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Exploring Benefits of Emotional Support Animals (ESAs): A Longitudinal Pilot Study with Adults with Serious Mental Illness (SMI)

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While anecdotal accounts describe mental health recovery-related benefits of having Emotional Support Animals (ESAs), to date there have been no studies on such within peer-reviewed journals. This pilot study yields data on how ESAs may facilitate mental health recovery and related benefits for persons with Serious Mental Illness (SMI). Through an ESA placement program, the Hope and Recovery Pet program (HARP), shelter dogs and cats were placed as ESAs with adults (N=11) with SMI. A longitudinal mixed method research design was utilized to explore potential ESA impact. Pre- and post-placement data from participants was collected on depression, anxiety, and loneliness. Biomarker data (saliva analytes assessing oxytocin, cortisol, alpha amylase) were collected before and after ten-minute interactions with ESAs at 1, 3, 6, 9, and 12 months. Qualitative data was collected twelve months post-placement. Significant reductions in anxiety, depression, and loneliness scale scores via the Beck Anxiety Inventory (BAI), Beck Depression Inventory (BDI), and UCLA Loneliness Scale (UCLA), respectively, were found. While not significant, there was a pattern of oxytocin increase and cortisol decrease after ten minutes of ESA interaction. Qualitative data indicated participants attributed their improvements in mental health and well-being to their respective ESAs. Findings underscore the need for continued research on ESA companionship as a mental health recovery support.

Keywords: emotional support animal; serious mental illness; mental health recovery; One Health

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Impact Statement: This pilot study offers the first peer-reviewed published data on how ESAs can ameliorate impairment and support mental health recovery. Mixed method findings suggest ESAs may help support a range of outcomes related to mental health recovery and provide a rationale for continued research on such.

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Animal companionship is associated with a range of physical, psychological, and social benefits for humans (Wells, 2019). Based on the potential of a serious mental illness to impact physical, psychological, and social domains of human functioning, individuals with serious mental illnesses (SMI) may find such benefits of animal companionship to be particularly helpful. SMI is defined by the National Institute of Mental Health (2019) as: "…a mental, behavioral, or emotional disorder resulting in serious functional impairment, which substantially interferes with or limits one or more major life activities" (no page number). Despite ongoing or intermittent symptoms, people with SMI can experience substantial improvements in well-being, quality of life, and other important aspects of life. The framework of mental health recovery encompasses such improvements, going beyond traditional mental health outcomes such as symptom frequency and hospitalization to include individualized experiences of hope, active growth, safety, symptom management, social support, and wellness (Lusczakoski et al, 2014). Although companion animals have been identified by individuals with SMI as important supports and facilitators of mental health recovery-related outcomes (Brooks et al, 2016, 2018; Wisdom et al., 2009; Zimolag & Krupa, 2009), there is currently no peer-reviewed published research on the impact of companionship of animals specifically identified as Emotional Support Animals (ESAs). The overarching aim of this article is to take a first step toward addressing this gap, through reporting findings of a longitudinal mixed-method study on the perceived impact of ESAs among a sample of adults with SMI.

Understanding the Role of ESAs

The term "Emotional Support Animals" emerged in the United States through several federal discrimination-related disability legislative acts. An ESA can be defined as a companion animal (pet) who helps to reduce disability-related impairment for a particular person through the animal's presence and everyday interactions. The animal needs no special training or certification to be an ESA. Verification of a person's disability-related need for an ESA by the person's treating clinician or healthcare professional via a simple written statement, commonly referred to in practice as an ESA letter, conveys federally recognized legal ESA status for the animal serving as such (U.S. Department of Housing and Urban Development (HUD), 2020). With regards to such provision of verification, HUD (2020) clearly states that clinician knowledge gleaned through routine clinical practice is an adequate and appropriate information source: "when providing this information, health care professionals should use personal knowledge of their patient/client – i.e., the knowledge used to diagnose, advise, counsel, treat, or provide health care or other disability-related services to their patient/client" (p.16). Claims that an expert disability evaluation from a forensic specialist clinician – one who is not providing ongoing treatment or healthcare services to the person being evaluated – is necessary to verify disability criteria for ESA eligibility (Younggren et al, 2019) are thus unsubstantiated and inaccurate.

Currently, federal recognition of ESAs occurs within the Fair Housing Act (FHA), where it is stated that emotional support from a companion animal can be disability-ameliorating and thus needed and protected as a disability accommodation within housing (HUD, 2020). It is important to note that different disability-related policies utilize different definitions of disability. Disability entitlement-related policies utilize far more stringent definitions than disability anti-discrimination policies such as the FHA. For instance, people who would not meet the disability eligibility criteria for financial supports provided through the Social Security Act and state level workers compensation laws can quality as having a disability under the FHA, and are thus eligible for FHA-protected accommodations such as ESAs (HUD, 2020).

Within the FHA, disability is simply and straightforwardly defined as "a physical or mental impairment that substantially limits one or more major life activities" (HUD, 2020, p. 9). HUD recently issued guidance that individuals who meet the diagnostic criteria for certain disorders - such as Major Depressive Disorder, Bipolar Disorder, Post-Traumatic Stress Disorder, Obsessive-Compulsive Disorder, and Schizophrenia - automatically meet the FHA definition of disability (U.S. Department of Housing and Urban Development (HUD), 2020). Readers are referred to Hoy-Gerlach, Vincent and Hector (2019) and the HUD (2020) notice *Assessing a person's request to have an animal as a reasonable accommodation under the Fair Housing Act* for a thorough explication of whether and how to verify ESA need for FHA accommodation.

Until January 2021, ESAs were also recognized as an accommodation within the Air Carrier Access Act (ACAA). The U.S. Department of Transportation implemented amendments eliminating ESAs as air travel accommodations which will go into effect in 2021 (U.S. Department of Transportation, 2020). Of importance, ESAs have never been recognized by the Americans with Disability Act (ADA) as an accommodation within public spaces prohibited to pets; unlike individuals with service animals who are taught to perform specific tasks to alleviate disability, individuals with ESAs do not have public access rights to bring their ESAs into public spaces (American Veterinary Medical Association (AVMA), 2017).

Empirically-supported benefits of human-animal interaction (HAI) – spanning the physical, psychological, social, and emotional dimensions of human functioning – help to illuminate how animal companionship may function as a disability accommodation. Cross-walking these HAI benefits to symptoms and impairment from a given person's mental or physical health condition can provide the "nexus" between that person's condition and a disability-related need for the animal (Hoy-Gerlach et al, 2019). As summarized by Hoy-Gerlach et al (2019):

> The clinical rationale for an ESA is essentially a delineation of how the biopsychosocial aspects of a person's functioning that are adversely impacted by a chronic mental illness may be ameliorated by the biopsychosocial benefits of [human-animal bond] HAB. For example, a person living with debilitating depression may experience challenges with motivation (impairment in psychological functioning) and isolation (impairment in social functioning). Behavioral activation of ESA care and socialization are HAB benefits which directly impact isolation and motivation. Thus, this person may experience symptom amelioration through ESA companionship. (p. 205-206)

Knowledge of how HAI benefits may help ameliorate symptoms and related distress and impairment can be acquired by clinicians through the range of mechanisms used for knowledge dissemination in mental health practice, such as: continuing education; consultation; courses; and supervision.

Clinicians in various health and mental health professions are approached by clients with requests for ESA verification letters, and the value of and need for ESAs has been recognized and codified in U.S. federal law, however, there is currently no peer-reviewed published research that focuses explicitly on the impact of ESAs. Such research could inform understandings of the mechanisms through which people living with chronic health conditions such as SMI may benefit from ESAs, as well as how to better leverage such benefits for human well-being. Understandings of how ESAs may help ameliorate disability-related impairment are currently extrapolated from existing peer-reviewed literature on human biopsychosocial benefits associated with living with companion animals. The overarching aim of this research article is to begin to address this gap in

research literature on ESAs through providing a pilot exploration of how ESAs may benefit adults with SMI.

The Biopsychosocial Benefits of Human-Animal Interaction (HAI)

While there is not yet a body of empirical literature on ESA benefits, the related empirical literature evidencing companion-animal related HAI benefits (henceforth referred to as HAI benefits) for people can be situated and understood within recognized dimensions of human-functioning: physical, emotional, social, and psychological (Hoy-Gerlach & Wehman, 2017). Recent reviews have highlighted reductions in depression and anxiety associated with animal companionship. In a review on HAI and older adults, both animal-assisted therapy and companionship via living with animals were associated with decreased depression and loneliness, improved cardiovascular health, and increased physical activity (Krause-Parello et al, 2019). Gee and Mueller (2019) similarly found in a systematic review that having a pet was associated with decreases in loneliness and depression and improved cardiovascular health in older adults, while cautioning causality assumptions about such. Hughes et al (2020) likewise found in a systematic review of 70 articles that companion animals - whether as pets or through interventions - were associated with reduced symptoms of depression and anxiety, and improvements in blood pressure and heart rate variability in older adults. The evidence of cardiovascular benefits associated with having a dog is robust enough that the American Heart Association put out a scientific statement stating that having pet, particularly a dog, is likely associated with decreased cardiovascular risk and may have some causal role in such (Levine et al, 2013).

HAI benefits do not occur isolated from each other, but rather, often augment each other. Beetz and colleagues (2012), in a review of 69 empirical studies, stated:

> …*well-documented effects of HAI in humans of different ages, with and without special medical, or mental health conditions are benefits for* [emphasis added]: social attention, social behavior, interpersonal interactions, and *mood* [emphasis added]; stress-related parameters such as cortisol, heart rate, and blood pressure; self-reported fear and *anxiety* [emphasis added]; and mental and physical health, especially cardiovascular diseases" (p.1).

Beetz and colleagues (2012) further proposed, based on their review of empirical research on HAI benefits, that "…the activation of the oxytocin system plays a key role in the majority of these reported psychological and psychophysiological effects of HAI" (p.1), referring to such as a stress-mediation response.

Oxytocin and Human-Animal Interaction

Oxytocin is a hormone associated with affiliative bonding in addition to being released during interactions with people that one is attached to, it can also be triggered through stroking, holding, or even gazing (Nagasawa et al, 2015) at one's companion animal. Oxytocin has been measured during the formation of affiliative bonds (Beetz et al., 2015); affiliative bonds are present in social bonding, sexual activity, maternal bonding (i.e. lactation), cooperation, forgiveness, and empathy (Cassidy & Shriver, 2002). The release of oxytocin associated with affiliative bonds can help offset physiological reactions associated with human stress responses; for instance, oxytocin is associated with reduced heart rate, respiration rate, and blood pressure (Beetz et al, 2012).

Numerous studies have explored physiological affiliation behaviors between humans and dogs using the bonding biomarker oxytocin and stress biomarkers cortisol and alpha amylase. Odendaal (2000) designed a study with humans (n=18) and dogs (n=18) using such parameters to identify positive interaction; this research found a significant increase in oxytocin as well as a decrease (although not significant) in cortisol. Nagasawa et al. (2009, 2015) researched and

demonstrated mutual effect of both dogs and their owners on the peripheral oxytocin levels of both when gazing and physical contact between them occurred. MacLean et al. (2018) furthered this line of inquiry by measuring affiliative bonding within HAI by comparing salivary and blood plasma oxytocin samples; evidence from this research suggested that salivary oxytocin – a less invasive measure – could be collected and reliably measured in HAI research.

Levels of oxytocin were found to peak between one and five minutes after the introduction of a stimulus (e.g. a dog) in participants' blood (Handlin et al., 2011). Petting a dog for as little as 2 minutes or sharing eye contact for as little as 15 seconds can begin to induce a positive biological response in both human and dog in bonded pairs (Nagasawaet al., 2009). Thus, the initial release of oxytocin may be relatively quick and may last in the body-system for a prolonged time. Current research has typically measured oxytocin in 5 or 10-minutes intervals (MacLean, 2017; Vincent et al., 2020).

Animal Companionship and Mental Health Recovery

The benefits of bonds between people with SMI and their companion animals (not identified as ESAs) is the focus of an emerging body of peer-reviewed literature (Brooks et al 2016; Brooks et al 2018; Brooks et al, 2019; Wisdom et al, 2009; Zimalog & Krupa, 2009; Zimalog & Krupa, 2010). While none of these studies addressed ESAs specifically, participants expressed a range of ways their respective companion animals mitigated aspects of impairment related to living with a SMI. Examples of such, congruent with a mental health recovery lens, include: social support (Brooks et al 2016; Brooks et al, 2019); higher levels of community integration (Zimalog & Krupa, 2010); increased feelings of self-efficacy and empowerment (Wisdom et al, 2009); and having a source of "consistency, unconditional support, and acceptance" that helped to mitigate stigma experiences related to mental illness (Brooks et al, 2019, p.329). In a study of self-care strategies identified by individuals with bipolar disorder, "spending time with your pet or other animals" was ranked as one of the top self-care strategies, and reported to be perceived as "very helpful" (Wynter & Perich, 2019, p. 138).

Peer-Reviewed Studies of ESAs

Authors of this article did an extensive literature search on ESA studies; 576 peer-reviewed journal databases were searched through EBSCOhost Research Platform using the term "emotional support animal*", most recently in May 2020. Inclusion criteria included: primary empirical research study that addressed ESAs; English language; and published in peer-reviewed journal. Three articles were located that met this inclusion criteria.

Each of these three articles reported on descriptive studies of understandings of ESAs within particular sub-populations (other than individuals living with ESAs): the general public (Schoenfeld-Tacher et al, 2017); professional veterinary programs (Schoenfeld-Tacher & Kogan, 2017); and university counseling centers (Kogan et al, 2016). Findings indicated while members of the public had concerns about the ESA access on airplanes, the majority perceived ESAs as a legitimate role and felt there was a low amount of ESA misrepresentation (Schoenfeld-Tacher et al, 2017). Kogan and colleagues (2016) found that in a sample of university counseling centers (N=248), the majority of centers were not being asked often to write ESA verification letters; comments on the survey indicated that many counseling staff members felt uncertain about how to respond to ESA verification letter requests, and a need for ESA-related campus policy development was identified. In a survey of 28 professional veterinary medicine programs, Schoenfeld-Tacher and colleagues (2017) found that only a third of veterinary programs had received a student request to have an ESA on campus in the past two years, and a need for ESA-related campus policy development was again identified.

Methods

The Hope and Recovery Pet Program

To help leverage human-animal interaction (HAI) benefits for individuals with SMI, a pilot program known as the Hope and Recovery Pet (HARP) was developed to place shelter animals as ESAs for adults with SMI. HARP operates through a collaboration between the Toledo Humane Society (THS), a large regional non-profit healthcare system known as ProMedica, and the University of Toledo. HARP clients are individuals with SMI who are on a fixed income and may not otherwise be able to afford an ESA; food, supplies and veterinary care for ESAs are provided through HARP for the duration of an ESA placement.

To help ensure the welfare of both the humans and animals involved, inter-professional collaboration between human and animal service providers is an integral component of HARP. Ongoing monitoring and support of the ESA placement is provided by a HARP intern and other designated staff, including humane society staff. A community advisory committee for HARP is comprised of various stakeholders, including veterinary and humane society staff, who provide ongoing input on HARP operations. If a HARP client needs hospitalization or is otherwise temporarily unable to care for the ESA, foster care for the ESA is provided through THS at no cost to the HARP client. If for any reason the HARP client is permanently unable to care for the ESA, THS will take the ESA back and re-home the animal. A locally owned veterinary practice that focuses on veterinary service accessibility, the Community Pet Care Clinic, provides veterinary services to all HARP ESAs, as well as ongoing input to HARP through the advisory committee. Supporting the ongoing well-being of both human clients and the animals serving as ESAs are of paramount importance within the HARP model.

HARP goals are consistent with the One Health framework; One Health has been embraced by the World Health Organization, and can be briefly explicated as an approach that explicitly acknowledges and strives to leverage connections between human health, animal health, and environmental health to gain added value/benefit within and across these areas (Hediger et al, 2019). The goals of HARP are two-fold: 1) to improve health and wellness for individuals living with mental illness; and 2) to increase placement opportunities for homeless shelter animals through developing a program model that could be replicated through partnerships between other healthcare systems and humane societies.

Participants

Through convenience sampling, all study participants were recruited from the HARP Program. Study eligibility criteria was generally consistent with HARP program eligibility and as follows: SMI with prominent depression and/or anxiety symptoms; psychiatrically stable as per referring provider; stable housing; living alone and at risk of social isolation (as per referring provider); no current pet; low income via Medicaid eligibility; sober at least one year if diagnosed with substance use disorder; and no history of violence toward animals or people. The initial sample consisted of twelve HARP participants. The average participant age was 53.67 years; four identified as African American (33%), six as Caucasian (50%) and two as multi-racial (17%). Primary diagnoses for participants were Major Depressive Disorder (MDD) (63%), Bipolar Disorder (18%), and Schizoaffective Disorder (18%). Demographic variables were included in analyses to contribute toward a foundation for additional research on factors relevant to ESAs.

At the time of enrollment in the study, participants had not yet obtained their ESAs. All participants adopted shelter animals as ESAs from the Toledo Humane Society, through the HARP program. As per HARP program criteria, each participant was offered the option of adopting a dog (one year of age or old) or a cat or kitten. Each participant selected their respective ESA, in

consultation with humane society staff who helped guide them to candidates based on their expressed preferences. Animal care needs, size, temperament, and energy level are all considerations discussed pre-adoption with humane society staff. Seven participants adopted a cat or kitten (58%) and five adopted a dog (42%). One participant withdrew from the study, resulting in a final sample size of 11 participants. From the time of ESA adoption to the completion of this study, each participant resided with their respective ESA about 12 months. See Table 1.

Table 1.
Description of sample

	N	%			
Gender					
Male	2	22			
Female	9	78			
Ethnicity					
African American	3	27			
Multi-Racial	2	18			
Caucasian	6	55			
Diagnosis					
Major Depressive Disorder	5	45			
MDD + PTSD	1	9			
MDD + GAD	1	9			
Bipolar Disorder	2	18			
Schizoaffective	1	9			
Schizoaffective + PTSD	1	9			
Pet Type					
Cat	6	55			
Dog	5	45			
	n	Mean	SD	Min	Max
Age	11	52.46	7.51	40	74

Hypotheses and Design

To explore how living with ESAs impacted aspects of mental recovery for adults with SMI, research hypotheses were derived from the related literature delineated in the previous section. To explore these hypotheses, our team developed a research evaluation plan comprised of three components: 1) evaluation of any changes in bonding and stress biomarkers; 2) evaluation of any changes in depression, anxiety, and loneliness; and 3) qualitative interviews to obtain lived experience data.

Biomarker Hypotheses

H1: Participants will experience a significant increase in oxytocin after 10-minute interactions with ESAs

H2: Participants will experience significant decreases in cortisol and alpha amylase after 10-minute interactions with ESAs

Depression, Anxiety and Loneliness Hypotheses

H3: Participants will experience a significant decrease in anxiety symptoms at 12 months post-ESA placement

H4: Participants will experience a significant decrease in depression symptoms at 12 months post-ESA placement

H5: Participants will experience a significant decrease in loneliness at 12 months post-ESA placement

Data Collection and Measures

A 12-month longitudinal, mixed method case study design was utilized. All study protocols and processes were reviewed and approved by the University of Toledo Institutional Review Board prior to commencing. Participants adopted shelter animals (dogs or cats) through HARP as ESAs, remained enrolled in HARP, and were followed for a twelve-month period from their respective ESA adoption dates. All study procedures were reviewed and approved by the University of Toledo Institutional Review Board prior to the study commencing. As with all ESAs placed through HARP, animal welfare was monitored on an ongoing basis through the HARP Program, in accordance with HARP's operation policies. Data was collected from participants at their homes by the principal investigator and/or a trained research assistant via: salivary biomarker samples (pre-ESA placement and 1, 3, 6, 9, and 12 months post-ESA placement); depression, anxiety and loneliness scales (pre-ESA placement and 12 months post-ESA placement); and open-ended questions comprising a qualitative interview (12 months post-ESA placement).

Biomarker Data Collection

To see whether physical interactions with the ESAs were associated with oxytocin release and subsequent decreases in cortisol and/or alpha amylase, biomarker data was collected. Oxytocin activity was measured using a RayBio Enzyme Immunoassay Kit (RayBiotech, EIA-OXT, Norcross, GA). Cortisol activity was determined using Salimetrics Enzyme Immunoassay Kit (Salimetrics, I-3002, State College, PA). Alpha-amylase activity was measured using a kinetic enzyme assay kit (Salimetrics, I-1902, State College, PA). Prior to ESA placements, saliva samples were collected from each participant to establish a baseline in each of these biomarkers. The passive drool approach was used for all saliva collection. One-month post ESA placement, a home visit was conducted to: 1) obtain a saliva sample at the beginning of the visit; 2) have the participant do a focused pleasant interaction (stroke, hold, play with, talk to) their respective ESA for a period of ten minutes, and; 3) obtain a second saliva sample following ten minutes of focused interaction with the ESA. Samples were stored in a mobile cooler and transported to the University X Cardiopulmonary and Metabolism Research Laboratory (CMRL) for storage and analysis. This process was repeated at three months, six months, nine months, and twelve months from ESA placement. Samples were stored at -80 °C until the analysis. The time of day of saliva was collected varied due to participant schedule constraints. This was a methodological weakness, as due to a circadian rhythm cortisol peaks in the morning and declines throughout the day (Mohd Azmi et al, 2021).

Data Collection on Depression, Anxiety, and Loneliness

To examine whether the presence and severity of depression, anxiety, and loneliness changed over time after ESA adoption, standardized measures with strong psychometric data – the Beck Depression Inventory (BDI), the Beck Anxiety Inventory (BAI), and the University of California Los Angeles (UCLA) Loneliness Scale Version 3 – were used to respectively operationalize these concepts. In an evaluation and meta-analysis of psychometric properties of the BDI, a mean coefficient alpha of .81 for nonpsychiatric patients was found; mean correlations of BDI with clinical ratings were .72 for psychiatric patients (Beck et al, 1988). Within a meta-analysis, the BAI was found to have high internal consistency (.91) and good test-test reliability (.66) in clinical samples (Bardhoshi, Duncan, & Erford, 2016). In an evaluation of the UCLA Loneliness Scale Version 3 psychometrics, Russell (1996) found that the measure was internally consistent (.89 to .91) with good test-rest reliability (.73); convergent validity was found through strong correlations with other measures of loneliness. The BDI, BAI, and UCLA Loneliness Scale

Version 3 were completed by participants at their homes prior to ESA adoption and at 12 months post-ESA adoption. All information was entered into SPSS 24.0.0.0 for analysis.

Qualitative Data Collection

At 12 months post-ESA placement, the principal investigator completed in-person, semi-structured, digitally recorded interviews with participants. Interviews were completed in each participant's home and lasted between forty minutes and two hours. The interview question format was derived from a qualitative questionnaire developed by Charmaz (2003) to generate a data-driven explanation of *how* phenomena occur through concrete experience and social processes. Questions were adapted for this specific study through qualitative data from a previous unpublished study with 3 HARP participants. All interviews were professionally transcribed and uploaded into ATLAS.ti.8 for analysis.

Results

Biomarker Analysis and Findings

All biomarker salivary analysis was conducted in the Cardiopulmonary and Metabolism Research Laboratory at the University of Toledo by Dr. Barry Scheuermann, co-investigator on this evaluation. Oxytocin concentration was determined using a RayBio Enzyme Immunoassay Kit (RayBiotech, EIA-OXT, Norcross, GA) with an inter-assay CV of 15%, a minimal detectable concentration of 3.6 ng/ml and a range of 0.1 to 1,000 ng/ml. Cortisol concentration was determined using Salimetrics Enzyme Immunoassay Kit (Salimetrics, I-3002, State College, PA) with an inter-assay CV of 20% and a functional sensitivity concentration of 0.028 ug/dl. Alpha-amylase activity was measured using a kinetic enzyme assay kit (Salimetrics, I-1902, State College, PA) with an inter-assay CV of 5.8%. The lower limit of sensitivity was determined by the change in absorbance corresponding to 2.0 U/ml. A calibration curve was determined for each plate and used to calculation the final concentrations (cortisol, oxytocin) or activities (alpha-amylase). Each saliva sample was measured in duplicate and the average optical density (OD) for the paired samples was used for further calculations.

Values for each individual measure at each time point was entered into a spreadsheet for statistical analysis. A two-way analysis of variance with two repeated measures (time vs. before and after focused interaction) was used to examine possible differences. A significant F-ratio was further analyzed using the Student-Neuman Keuls post hoc test, when appropriate. While there were observable patterns of decrease in cortisol and increase in oxytocin after focused ten-minute ESA interactions, and the highest oxytocin increase occurred at 12 months (see Figures 1 and 2), results of the analysis indicated these changes were not statistically significant, nor were there significant differences across the duration of the study (i.e. no main effect for time). Analyses were also run using a non-parametric test, e.g., the Friedman test, and no statistically significant differences were detected.

Figure 1

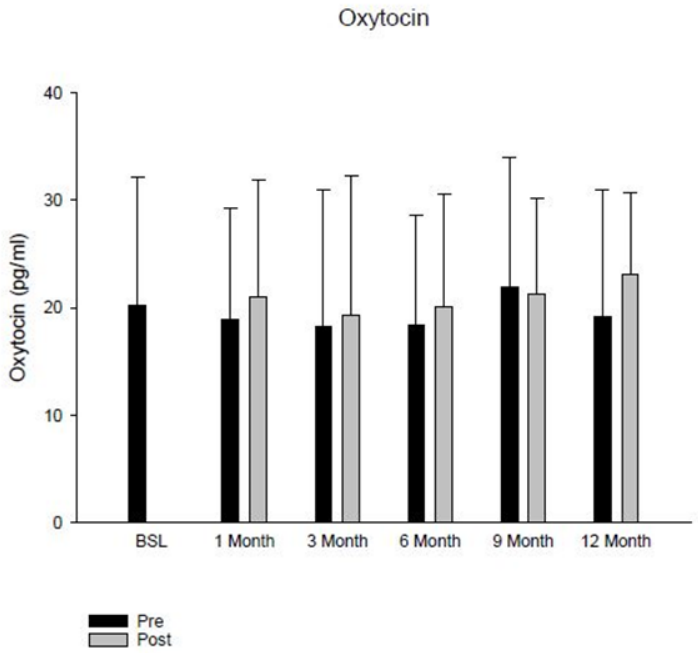
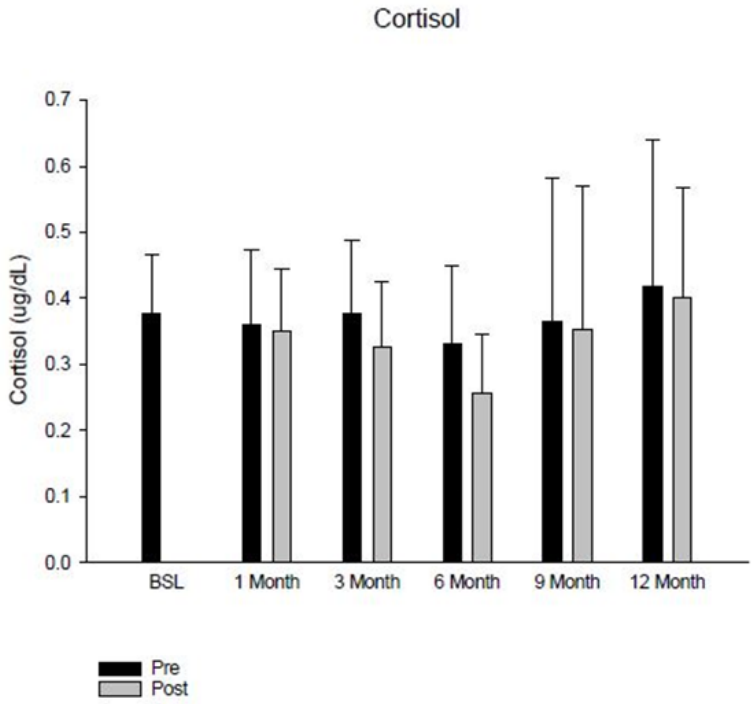
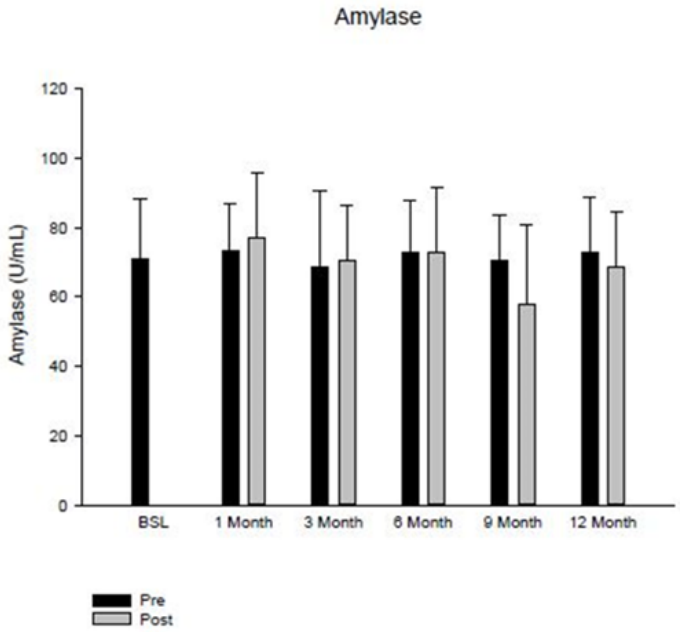


Figure 2



There was no consistent pattern in alpha-amylase level changes (see Figure 3).

Figure 3



Data Analysis and Findings on Depression, Anxiety, and Loneliness

Paired sample t-test were conducted to explore whether there was a relationship between the intervention (adopting and living with ESA for 12 months) and participants' scores of loneliness, depression, and anxiety on the respective instruments. Analysis conducted to examine the impact of intervention on participants experiences of loneliness indicated that there was a statistically significant decreases in UCLA Loneliness Scale scores from Time 1 (M=59.20, SD=9.47) to Time 2 [M=49.90, SD=13.66, t(10)=3.80, p=.004]. The eta-squared statistic (.62) indicated a large effect size. Results further showed that 18 of 20 items on the loneliness scale scored a lower mean value after intervention; of these, 4 were statistically significant. See Table 2. The loneliness scale item in Table 2 pertaining to finding companionship was reverse-scored, and who companionship was found from (e.g., from humans, the ESA, or both) was not defined beyond what was presented on the scale instrument. While the UCLA instrument has been widely utilized in studying the effects of animal companionship on people, such vagaries having been increasingly identified as issues, and it was recently recommended that a new instrument be developed to explicitly measure such (Gilby & Tanni, 2020).

Table 2.
UCLA Loneliness Scale

Scale Item	Time 1	Time 2	t(p)
	Mean (SD)	Mean (SD)	
Feel that you lack companionship	3.81(.40)	2.18(.98)	5.87(p=.001)
Feel alone	3.36(.67)	2.18(.75)	4.48(p=.001)
Feel isolated	3.63(.67)	2.54(1.12)	3.18(p=.01)
Feel can find companionship	2.90(.83)	2.09(1.13)	2.32(p=.04)
UCLA Loneliness Scale	59.20(9.47)	49.90(4.32)	3.80(p=.004)

Paired sample t-test conducted to examine the impact of intervention on participants experiences of depression indicated that there was a statistically significant decrease in Becks Depression Inventory (BDI) total scores from Time 1 (*M*=21.09, *SD*=8.43) to Time 2 [*M*=14.64, *SD*=7.03, *t*(10)=2.48, *p*=.03]. The eta-squared statistic (.41) indicated a large effect size. Results indicated that on the BDI scale 19 out of 21 items scored a lower mean value after intervention; 5 of which were statistically significant. See Table 3.

Table 3.
Significant Items and Total Score for Beck's Depression Inventory (BDI)

Scale Item	Time 1	Time 2	t(*p*)
	Mean (SD)	Mean (SD)	
Discouraged about future	.90(.83)	.36 (.50)	2.20 (*p*=.05)
Being punished	1.09(1.04)	.36 (.50)	2.39(*p*=.04)
Critical of myself	1.27(.64)	.90(.70)	2.39(*p*=.04)
Lost interest in other people	1.09(.70)	.54(.52)	3.46(*p*=.006)
Problem sleeping	1.63(1.02)	.63(1.02)	3.70(*p*=.004)
BDI Total Score	21.09(8.43)	14.64(7.03)	2.48(*p*=.03)

Paired sample t-test conducted to examine the impact of intervention on participants experiences of anxiety indicated that there was a statistically significant decrease in Becks Anxiety Inventory (BAI) scores from Time 1 (*M*=23.55, *SD*=9.81) to Time 2 [*M*=17.73, *SD*=11.79, *t*(10)=2.24, *p*=.049]. The eta-squared statistic (.36) indicated a large effect size. There were not statistically significant changes in individual mean item scores on BAI.

To examine whether there were significant differences in participants' experiences of loneliness, depression, or anxiety in term of gender, ethnicity, pet type, age, and diagnosis, Mann-Whitney (IV 2 categories) and Kruskal-Wallis H Test (IV 3 categories) were conducted for pre-and-post intervention data. An examination of pre and post UCLA, BDI, and BAI scores indicated that after intervention there was a statistically significant difference in participants experiences of loneliness by gender (U =.50, *p*=.045) with a mean rank of 10.25 for males and 5.06 for females. That is, women reported lower levels of loneliness after the intervention as compared to men. There were no other significant mean rank differences in UCLA, BDI, and BAI scores related to gender for pre-post conditions.

The species of ESA was related to reported differences in depression levels of the participants. Twelve months after ESA adoption, there was statistically significant difference in participants experiences of depression by ESA species (U=26, *p*=.044) with a mean rank of 4.17 for cat and 8.20 for dogs. Individuals with feline ESAs experienced lower levels of depression twelve months after ESA placement. The type of ESA the participant interacted with did not have any other significant mean rank differences in UCLA, BDI, and BDA scores for pre-post conditions. Results suggest that prior to ESA placement, younger participants reported higher levels of loneliness as compared to older participants. Prior to intervention there was a statistically significant difference in loneliness by age [H (2) = 6.16, p=.046] with a mean rank of 10.50 for participants younger than 50, 5.50 for participants in the age category of 50-59, and 1 for participants who were greater than or equal to 60. Age did not have any other significant mean rank differences in UCLA, BDI, and BDA scores for pre-post conditions.

Results also suggest that the type of diagnosis affected depression levels among the participants prior to ESA placement. Individuals with co-occurring mood and anxiety disorders

had higher levels of depression prior to ESA placement. There was a statistically significant difference in participants recordings on depression scale by diagnosis (U=24, *p*=.014] with a mean rank of 10.00 for participants diagnosed with mood and anxiety disorder and participants diagnosed with mood disorder reported a mean rank of 4.5 , study participants did not have any other significant mean rank differences in UCLA, BDI, and BDA scores for pre-post conditions. There were no other significant mean rank differences in UCLA, BDI, and BAI scores for pre-post conditions by ethnicity.

Qualitative Data Analysis and Findings

According to Longhofer and colleagues (2013), substantive significance is defined as ‘‘…the consistency of a theme across and within study participants”. To identify themes of substantive significance related to the experience of having an ESA, a thematic analysis approach was used. Inductive open first-level coding was completed by the principal investigator, using in vivo language from the participants; e.g., “*good listener*” and “*kept me on even keel*”. After open coding was completed, codes were compared, sorted and coded into more abstract codes using both inductively derived higher level codes and the following “a priori” codes identified from the human-animal interaction (HAI) literature: psychological benefits; social benefits; emotional benefits; and physical benefits. Coding continued until all data had been accounted for and integrated into umbrella themes that provided an explanatory framework. Through integrating the vivo themes within the empirically established HAI benefits, processes emerged that served to help explain *how* HAI benefit were conveyed. While mental health recovery goes beyond traditional mental health outcomes such as symptom reduction, to limit scope and focus, themes and analysis related to psychological benefits are reported in this article. Additional qualitative findings related to broader mental health recovery outcomes will be presented in a future manuscript.

Five unique constructs related to psychological HAI benefits emerged from the qualitative interviews: Global mental health improvement, Behavior activation/motivation, Comfort/affection, Distraction from symptoms, and Soothing/calming (Table 5). All participants voiced experiencing overall global improvement in mental health, which they attributed to having their respective ESAs. Similarly, all participants reported that their ESAs served to motivate them and activate behaviors related to better self-care and daily routine, which they then associated with improvements in mental health. All participants also made a reference to their ESA as being a source of comfort which they reported helped them to “feel better”. Distraction from mental health symptoms through ESAs engaging their attention was referenced by six of eleven participants. Seven of the eleven participants reported that their ESAs were soothing/calming to them, which they associated with reductions in symptoms (anxiety, crying, feelings of sadness, agitation). These participants related the soothing/calming feeling with touching/cuddling/direct physical contact with their ESAs, who were engaging in proximity-seeking behavior with them.

Table 5

Qualitative findings of perceived psychological HAI Benefit

Construct	Sample quotes
Global mental health improvement	● “If it wasn't for him, there's no telling where I would be at right now. Mentally, physically, and emotionally, I’m better. That is how I feel about [ESA name]. [ESA name] has did what he was supposed to do and then some.’ ● “I still have anxiety and depression, but I have a lot more minutes during the day where I'm smiling. Because of him

	[the ESA]. I have a little more hope now. I actually look forward to things…" ● "My mental health is much better than what it was before [getting the ESA]. I'm happier, more content. She makes me laugh." ● "She's been really helpful over the past year. She's helped with my depression, having her here…"
Behavior activation/motivation	● "…It was something to get up for when before I couldn't get up, when I didn't feel like getting up, when there wasn't anything to get up for... There was no accountability. But she wakes me because she is hungry. It's like oh yeah, okay kit. When she licks my ear or-- I have to put a blanket over my face. If she licks my ear or eyebrow or something, it's like yeah, I am getting up." ● "I am out more. I am at the park every day because I feel like he has to have a walk. He is the one that gets me out the door for that. I would never go to the park otherwise." ● "She made me love her to the point where yes, I want that responsibility. I see what it's helping me do. It's helping me get up and do things I can't do for just myself. That is getting up and do more than get a cup of coffee. I have to get up and feed somebody else and make sure they got their coffee."
Comfort/affection	● "She is comforting to me when I am feeling sad or don't feel good." ● "He's been a huge comfort to me, he really has, helps lift my spirits." ● "When I'm not feeling well, having a moment, she helps me feel better, gives love and attention."
Distraction from symptoms	● "She knows I am sad. She will just come over and start nibbling and licking on my toes. Why are you biting me? I didn't do anything, I am just sitting here. I am not even calling you or playing with you. But yeah, she does that. I say yes [ESA name], I know, I am better. I am not thinking about it, I am good. Without her I think I would have been locked up somewhere because I lost my mind. Depressed." ● "…because when my head is getting full and overwhelmed with things, I can't get stuck in that because I have her to focus on, she comes up and it gets me out of my head."
Soothing/calming	● "When I'm not feeling so good, mood- or nerve-wise, he gives me that cute little look and will cuddle his way next to me, and we chill." ● "She is helping keep me even keeled. I think about a year ago if I had been in the situation I have been in lately, a year ago I would probably be in the hospital right now, but she sits on me and keeps me even."

Discussion

Given the lack of statistical significance in biofeedback measures, the statistically significant improvements on self-report measures of anxiety, depression, and loneliness, and the positive accounts of ESAs as beneficial for mental health within qualitative interviews, this study yielded mixed results. Insights from qualitative findings into the mechanisms for how ESAs were perceived to promote aspects of mental health recovery aligned with prior literature and provide positive support for ESA companionship as an intervention. Given the lack of design controls, the statistically significant decreases in participants' BDI, BAI, and UCLA Loneliness Scale Scores can certainly be related to factors other than ESAs over the 12-month study period. These findings are consistent with prior research showing reductions in loneliness (Powell et al, 2019) and attenuated anxiety and depression symptoms (Hughes et al, 2020) associated with adult involvement with companion animals. As the first empirical study to quantify such as related to ESAs, there is no previous literature on ESA benefits with which to benchmark these findings. It is the authors' hope that this data may serve as preliminary benchmarks for future related research. There were no controls within this study, and participants continued to utilize ongoing services with their respective mental health providers during this time. These quantitative findings thus need to be interpreted with caution, as a beginning step toward developing an empirical understanding of how ESAs can partner with humans to support mental health recovery.

Within the 12-month post-ESA adoption qualitative interview data, participants unanimously endorsed their respective ESAs as a pivotal factor in their self-reported mental health improvements, citing ESAs as both ameliorating specific symptom experiences and contributing to overall mental health improvement. Numerous examples were given in the qualitative data in which the participants experienced some form of anxiety and/or depression symptoms and obtained partial or at times total relief after interaction with their respective ESAs. In some instances participants reported initiating the contact with their ESAs, whereas at other times participants reported that their ESAs "knew" they were struggling and initiated contact with them without prompting, which distracted from psychiatric symptoms and/or offered direct physical contact that participants found comforting. Qualitative findings from this study are consistent with the previous literature on mental health recovery-related benefits of animal companionship reported by individuals with SMI; in addition to comfort and support, ESAs were perceived to provide a range of related benefits (Wisdom et al, 2009; Zimolag & Krupa, 2009; Brooks et al, 2016).

Biomarker data findings were not statistically significant; however, the data did demonstrate a pattern of increases in oxytocin and decreases in cortisol after participants engaged in 10-minute focused positive interactions with their ESAs. This pattern is supported by the literature which indicates an increase in oxytocin post human-animal interaction (e.g. Nagasawa, 2015; Vincent, 2019). The biomarker patterns displayed by the oxytocin and cortisol data can be situated within qualitative findings, e.g. participants reporting petting their ESAs (associated with oxytocin release) and then "feeling better" (associated with oxytocin increase and cortisol decrease).

Due to participant schedule constraints, biomarker data was collected at varying times during the day. Ideally, due to the daily diurnal rhythm cycle entailed in cortisol release, saliva samples of cortisol would be taken at the same time each day for a given participant; this may have served as a confound in cortisol measurement. The small sample may also have precluded

detection of any significance in the observed changes in oxytocin and cortisol. Future research should utilize a larger sample and collect saliva samples at consistent times for participants. While widely considered a marker of sympathetic nervous system activation, reliability, and generality of salivary alpha amylase as an indicator have not been consistent (Petrakova et al, 2015). The lack of a pattern in alpha-amylase after ESA interactions might be related to the small sample size, and/or inconsistency issues reported in previous literature.

As an exploratory pilot study, limitations are numerous and important to keep in mind. Findings of this study are not generalizable; this was not a randomly selected or assigned sample, and there was no control or comparison group. Rather, findings from this study offer a rationale for additional and more nuanced research on ESA benefits. For instance, findings indicated differences in participant experiences based on demographics, diagnoses, and animal species; such warrant additional investigation. This study demonstrated feasibility of collaboration between a humane society, a human healthcare system, and a university to run an ESA placement program. Findings indicated improvements in human and animal well-being, consistent with the One Health approach; homeless animals from humane societies were reported to be excellent ESAs who conveyed benefits of HAI, and the people who benefited in turn provided caring homes for animals in need. Evaluation, replication, and expansion of partnership models such as HARP – which leverage mutually beneficial bonds between people and animals – offer promise for both human and animal well-being.

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