INOVA HEALTH SYSTEM

CLINICAL RESEARCH PROTOCOL

Efficacy of Animal Assisted Therapy In the Treatment of Patients With Traumatic Brain Injuries

Principal Investigator:
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Sponsor:
None

Site of Investigation: Inova Fairfax Hospital
Date of Protocol: June 1, 2014
Approved by IRB # 12-1216

ABSTRACT

Title: Efficacy of Animal Assisted Therapy in the Treatment of Patients with Traumatic Brain Injuries

Short Title: AAT in TBI

Rationale: The purpose of this study is to determine if patients who sustain traumatic brain injuries (TBI) and receive animal assisted therapy (AAT), using handler/dog teams registered to provide AAT, have improved functional outcomes in the intensive care units (ICU) and acute care hospital over those patients with TBI receiving no AAT.

Animal Assisted Care (AAC) is an ongoing and well-established program on the Inova Fairfax Hospital campus. AAT involves goal directed interactions with therapy dogs and their handlers designed to improve human physical, social, emotional and/or cognitive functioning.

Aims:

Aim 1: To determine if the use of animal assisted therapy in the plan of treatment of patients with TBI results in differences in scores on the Ranchos Los Amigos Scale, Glasgow Coma Scale, and in an increased ability to follow commands from those who do not receive AAT.

Aim 2: To determine if the use of animal assisted therapy in the plan of treatment of patients with TBI are discharged with a different degree of cognitive function than those who did not receive AAT.

Study Type: Prospective, experimental case-control study.

Study Design: The study population will include adult patients admitted to the trauma intensive care unit (TICU) of the Inova Fairfax Hospital with a TBI. Target enrollment will be 100 patients. Enrollment duration will be for 2 years from IRB approval.

Inclusion criteria:

- Patients aged 18-85 years admitted to TICU with severe TBI as identified by GCS $\leq$ 8 upon admission, or who progress within 96 hours of admission into a severe TBI as evidenced by a decrease in GCS to GCS<8.
- Those below GCS 5 will be considered for inclusion when they progress to GCS 5 or above.

Rationale: A GCS $\leq$ 8 meets the medical definition of a TBI. Experience of the Inova AAC Program and Trauma Team patients have demonstrated the best patient responses to AAT occurring when the patients have a GCS $\geq$ 5.

Exclusion criteria:

Patients…

- who are intoxicated upon admission who experience resolution of neurological symptoms within 24 hours
- with a GCS $\leq$8, who have no evidence of a TBI and have a blood alcohol level above the legal limit in the state of Virginia (0.8 or higher).
- with a known diagnosis of dementia prior to admission; patients who dislike or are allergic to dogs
- under isolation precautions with the exception of neutropenic precautions for any reason, including MRSA, C Diff, or VRE.
- unable to speak Spanish or English.
- those who would have religious/cultural reasons for avoidance of dogs
- patients who have a splenectomy

Study Methodology: Patients meeting study criteria will be enrolled in the study and randomized into either the intervention or control group. Those randomized into the intervention group will receive the animal-assisted therapy up to three times weekly, in addition to their usual care. Those randomized into the control group will receive standard of care.

Statistical Methods

Aim 1: The primary outcome for analysis will be the difference in Rancho Los Amigos Scale (RLAS) scores from pre-intervention to post--intervention (ΔRLAS). Weekly ΔRLAS will be compared between the AAT group and controls using nonparametric Wilcoxon rank sum tests (Mann-Whitney U tests). This analysis will be stratified by weeks 1-4 to determine whether the difference in ΔRLAS between AAT and controls changes over time.

Aim 2: The outcome for analysis will be the difference in Level of Commands (LOCmds) and Glasgow Coma Scale (GCS) and movement of extremities from pre-intervention to during-intervention and will be analyzed using the same methodology as in Aim 2.

1. INTRODUCTION

1.1 .Specific Aims

Aim 1: To determine if the use of animal assisted therapy in the plan of treatment of patients with TBI results in differences in scores on the Ranchos Los Amigos Scale, Glasgow Coma Scale, and in an increased ability to follow commands from those who do not receive AAT.

Aim 2: To determine if the use of animal assisted therapy in the plan of treatment of patients with TBI are discharged with a different degree of cognitive function than those who did not receive AAT.

1.2 .Hypothesis

Hypothesis 1 Patients sustaining TBI who participate in AAT will experience a faster and higher elevation in RLAS, GCS scales and the ability to follow commands than those TBI patients who do not receive AAT.

Hypothesis 2 Patients sustaining TBI who participate in AAT will experience a faster and higher elevation in cognitive function (as evidenced by the ability to follow multiple commands) than those TBI patients who do not receive AAT.

1.3. Background and Significance

Patients who have sustained TBI can have significant decreases in their level of consciousness. This can interfere with the patients' abilities to (1) actively participate in their recovery and can inhibit their ability to breathe without artificial support, (2) obtain adequate nutritional input, and to (3) follow commands to increase range of motion and physical strength. Several of these patients have long intensive care unit and acute care lengths of stay.

The costs associated with the care of patients with TBI are quite high. In 1995, the total direct and indirect financial costs of patients with traumatic brain injuries were estimated at $56 billion [1]. Schootman et al., estimate 254,500 TBIs required hospitalization in 1996 within the United States, with 5.4 billion US dollars charged to treat these injuries during acute hospitalization [2]. Patient age, increasing severity of injury and urban teaching hospitals were associated with higher charges. McGarry et al estimated the cost of hospitalization for moderate, serious, severe or critical TBI to be $8,189, $14,603, $16,788 dollars, and $33,537 respectively [3]. Costs also varied by injury type, averaging $20,084 for gunshot wounds, $20,522 for motor

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vehicle crashes, $15,860 dollars for falls, and $19,949 for blows to the head. In this study we seek to demonstrate that the introduction of AAT can increase level of consciousness and cerebral function earlier and, therefore decrease cost of the provision of care to these patients.

Animal Assisted Care (AAC) is an ongoing and well-established program on the Inova Fairfax Medical campus. The main objective of the Animal Assisted Care Program is similar to the Pet Partner's© Program objective, which is to improve the patients' well-being through meeting some of their physical and emotional needs with the use of animals in the acute care environment[4].

The AAC Program provides five modalities of therapeutic interventions (also known as animal assisted interventions (AAI):

1. **Animal Assisted Activities or Visitation—**the Pet Partner Team© Training Manual defines these as goal-directed activities designed to improve patients' quality of life through utilization of the human/animal bond. Animals and their handlers must be screened and trained. Activities may be therapeutic but are not guided by a credential therapist. [5]

2. **Animal Assisted Therapy (AAT)**--the Pet Partner Team© Training Manual defines AAT as utilizing the human/animal bond in goal-directed interventions as an integral part of the treatment process. AAT is directed and/or delivered by a health/human-service professional with specialized expertise and within the scope of practice of his/her profession. AAT is designed to improve human physical, social, emotional and/or cognitive functioning. [i] Since a healthcare professional will be measuring patient response, this is the mode of Animal Assisted Intervention which will be utilized for completion of this study. Examples of AAT currently in use at Inova Fairfax Hospital Campus and AAC Program include, but are not limited to: encouraging a patient with decreased LOC to open eyes or to follow commands; having a dog lie beside a terminally-ill patient who is active in the dying process; having the patient throw or kick a ball to the dog to increase strength in extremities; having a dog present to decrease pre-procedure, intra-procedure, and post-procedure stress.

3**. Personal Assistance Therapy**—demonstrates the tasks service animals are able to provide for patients with physical, mental, and/or developmental disabilities. Provides resources and assists patients in completing paperwork to obtain service animal

4. **Service Animal Education**—provides education and support patients who have their service animals accompany them while they are hospitalized. Also, supports and assists staff in understanding their roles and responsibilities when providing care to a patient with a service animal

5. **Visit with Patient's Own Animal**—provides long-term and terminally ill patients with an opportunity to visit with their own dogs and to incorporate their dogs into the patients' plans of care

Over nearly 12 years, the Inova Fairfax AAC program has conducted more than 23,000 interventions to hundreds of patients. At present, the program involves approximately 26 handler/animal teams. The dogs are typically owned by families and live in homes; they are not bred and kenneled specifically and exclusively for the purpose of serving as therapy dogs. Dog owners interested in volunteering with their animal must meet a series of requirements to participate:

- Registration by Pet Partners (formerly known as Delta Society), an international organization specializing in the education, evaluation, and registration of AAI handler/animal teams.
- Completion of Inova Volunteer Services requirements
- Maintenance and provision of documentation of annual health screening requirements for animal and handler
- Adherence to Inova Health System and IFMC AAC policies and procedures

The program adheres to the Association of Professionals in Infection Control (APIC) and Center for Disease Control (CDC) guidelines for safely and responsibly incorporating therapy animals into patient care. Patients who are considered ineligible for the programs include those with allergies or in isolation precautions, with the exception of neutropenic precautions. There have been no incidences of zoonotic transmission of diseases in patients, handlers, or animals from inception to current date.

Few studies have assessed animal assisted interventions and their effectiveness in a quantitative fashion. Even fewer studies have assessed the effectiveness of animal assisted interventions in the critical care setting. In June 1999, Giuliano, Bloniasz, and Bell discussed the implementation of a pet visitation program in critical care, but clearly identify that the program is for visitation or AAA. Furthermore, they state, "We have no quantitative research data to document that these visits are actually helpful to patients in any measureable way, although we certainly hope to have some soon." [vii] Coakley and Mahoney assessed patients receiving AAI in an acute care medical-surgical care setting and found that "patients had significant decreases in respiratory rate and pain and a corresponding increase in energy levels following the pet therapy intervention." [viii] In this study we hope to provide a quantitative assessment of the effectiveness of AAT in the critical care and acute care environments.

A study done by Cole, Gawlinski, et al in 2007 demonstrated that patients hospitalized with advanced heart failure who received a visit from a volunteer and a dog had lower cardiopulmonary pressures, neurohormone levels, and anxiety levels than did patients visited by a volunteer only and patients given usual care at rest (control group).[ix]

In 2010, Lee and Higgins [x] assessed the use of adjunctive therapies in the critically ill and stated, "No studies were found that examined whether pet visitation has a role in the care of critically patients and the chronically critically ill". Unfortunately, other than the study done by Cole et al, this is still true three years later.

1.4. Preliminary Studies

Theoretically, there is risk of zoonotic infection to the patient from the dog and from the patient to the dog. However, a study presented by Inova Fairfax Hospital Campus Trauma Services and Animal Assisted Care Program to the Association of Professionals in Infection Control (APIC) in March 2010 demonstrated a zero infection rate in dogs and patients when APIC guidelines are used during AAT.[xi]

2. STUDY DESIGN AND SUBJECT SELECTION

2.1. Study Type: This is a prospective, experimental study examining the effects of animal assisted therapy on patient's level of consciousness and cognitive functioning.

2.2. Setting/Location: Research will be conducted at Inova Fairfax Hospital located in Falls Church, VA.

2.3. Duration of Study: The study period will be for 2 years.

2.4. Number of Subjects: In 2011, approximately 100 patients were treated by IFH Trauma Services for TBI with a GCS $\leq$8. Target enrollment over the two years will be 100, with approximately 50 patients in each of the two study groups.

2.5. Study Population

2.5.1. Gender of Subjects: Subjects of both genders will be included in the study.

2.5.2. Age of Subjects: The age range of enrolled subjects will be 18-85 years old.

2.5.3. Racial and Ethnic Origin: This pilot study will include English and Spanish speaking patients only; there are no enrollment restrictions based upon race or ethnic origin. However, to ensure understanding of consent, enrollment will be limited to those who speak Spanish or English.

2.5.4. Vulnerable Populations: Participants who do not speak English or Spanish will be excluded. Study participants will have access to translation/interpreter services provided at Inova Fairfax Hospital. If a patient is unable to consent for themselves, a legally authorized representative may consent for them.

2.6. Recruitment: Patients admitted to the Trauma Intensive Care Unit will be considered for the study. The PI will review the trauma patient admission lists for patients and a study team member will ask those meeting inclusion criteria to participate in this research study. In most case the patient will be unable to consent for themselves and a LAR will be asked to consent. Consent will be obtained by Leslie Horton (PI), and the ICU nurses identified as subinvestigators.

The bedside nurse who is caring for the patient on the shift when the patient is enrolled will not be the person who is obtaining consent.

2.7. Inclusion Criteria:

- Patients aged 18-85 years admitted to TICU with severe TBI as identified by GCS $\leq$ 8 upon admission, or who progress within 96 hours of admission into a severe TBI as evidenced by a decrease in GCS to GCS<8.
- Those below GCS 5 will be considered for inclusion when they progress to GCS 5 or above.

2.8. Exclusion Criteria:

Patients…

- who are intoxicated upon admission who experience resolution of neurological symptoms within 24 hours
- with a GCS $\leq$8, who have no evidence of a TBI and have a blood alcohol level above the legal limit in the state of Virginia (0.8 or higher).
- with a known diagnosis of dementia prior to admission; patients who dislike or are allergic to dogs
- under isolation precautions with the exception of neutropenic precautions for any reason, including MRSA, C Diff, or VRE.
- unable to speak Spanish or English.
- those who would have religious/cultural reasons for avoidance of dogs.
- patients who have a splenectomy

3. STUDY METHODS AND PROCEDURES

All patients admitted to the TICU will have a documented GCS in the medical chart as a part of clinical care. Leslie Horton (LH), the study PI, and the Trauma Intensive Care Unit RN subinvestigators will screen the TICU census daily for new patients to identify those admitted with GCS $\leq$ 8 that meet study criteria. Eligible patients will be followed by the PI or the TICU RNs until the patient is assessed at GCS of 5 or above.

1. Patients with a GCS of 5 or above will be screened for eligibility. Those eligible will be invited to participate and consent will be obtained by study personnel.
2. Consenting subjects will be randomized to the intervention or control arm of the study

3. For patients randomized to the intervention arm, study personnel (PI or TICU RNs) will request a doctor's referral. A referral will be made to LH who will arrange for the patient to receive the intervention with the dog.
4. The control group will be receiving standard of care bedside interventions. During the control measurement period, the only person present will be the bedside nurse who records the measurements.
5. Study personnel will record the RLAS, GCS, Level of Commands, and Movement of Extremities within 24 hours of obtaining consent and order.

Intervention Group

1. When the patient is randomized to the treatment arm, the PI will refer the case to one of the AAC handler/dog teams approved for work on the study for the intervention. The AAC handler will respond within 3 days and will request data measurements be taken by the bedside RN. These measurements will include (see attachments for data collection sheet):
    A. RLAS Score
    B. GCS Score
    C. Level of Command (LOCmd)-0, 1 or 2 or 3-step
    D. Movement of Extremities
2. Following the recording of the above measurements, the AAC team will provide AAT to the patient.
3. Immediately following the intervention, the same scores will be measured by the same licensed healthcare professional.
4. AAT and measurements of the same data will continue up to three times weekly after the initial measurements and will be listed on data collection sheets. If the patient is unavailable for AAT at the time of the scheduled intervention, the research team will document "unavailable," indicate the reason for unavailability. The patient will remain in the study and data collection will continue until the patient is discharged, reaches RLAS 7, or have been hospitalized $\geq$ 28 days. If the patient has been discharged from the study but remains in the hospital, he/she may continue to receive AAT.

Control Group

1. When the patient is randomized to the control arm, data measurements will be taken by the bedside RN. Variables to be collected include:
    A. RLAS Score
    B. GCS Score
    C. Level of Command-0, 1 or 2 or 3-step (see same data collection sheet).
    D. Movement of Extremities
2. The control group will be receiving standard of care bedside interventions. During the control measurement period, the only person present will be the bedside nurse who records the measurements. RLAS, GCS, and Level of Command and movement of extremities will be measured by the same licensed healthcare professional before and after each interaction with the healthcare professional.
3. The PI will be responsible for collecting measurements of the same data up to three times weekly after the initial measurements until they are discharged, reach RLAS 7, or have been hospitalized $\geq$ 28 days.

When the subject is moved to a different unit, study personnel will continue to be responsible for ensuring the study measurements, as measured by the bedside nurse, are recorded on the data collection form.

Methods for Tracking Recruitment and Retention. Study personnel will:

- Screen the trauma services database to determine the number of patients appropriate for the study.
- Keep detailed notes regarding the number of patients identified as potential participants by the study personnel to determine the percentage of eligible patients approached for inclusion into the study to determine the efficacy of our program to treat this population

- Keep detailed logs reflecting the number of patients approached to participate and the reasons for declining participation and for loss to follow up to determine the willingness of participants to consent to participate and remain in the study.

Preliminary analysis will be completed at the 2 year mark to determine if the appropriate number of subjects have been enrolled, or whether the subject number would need adjustment due to mortality from the disease condition. If more subjects are needed, a request for study extension with increased enrollment approval will be requested.

3.3. Randomization: Randomization will be done on a 1:1 ratio with Microsoft excel generating random participation. Sealed, opaque, sequentially numbered envelopes will be used to select the group in which each patient is enrolled.

3.4. Endpoints/Outcome Measures
Patients enrolled in the study will participate until any of the following occurs:

1. choose to no longer participate
2. develop animal allergies
3. reach a RLAS of 7 or above
4. are discharged
5. are hospitalized for greater than or equal to 28 days.

3.5. Consent/Assent: Informed consent will be obtained by the PI or TICU RNs who are sub-investigators on the study. Patients or legally authorized representative of potential subjects will give consent. Patients who do not speak English or Spanish will not be consented.

3.6. Monitoring Subjects and Criteria for Withdrawal of Subjects from the Study.
Criteria for withdrawing subjects from the study are at patient and/or patient LAR request.

4. STATISTICAL CONSIDERATIONS/DATA ANALYSIS

4.1. Sample Size: We estimate that approximately 85% of the patients with TBI will consent for this study. In consideration of the study's endpoints, it is expected that approximately 50 patients will be in each of the two study groups.

4.2. Method of Data Analysis
Aim 1: To determine if the use of animal assisted therapy in the plan of treatment of patients with TBI results in higher scores on the Ranchos Los Amigos, Glasgow Coma Scale, an increased ability to follow commands, and an increased movement of extremities than those who do not receive AAT.

The difference in RLAS scores from pre-intervention to post the intervention will be the primary outcome for the analysis. The outcome, ΔRLAS, will be defined as RLAS during AAT/sham – RLAS pre-AAT/sham. ΔRLAS from each study visit (AAT or sham) will be averaged over each week of the study (weeks 1-4). To address the primary hypothesis, weekly ΔRLAS will be compared between the AAT group and controls using nonparametric Wilcoxon rank sum tests (Mann-Whitney U tests) in order to determine whether the AAT group has significantly higher ΔRLAS. This analysis will be stratified by weeks 1-4 to determine whether the difference in ΔRLAS between AAT and controls changes over time.

The difference in LOCmd scores and movement of extremities will be a secondary outcome of this study. ΔLOCmds and movement of extremities will be defined similarly to ΔRLAS, as the LOCmds and movement of extremities during AAT/sham – LOCmds and movement of extremities pre-AAT/sham, and the mean ΔLOCmds and movement of extremities will be calculated for each week of the intervention (1-4). Weekly

ΔLOCmd scores and movement of extremities will be compared between study groups (AAT vs. controls) using nonparametric Wilcoxon rank sum tests. This analysis will be stratified by weeks 1-4 to determine whether the difference in ΔLOCmd and movement of extremities between AAT and controls changes over time.

GCS scores are routinely collected every hour by the TICU nursing staff. Medical charts will be reviewed to record the GCS scores during the hour immediately before and immediately after the intervention (or sham) is implemented. ΔGCS will be defined as GCS after AAT/sham – GCS pre-AAT/sham. Weekly ΔGCS scores will be compared between study groups (AAT vs. controls) using nonparametric Wilcoxon rank sum tests. This analysis will be stratified by weeks 1-4 to determine whether the difference in ΔGCS between AAT and controls changes over time.

Aim 2: To determine if the use of animal assisted therapy in the plan of treatment of patients with TBI are discharged with a higher degree of cognitive function than those who did not receive AAT.

To address the primary hypothesis, weekly ΔRLAS will be compared between the AAT group and controls using nonparametric Wilcoxon rank sum tests (Mann-Whitney U tests) in order to determine whether the AAT group has significantly higher ΔRLAS. This analysis will be stratified by weeks 1-4 to determine whether the difference in ΔRLAS between AAT and controls changes over time.

The difference in LOCmd scores will be a secondary outcome of this study. ΔLOCmd and movement in extremities will be defined similarly to ΔRLAS, as the LOCmds and movement of extremities during AAT/sham – LOCmds and movement of extremities pre-AAT/sham, and the mean ΔLOCmds and movement of extremities will be calculated for each week of the intervention (1-4). Weekly ΔLOCmd scores and movement of extremities will be compared between study groups (AAT vs. controls) using nonparametric Wilcoxon rank sum tests. This analysis will be stratified by weeks 1-4 to determine whether the difference in ΔLOCmds and movement of extremities between AAT and controls changes over time.

4.3. Data Storage: The data will be stored on a password protected computer in the AAC office for three years in a Microsoft Excel 2010 database and then destroyed. Only study personnel will have access to these data.

4.3.1. Data Management: Information about study subjects will be kept confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Privacy and confidentiality of all enrolled patients will be maintained. All data collection tools will be taken to the AAC Office and will be entered by LH into the secure study data base. Consent documents and the regulatory binder will be kept in the Trauma Research Manager's office. The Trauma Department suite is locked, and the Trauma Research Manager's office is locked.

4.3.2. Records Retention: The data will be stored for three years in a Microsoft Excel 2010 database and then destroyed.

5. HUMAN SUBJECTS PROTECTION (RISKS, BENEFITS, and ALTERNATIVES)

5.1 Risks

- Loss of confidentiality.
    - To decrease risk of this, all study participants are assigned a random study identification number.
- Zoonotic infection to the patient from the dog and from the patient to the dog.
    - A study presented by Inova Fairfax Medical Campus, Trauma Services, and Animal Assisted Care Program to the Association of Professionals in Infection Control (APIC) in March 2010 demonstrated a 0-infection rate in dogs and patients when APIC guidelines are used during AAT.

- Dog bite or scratch from interactions with the animal when the dog gets onto the participant's bed or as a result of retaliation from harm done by a patient without impulse control.
    - To decrease this risk, the dogs' temperaments are assessed using the Pet Partners Team Evaluation criteria and registration and the handlers are taught proactive measures in difficult situations with patients per Pet Partners Team Instruction and registration criteria.

5.2. Benefits
Patients may not benefit directly from this study; however there will be benefit to our knowledge of animal assisted care and TBI treatment. If this study demonstrates that interaction with animals improves cognitive function in coma patients and decreases length of stay in the intensive care unit and acute care hospital, the impact could be significant from a societal and individual perspective. As such, this study has the potential to elevate animal-assisted therapy into a recognized professional, therapeutic intervention rather than simply a nice diversion for patients during their hospital stay.

5.3. Alternatives: The study is voluntary. The alternative is not to participate in the research.

5.4. Confidentiality: There is risk to the patient for possible exposure of confidential data. To minimize this risk, patients will be assigned a study number; personal identifiers will not be stored in the same database as the study data.

6. SUBJECT COMPENSATION

6.1. Cost: There are no costs to participants.

6.2. Payment: Participants will not be paid for their participation.

7. ADVERSE EVENT REPORTING: Adverse events will be documented according to IFMC IRB protocol. All adverse events will be reported to the appropriate personnel within the allowed time limit.

8. FUNDING: This is an unfunded, investigator-initiated study.

9. CONFLICTS OF INTEREST: The Animal Assisted Care Coordinator is contracted by Inova Fairfax Hospital Administration to oversee AAI services. The Inova Health Systems Compliance Officer has reviewed the contract and has found no conflicts of interest in the AAC Coordinator being the primary investigator of this study.

10. FACILITIES AND EQUIPMENT: The study setting will be Inova Fairfax Hospital.

11. OUTSIDE CONSULTANTS/COLLABORATORS: There are no outside consultants/collaborators

12. CONTRACTURAL AGREEMENTS: Not applicable.

13. REFERENCES
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