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Effects of animal-assisted therapy on the health of patients after a stroke: a randomized controlled trial

Submission date	Recruitment status	[_] Prospectively registered
10/05/2018	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
31/05/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/03/2022	Circulatory System	

Plain English summary of protocol

Background and study aims
A stroke is a condition that can give rise to consequences such as cognitive and physical constraints, which sometimes manifest themselves in the psychological condition of the patient. Such patients commence rehabilitation as soon as is possible, which involves a multi-disciplinary approach to treatment. Supplementing the care they receive with animal-assisted therapy (AAT), in a supportive capacity, has the potential to streamline therapeutic methods.

Who can participate?
Patients who have experienced a stroke

What does the study involve?
Participants are randomly allocated to the control group or the experimental group. The control group receive standard therapy, while the sessions of the experimental group are supplemented with animal-assistance therapy (AAT), facilitated through a dog being present as an aid to the therapeutic team. Blood pressure, heart rate and satisfaction are measured before and after therapy.

What are the possible benefits and risks of participating?
Possible benefits include improving the health of the patient and helping to determine the real effect of animal assistance therapy. Possible negatives could be unintentional injury to the animal.

Where is the study run from?
Central Military Hospital in Prague (Czech Republic)

When is the study starting and how long is it expected to run for?
March 2013 to December 2015

Who is funding the study?
Ministry of the Interior of the Czech Republic

Who is the main contact?
Kristýna Machová
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
108-93/3-2013-ÚVN

Study information

Scientific Title
Effects of animal-assisted therapy on the health of patients after a stroke: a randomized controlled trial

Study objectives
If AAT is included in the stroke treatment process, physiological values and mood improvement will decrease.

Ethics approval required
Old ethics approval format

Ethics approval(s)

1. Ethical committee of Central Military Hospital in Prague, 108-93/3-2013-ÚVN -1.11.2013
2. Ethical committee of Czech University of Life Sciences, 09/2017

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Patients after stroke

Interventions
Participants were randomly allocated into the control and experimental groups using envelopes. The experimental group experienced standard therapy supplemented with animal-assistance therapy (AAT), facilitated through a dog being present as an aid to the therapeutic team. The goal of the work was indicated by a physician, these were areas of improvement of cooperation, improvement of cognitive skills, prevention of hospitalization syndrome, development of gross and fine motor skills. Individual areas were promoted by practicing with the dog, rewarding it and motivating the dog to participate in therapies. The dog has been included in other therapeutic methods such as physiotherapy and ergotherapy, ongoing group and individual therapy. Total duration of intervention was for 6 weeks for each patient.

The control group only received normal treatment (individual and group physiotherapy and ergotherapy).

The tools primarily applied to measure the outcomes were the Barthel index, Morse fall risk scale and Norton pressure sore risk assessment scale, blood pressure and heart rate, whereas the Likert scale was employed to discern the mood of the patients.

Intervention Type
Behavioural

Primary outcome measure
1. Blood pressure and heart rate measured using a pressure gauge on the first day of the study, in the following six weeks on average two to three times a week, and then at the end of the study

2. Satisfaction evaluated using a questionnaire composed of statements responded by the respondent to the Likert scale, which makes it possible to ascertain not only the content of attitude but also its approximate strength (Likert, 1932; O'Neill, 2017). This is a 10-point scale, which demonstrates the client's mood that day. The clients in the experimental and control groups responded to the question "How do you feel today?" on a scale of one to ten, one marking the worst possible subjective variation, and ten points marking the maximum. Patients in the experimental group were asked at the start of therapy and after it was terminated, patients in the control group were interviewed twice a week on the same day with an hourly interval when the patient was in the normal hospital mode.

Secondary outcome measures
1. Self-sufficiency involving self-service activities (dressing, hygiene), locomotive functions or stool or urine retention, evaluated using the Barthel Index (Mahoney & Barthel, 1965; Prodinger, O'Connor, Stucki, & Tennant, 2017)
2. Fall risk, evaluated using the Morse fall risk scale (Forrest, Chen, Huss, & Giesler, 1989; Morse, Morse, & Tylko, 1989)
3. Pressure sore risk, evaluated using the Norton scale score risk of decubitus (Chen, Zha, & Liu, 2017; Norton, McLaren, & Exton-Smith, 1962)
The tests were selected on the basis of consultation with a rehabilitation physician who is also a professional consultant. Testing was carried out according to the standard procedure of the UCI. The tests were performed at the beginning of the six-week cycle of dog therapy and after it was completed.

Overall study start date
01/03/2013

Completion date
30/12/2015

Eligibility

Key inclusion criteria
1. Patients who were expected to stay in the rehabilitation and physical medicine department for at least six weeks
2. Diagnosed with spasticity
3. Cognitive function above the dementia threshold
4. Do not suffer from any disease that may affect the excretion of cortisol and do not receive corticoids
5. All patients expressed the desire to have a dog present in their rehabilitation

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants

20

Total final enrolment
15

Key exclusion criteria
Use of drugs to lower cortisol level

Date of first enrolment
01/03/2013

Date of final enrolment
30/06/2015

Locations

Countries of recruitment
Czech Republic

Study participating centre
Central Military Hospital in Prague
Prague
Czech Republic
16902

Sponsor information

Organisation
Czech University of Life Sciences

Sponsor details
Kamýcká 126, Praha 6
Prague
Czech Republic
16800

Sponsor type
University/education

ROR
https://ror.org/0415vcw02

Funder(s)

Funder type
Government

Funder Name
Ministerstvo Vnitra České Republiky

Alternative Name(s)
Ministry of the Interior of the Czech Republic

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Czech Republic

Results and Publications

Publication and dissemination plan
The trialists plan to publish in PLoS one.

Intention to publish date
30/08/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Kristýna Machová (machovakristyna@af.czu.cz). Possible viewing of documents is possible only after approval by the Ethics Commission. The data is stored for a period of time, because it is part of the nursing documentation. The decision to consult depends on the Military Hospital's decision. All data is anonymous.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		06/09/2019	04/03/2022	Yes	No