participants should be allowed to refer to the informed consent form when answering these questions but should be encouraged to respond in their own words. If a participant has trouble understanding one of the questions on the UBACC, rephrase the question. Rate the participant's responses on a scale of 0-2, with '0' being the lowest (little to no understanding of this aspect of the study) and '2' being the highest (clear understanding of this aspect of the study). A score of 15 or higher is needed for inclusion in the study. Those scoring 14 or less will be excluded.

Note: The UBACC is intended to be modified based on the given study. Permission was granted and fees were paid to JAMA Network for the use of the UBACC.

Jeste, D. V., Palmer, B. W., Appelbaum, P. S., Golshan, S., Glorioso, D., Dunn, L. B., Kim, K., Meeks, T., & Kraemer, H. C. (2007). A new brief instrument for assessing decisional capacity for clinical research. *Archives of General Psychiatry, 64*(8), 966-974. https://doi.org/10.1001/archpsyc.64.8.966

APPENDIX E

DEMOGRAPHIC SURVEY

7. What is your age?
8. What is your biological sex? (Please circle the best response)

   Male Female Other
9. What is your ethnicity? (Select all that apply)
   1. American Indian or Alaska Native
   2. Asian
   3. Black or African American
   4. Hispanic or Latino
   5. Native Hawaiian or Other Pacific Islander
   6. White
10. What is your highest achieved education level? (Please circle the best response)
    1. Less than high school
    2. High school diploma or equivalent
    3. Completed some college, no degree
    4. Post-secondary non-degree award
    5. Associate's Degree
    6. Bachelor's Degree
    7. Graduate Degree (including Master's, Doctoral, and/or professional degrees)
11. What is your marital status? (Please circle the best response)

    Single Separated Married Divorced Widowed
12. Do you live within a 45-mile radius of Colorado Springs?

    Yes No
13. Do you have any pets in the home? (Please circle the best response)

    Yes No

    If you answered yes to question 7, please complete questions 8-10.

    14. What type of pet do you have?

        Dog Cat Other
    15. Is your pet trained as a service animal or therapy animal?

        Yes No
    16. What is your dog's age?

17. Do you own a smart phone (Apple iOS 15 or higher, or Android 9 or higher)?

Yes No

18. Are you receiving treatment for anxiety and/or depression?

Yes No

If you answered 'yes' to question 12, please complete question 13.

a. Please circle the answer that best describes your anxiety and depression treatment.
    i. I recently started a new treatment
    ii. I have an established ongoing routine that I have been taking part in.

ICU Admission Information

1. Why were you admitted to the ICU?
    a. Sepsis
    b. Respiratory Insufficiency/Failure
    c. Cardiac diagnosis (e.g., Myocardial Infarction)
    d. Surgical Procedure
    e. Gastrointestinal/Hepatic Diagnosis
    f. Neurological Diagnosis
    g. Traumatic accident
    h. Other
2. How long were in the ICU?
3. Were you on the ventilator during your ICU stay? Yes No
    a. If yes, how long were you on the ventilator?

Additional Questions:

Additional screening questions will be added to the demographic form for potential participants being screened outside of the hospital setting:

15. When were you discharged from the hospital?

16. Where did you see the recruitment flyer?
    While in the hospital While at the clinic

If you answered "while at the clinic" proceed to questions 15-16

15. Were you discharged home?
    Yes No

16. Did your doctor give you any activity restrictions?

Yes No

All participants will be asked during the initial home visit:

Have you been prescribed any physical rehabilitation by your provider?

Yes No

APPENDIX F

DOG WALKING INTERVENTION INSTRUCTIONS

Intervention Group 2: Instructions

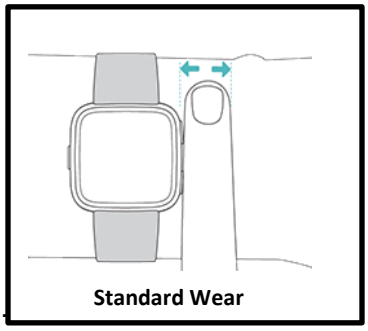
Weekly Dog Walking Instructions

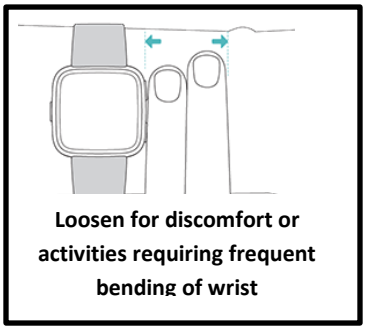
- Prior to your first dog walk, please read "Dog Walking, Step by Step." The information in the reading has important safety information and considerations when dog walking.
- Walk your dog three days per week for at least 30 minutes each of those days.
    - You do not need to walk all 30 minutes at the same time.
    - Your dog walk could be as short as 10 minutes each walk. In which case you would need to walk 3 times that day, for a total of 30 minutes.
        - Other examples:
            - 20-minute morning walk + 10-minute afternoon walk
            - 15-minutes morning walk + 15-minute afternoon walk
            - 10-minute walk after breakfast + 10-minute walk after lunch + 10- minute walk after dinner

Fitbit Monitor Instructions

How do I wear the monitor?

- The Fitbit monitor should be worn on your non-dog walking wrist. [Example, if you hold your dog's leash in your left hand, wear the Fitbit monitor on your right wrist]. If you frequently change your leash holding hand, wear the Fitbit monitor on your non-dominant hand.
- Wear the Fitbit monitor every day during waking hours during the 8-week study period.
- Wear the Fitbit monitor on top of your wrist. The back of your Fitbit monitor should be in contact with your skin.
- Make sure that your band isn't too tight. Wear it loose enough that it can move back and forth on your wrist.
- If you experience any discomfort or irritation, loosen the band. It is okay to loosen the band 2-3 finger widths during activities that require a lot of bending of the wrist.
- To reduce skin irritation and to ensure the monitor functions well, remove the Fitbit monitor prior to applying lotions, bug spray, sunscreen etc.
- The Fitbit is water resistant, so you do not need to remove during showers, but you can if you prefer.


Standard Wear


Loosen for discomfort or activities requiring frequent bending of wrist

For additional information on ware and care of your device, please visit: https://www.fitbit.com/global/us/product-care

How to Use the Monitor

- To function and collect data correctly, the Fitbit monitor requires you to download the Free Fitbit Mobile App on your smartphone and enable Bluetooth on your phone.
- The researcher will help set up your Fitbit monitor, the Mobile App, and a research assigned Fitbit account during the first visit and answer any questions you have.
- Please do not enable additional features on the Fitbit monitor or Fitbit Mobile App. They are programmed specifically for this research study.
- Prior to going to bed every night, please charge and sync your Fitbit monitor.
    - Charging your Fitbit:
        - Remove the Fitbit monitor and plug it in to charge the battery [the battery of the Fitbit monitor is good for approximately 3 days]
    - Syncing your Fitbit device:
        - The term "syncing" refers to the process that transfers physical activity information from your Fitbit monitor to the Fitbit account for researcher review.
        - Make sure Bluetooth is enabled.
        - Make sure your Fitbit monitor and phone are close together (within 20 feet)
        - Open the Fitbit Mobile App on your phone and push "sync now".

What Else do I Need to Know

- If you remove the Fitbit monitor for an extended period of time during the day, please write down the time you removed it and put it back on in your daily diary.
- The researcher will collect the Fitbit monitor at their final visit at the end of week 8.

Diary Log Instructions

- This is both a diary log and a schedule to help you remember what will be happening every week.
- Fill out this diary log every day.
- The log is divided by weeks into 7 days. Please complete each question for all of the seven days. Please try and be as accurate as possible—record the exact times if you can, or at least to the nearest 5 minutes of your estimated times.
- When you are done with a walk, write down when you started and stopped that walk. You will do the same thing for every walk you take with your dog. If you do not walk your dog on a given day, you can just write "n/a."
- There is also space for you to make **comments**. It is useful for us to know if you have had any difficulties with the monitors or anything you think we should know about your walking experiences.
- If you remove the device for longer than 10 minutes during the day, please write down the time that you removed the device and the time that you re-attached it in the comment section.
- At the end of week 8, the researcher will collect your diary log.

APPENDIX G

DIARY LOGS

Dog Walking Intervention Excerpt

Week	Day and Date	Time got out of bed *Remember to put Fitbit monitor on	Dog Walking						Total time dog walking (minutes)	Other comments (Example: If you removed your Fitbit monitor for an extended amount of time, please indicate that here)	
			Dog Walk 1		Dog Walk 2		Dog Walk 3				
			Start Time	End Time	Start Time	End Time	Start Time	End Time			
Prior to Start of Study: First home visit by researcher (65 minutes)											
Week 1	Day 1 Date:										
	Day 2 Date:										
	Day 3 Date:										
	Day 4 Date:										
	Day 5 Date:										
	Day 6 Date:										
	Day 7 Date:										
	Any other comments you think the researcher should know:										Remember to charge your Fitbit monitor when you go to bed
	Telephone call from researcher (5-10 minutes)										

Attention Control Education Intervention Excerpt

Week	Day and Date	Time got out of bed *Remember to put Fitbit monitor on	Educational Reading				Total time reading (minutes)	Did you apply any reading materials today? (yes/no)	How did you interact with your dog today?	Other comments (Example: If you removed your Fitbit monitor for an extended amount of time, please indicate that here)	
			Reading Session 1		Reading Session 2						
			Start Time	End Time	Start Time	End Time					
Week 3	Day 1 Date:										Remember to charge your Fitbit monitor when you go to bed
	Day 2 Date:										
	Day 3 Date:										
	Day 4 Date:										
	Day 5 Date:										
	Day 6 Date:										
	Day 7 Date:										
	Any other comments you think the researcher should know:										
	Telephone call from researcher (5-10 minutes)										

APPENDIX H

ATTENTION CONTROL INTERVENTION INSTRUCTIONS

Intervention Group 1: Instructions

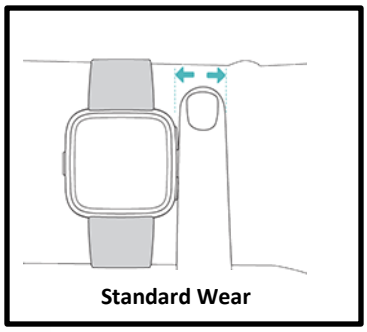
Weekly Reading Instructions

- You will receive a folder with reading materials inside. All the materials relate to dogs and dog health. There is a list of what materials to read each week.
- You will be assigned at least one reading every week.
- You can read the material any time you would like throughout the week. You do not need to complete it all in one sitting.

Activity Monitor Instructions

How do I wear the monitor?

- The Fitbit monitor should be worn on your non-dominant hand.
- Wear the Fitbit monitor every day during waking hours during the 8-week study period.
- Wear the Fitbit monitor on top of your wrist. The back of your Fitbit monitor should be in contact with your skin.
- Make sure that your band isn't too tight. Wear it loose enough that it can move back and forth on your wrist.
- If you experience any discomfort or irritation, loosen the band. It is okay to loosen the band 2-3 finger widths during activities that require a lot of bending of the wrist.
- To reduce skin irritation and to ensure the monitor functions well, remove the Fitbit monitor prior to applying lotions, bug spray, sunscreen etc.
- The Fitbit is water resistant, so you do not need to remove during showers but you can if you prefer.



Standard Wear

Loosen for discomfort or activities requiring frequent bending of wrist

For additional information on ware and care of your device, please visit: https://www.fitbit.com/global/us/product-care

How to Use the Monitor

- To function and collect data correctly, the Fitbit monitor requires you to download the Free Fitbit Mobile App on your smartphone and enable Bluetooth on your phone.
- The researcher will help set up your Fitbit monitor, the Mobile App, and a research assigned Fitbit account during the first visit and answer any questions you have.
- Please do not enable additional features on the Fitbit monitor or Fitbit Mobile App. They are programmed specifically for this research study.
- Prior to going to bed every night, please charge and sync your Fitbit monitor.
    - Charging your Fitbit:
        - Remove the Fitbit monitor and plug it in to charge the battery [the

battery of the Fitbit monitor is good for approximately 3 days]

- Syncing your Fitbit device:
  - The term “syncing” refers to the process that transfers physical activity information from your Fitbit monitor to the Fitbit account for researcher review.
  - Make sure Bluetooth is enabled.
  - Make sure your Fitbit monitor and phone are close together (within 20 feet)
  - Open the Fitbit Mobile App on your phone and push “sync now”.

What Else do I Need to Know

- If you remove the Fitbit monitor for an extended period of time during the day, please write down the time you removed it and put it back on in your daily diary.
- The researcher will collect the Fitbit monitor at their final visit at the end of week 8.

Diary Log Instructions

- This is both a diary log and a schedule to help you remember what will be happening every week.
- Fill out this diary log every day.
- The log is divided by weeks into 7 days. Please complete each question for every day. Please try and be as accurate as possible—record the exact times if you can, or at least to the nearest 5 minutes of your estimated times.
- When you have done any reading, write down when you started and stopped that reading session. You will do the same thing each time you read the materials assigned. If you do not do any reading on a given day, you can just write “n/a.”
- There is also space for you to make **comments**. It is useful for us to know if you have had any difficulties with the monitors or anything you think we should know about your reading experience.
- If you remove the device for longer than 10 minutes during the day, please write down the time that you removed the device and the time that you re-attached it in the comment section.
- At the end of week 8, the researcher will collect your diary log.

APPENDIX I

INFORMED CONSENT

Consent to Participate in Research

Study Title:

Feasibility and Acceptability of a Randomized Controlled Trial Comparing a Companion Dog Walking Intervention to a Companion Dog Education Intervention on the Psychological Health of Adult Intensive Care Unit Survivors: The POOCH Study

Authorized Study Personnel

Lindsey Nelson Secondary Investigator Phone: 320-224-6074 Email: lnr2m@mail.umkc.edu	Sue Lasiter Principal Investigator Phone: 816-235-6766 Email: LasiterR@umkc.edu

KEY INFORMATION

You are being asked to take part in this research study because you have had an illness or injury that required treatment in the intensive care unit (ICU). Research studies are voluntary and only include people who choose to take part. The purpose of this research is to find out the best way pet dogs can help with symptoms of depression and anxiety after surviving a critical illness/injury and being discharged home from the hospital. The total amount of time you would be in this study is eight weeks. During your participation you will be involved in one of two interventions. You will either walk your dog or read educational resources on dog health and care. Taking part in this research involves the following risks or discomforts: discomfort from laboratory blood draws, loss of confidentiality, and if participating in dog walking a risk of falls. Taking part in this study may include the following benefits: improved symptoms of depression, anxiety, and/or quality of life. The alternative to taking part in this study is to continue your normal care with your medical provider and/or seek care from a licensed psychologist, psychiatrist, or counselor to receive therapy and/or medications to help treat your anxiety or depression.

Please read this consent form carefully and take your time making your decision. As the researcher discusses this consent form with you, please ask her to explain any words or information you do not clearly understand. To help in your decision-making process you may wish to talk with your family and/or friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Lindsey Nelson will conduct the study and it is funded by SIGMA International Honor Society of Nursing and Doris Bloch Foundation.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to find out the best way pet dogs can help with symptoms of depression and anxiety after surviving a critical illness or injury and being discharged home from the hospital.

You are being asked to be in this study because you are an intensive care unit survivor, and you went home after you left the hospital. That means you had an illness or injury that required care and treatment in the intensive care unit. To participate, you must be at least 18 years of age, you must own a pet dog, it must be safe for you and your dog to participate, and you must have symptoms of depression or anxiety.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 30 people will take part in this study.

WHAT IS INVOLVED IN THE STUDY?

Screening
Screening will occur after consenting to the study. To know if you meet the requirements of the study, we will have you complete:

- A survey that tells us if you are having symptoms of depression.
- A survey that tells us if you are having symptoms of anxiety.
- A survey that tells us your understanding of the research study.
- A form about your demographic information such as biological sex, race, education, marital status, and employment. This same form will ask questions about your intensive care unit stay such as why you were admitted and how long you were there. The same form will also ask you about personal pets you may have, how far away you live from the hospital, if you own a smartphone, and if you recently began treatment for depression or anxiety.
- A form that helps us better understand the health and behaviors of your dog (for dog-owners only).
- A survey that asks about your health history and health status.

If you are eligible to participate, you will be randomly assigned to 1 of 2 treatment groups for the 8-week study period. This is similar to flipping a coin. You will have a 50% chance of being in one group or the other.

We will arrange a time to meet with you in your home 2 to 4 weeks after you are discharged. If it is not okay to meet in your home, we can arrange for another meeting place. During the meeting, the researcher will have you complete a brief assessment that helps us understand your balance and physical ability since being discharged home. You must show good balance and physical ability to be in the study. If you meet the requirements of the brief assessment, you will begin the study. We will give you a small activity monitor that you wear on your wrist that measures your activity, and a diary log for you to fill out throughout the study. The activity monitor will require you to download a free App on your phone to function and collect data appropriately.You will be

given instructions about your assigned intervention, how the activity monitor and diary log work, and the researcher will answer any questions you may have. During the meeting you will be asked to complete three surveys: The Center for Epidemiologic Studies Depression Scale (CES-D); The Spielberger State Trait Anxiety Inventory (STAI-AD); and The Short Form 36 (SF-36). The researcher will also draw a blood sample to measure your cortisol levels. The home meeting, surveys, and blood collection should take approximately 65 minutes.

Intervention Group 1: If you are assigned to this group, you will receive educational materials about dog health and care. You will receive the educational materials in a folder during the first home visit but will be assigned to specific material every week. Throughout the study you will learn more about first aid for dogs; summer and winter care tips; common illnesses such as leptospirosis and parvovirus; flea, tick, and parasite prevention; dog bite prevention; allergies; preventative care and keeping pets safe; and traveling with a dog. You will be asked to wear the activity monitor every day during waking hours and record in the diary log when you started and stopped reading the handouts throughout the 8-week study.

The researcher, Lindsey Nelson, will call you after the first week to review the intervention, discuss the educational materials that were sent to you, and answer any questions you may have. During weeks 1,2,3,5,6, and 7, the researcher will call you to discuss the most recent education materials you were sent and answer any questions you may have. The researcher will meet with you at your home (or an alternative location) at the end of weeks 4 and 8. During the week 4 visit, the researcher will ask how the intervention is going, answer questions, and collect the first 4-weeks of the diary log. The researcher will also be collecting the 3 surveys again (CES-D, STAI-AD, SF-36) and a blood sample for your cortisol level. On the final home visit during week 8, the researcher will address any questions or concerns you have, and will collect the activity monitor and diary log, the 3 surveys again (CES-D, STAI-AD, SF-36), a blood sample for your cortisol level, and an exit survey about your experience in the study. Total time involved for participants in intervention one is estimated to be 50-95 minutes per week.

Intervention Group 2: If you are assigned to this group, you will be asked to walk your dog in the locations of your choice at least 30 minutes a day, three times per week. You have the choice to complete all 30 minutes of dog-walking at once, or in sessions of at least 10 minutes. You will receive educational material on dog walking safety during the first visit prior to starting the intervention. You will be asked to wear the activity monitor every day during waking hours and record in the diary log when you started and stopped your dog walks throughout the 8-week study.

The researcher, Lindsey Nelson, will call you after the first week to review the intervention, discuss your dog walking, and answer any questions you may have. During weeks 1,2,3,5,6, and 7, the researcher will call you to discuss your dog walking and answer any questions you may have. The researcher will meet with you at your home (or an alternative location) at the end of weeks 4 and 8. During the week 4 visit, the researcher will ask how the intervention is going, answer questions, and collect the first 4-weeks of the diary log. The researcher will also be collecting the 3 surveys again (CES-D, STAI-AD, SF-36) and a blood sample for your cortisol level. On the final home visit during week 8, the researcher will address any questions or concerns you have, and will collect the activity monitor and diary log, the 3 surveys again (CES-

D, STAI-AD, SF-36), a blood sample for your cortisol level, and an exit survey about your experience in the study. Total time involved for those in intervention two is estimated to be 2 hours to 2 hours and 35 minutes each week.

Blood Draws
You will be asked to provide a blood sample so your Cortisol level can be measured. Cortisol is nicknamed the "stress hormone." Cortisol is a hormone made by your adrenal glands that can help us understand how your body is responding to physical or mental stress. We will draw about 1 mL of blood
by putting a needle into a vein in your arm. This is the standard method used to obtain blood for tests. We will take 1 mL of your blood a total of three times during the study (prior to starting the study, week 4, and week 8).

If you do not want to be in the full study
Even if you do not want to be in this study, we would like to obtain your age, biological sex, ethnicity, education, marital status, and employment. We would like to obtain the following information about your intensive care unit stay: the reason you were admitted to the hospital, how long you were in the in the intensive care unit, and if/how long you were on a ventilator. This information will not be connected in any way to you. It will be anonymous. We would like this information so that we can describe, in general, the group of people who chose not to be in our study. If you agree to provide this information, it will be obtained at the time of consent while you are in the hospital. You will fill out a paper survey addressing the information noted above that takes less than 5 minutes.

☐ _____Check the box and initial on the line if you are consenting to sharing demographic data, but do not wish to participate in the study.

HOW LONG WILL I BE IN THIS STUDY? You will be in this study for 8 weeks.

WHAT ARE THE RISKS OF THE STUDY?

There is a risk for loss of confidentiality. Every effort will be made to keep your information confidential; however, this is not guaranteed. Specific steps taken to lessen this risk are addressed below.

The risks of having blood drawn from your arm include some pain when the needle goes in and a slight risk of bruising and/or infection at that site. Some people get lightheaded, nauseous, or faint. You are less likely to have these problems if you drink at least 2 glasses of water and have a snack before the blood draw. The researcher is an experienced registered nurse who is trained in proper blood collection and will follow the guidelines for safe and clean blood sample collection. There is a risk of mild skin irritation from the activity monitor on your wrist. To reduce this risk, you will receive education on proper placement, application, and care of the monitor.

If you are assigned to the dog walking group, there is a risk of falling and/or injury. There is also a risk that your dog may break loose from you or become aggressive towards other dogs or

people. To lessen these risks, we ask you questions about your physical ability and health, and about your dog's health and behavior prior to beginning the study. If you or your dog do not meet the requirements, you will be unable to participate in the study. We will also give you information on safe dog walking habits prior to beginning the study.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

You may experience improvement in your depression and anxiety symptoms, and/or you may see improvement in your quality of life.

You may benefit in knowing that you are contributing to medical knowledge. We hope the information learned from this study will benefit other ICU survivors in the future.

However, you may not get any benefit from being in this research study.

The benefits to science and/or society may include better understanding of how pet dogs can help ICU survivors.

WHAT ALTERNATIVES ARE THERE TO PARTICIPATION IN THIS STUDY?

Instead of being in this study, you have these options:

Continue to follow your provider's normal course of care. You could also seek treatment for your anxiety and depression from a licensed psychologist, psychiatrist, or counselor. Treatments for depression and anxiety may include but are not limited to different forms of therapy and/or medications.

Please discuss these and other options with the investigator and your doctor.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?

The University of Missouri System, Authorization No. 00-018 requires research data to be retained for 7 years after the final report.

Reasonable steps will be taken to protect your privacy and the confidentiality of your study data. You will be given an enrollment number at the start of the study and your information will be saved linked to the number and not your name or other personal information that can identify you.

You will have the choice to fill out questionnaires and surveys using paper and pen, or directly on a laptop computer. Information collected on paper will be input into a computer by the researcher. Paper copies will be stored in a locked cabinet in the researcher's locked office and will only be seen by the research team during the study. Any electronic information will be stored on a secure server and password-protected computer in a locked office and will only be seen by the research team during the study.

The only persons who will have access to your research records are the study personnel, the Institutional Review Board (IRB), and any other person, agency, or sponsor as required by law.

HOW WILL MY INFORMATION BE USED IN THE FUTURE?

The information from this study may be published in scientific journals, presented at scientific meetings, or shared for educational purposes, but the data will be reported as group or summarized data and your identity will be kept strictly confidential.

Information collected from this study may be used for future research purposes or given to another researcher for future research studies without getting your permission. However, your name and other information that could directly identify you will be removed prior to use and will never be shared.

WHAT ARE THE COSTS TO YOU? There is no cost to you to be in this research study. The costs associated with the blood sample collection will be covered by the funding organization.

WHAT ABOUT COMPENSATION?

You will receive $20.00 for completing the first four weeks of the study, including the surveys and blood draws that are collected after week four.

You will receive another $30.00 for completing all 8 weeks of the study, including all surveys and the blood draw that are collected at the end of the study. If you complete the entire study, you will receive a total of $50. If you complete the full study, you will also receive a bandana for your dog with the study name: “The POOCH Study.”

WHAT SHOULD YOU DO IF YOU HAVE A PROBLEM DURING THIS RESEARCH STUDY?

Every effort to prevent any injury or harm resulting from this study will be taken by the researchers. Necessary care and professional services will be available to you, just as they are in the general community. If you believe medical care is necessary, you will contact your healthcare provider as usual. If you sustain any injury from this study, you will be responsible for the treatment and you will be responsible for covering the costs of that treatment. If your dog is injured or injures another person or dog, you will be responsible for any treatment and you will be responsible for covering the costs of that treatment. Participation in this research study does not take the place of routine physical examinations or clinic visits to your personal provider(s). If you believe you have been injured because of participating in this study, you are encouraged to contact the researcher Lindsey Nelson at 320-224-6074.

UMKC and CommonSpirit appreciate people who help it gain knowledge by being in research studies. It is not UMKC or CommonSpirit policy to compensate human subjects in the event this research results in injury/harm. In the event you have suffered an injury/harm as the result of participation in this research study, you are to advise the researcher Lindsey Nelson (320) 224-

6074 and contact the University Risk Management Office, telephone (573) 882-1181 who can review the matter and provide further information.

If you experience worsening of your depression and/or anxiety symptoms during the study period, please contact your primary care provider. If you experience a mental health crisis, please contact Colorado Crisis Services at 1-844-493-8255, or text the word "TALK" to 38255.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

Participation in this study is voluntary. You do not have to participate in this study. Your present or future care will not be affected should you choose not to participate.

You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. If you decide to stop participating in the study, we encourage you to talk to the researcher first to make sure it is safe to do so.

You can decide not to be in this research study, or you can stop being in this research study ("withdraw') at any time before, during, or after the research begins for any reason. Deciding not to be in this research study or deciding to withdraw will not affect your relationship with the researcher(s), with the University of Missouri Kansas City, or with Centura Health.

You will not lose any benefits to which you are entitled.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

You may ask any questions concerning this research and have those questions answered before agreeing to participate in or during the study.

For study related questions, please contact the researcher Lindsey Nelson (320)-224-6074.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to your participation in the research, or to obtain information about research participant's rights, contact the overseeing IRBs:

University of Missouri Kansas City
Institutional Review Board (IRB) Office
5319 Rockhill Road
Kansas City, Missouri 64110-2499
Phone: (816) 235-5927
Email: umkcirb@umkc.edu

CommonSpirit Health Research Institute
Institutional Review Board (CSHRI IRB)
198 Inverness Drive West
Englewood, Colorado 80112
Phone (toll-free): 1-844-626-2299
Email: cshri-irb@commonspirit.org

STATEMENT OF CONSENT

The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information. I have read or had read to me this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed copy of this consent form.

_____
Printed Name of Subject

_____ _____ _____
Signature of Subject Date Time

_____
Printed Name of Person Obtaining Consent

_____ _____ _____
Signature of Person Obtaining Consent Date Time

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VITA

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