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The role of dog-assisted therapy in rehabilitation, clinical recovery and improving quality of life

Submission date
14/03/2022

Recruitment status
No longer recruiting

Registration date
15/03/2022

Overall study status
Completed

Last Edited
13/06/2024

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Any neuromusculoskeletal illness (affecting the nervous system, muscles or skeleton) means a significant burden for the patient, including reduced quality of life. Animal-assisted therapy may be helpful in the rehabilitation process and in the treatment of patients. The aim of this study is to demonstrate the potential place and relevance of dog-assisted therapy in rehabilitation medicine and to confirm that therapy with dogs reduces patients' anxiety and pain, improves their quality of life, and advances their complex rehabilitation.

Who can participate?
Patients aged 18 years and over with neurological and musculoskeletal disorders (e.g. stroke, multiple sclerosis, arthrosis, amputation, bone fractures)

What does the study involve?
Patients in both the intervention group and the control group receive the same overall amount of therapy sessions, with an average of 2-3 hours of therapy per day. In the intervention group one physical therapy session is replaced with a dog therapy session, where patients receive the same training exercise but are assisted by a therapy dog.

What are the possible benefits and risks of participating?
Possible benefits are promoting rehabilitation and improving health and quality of life. A possible risk is dog hair allergy.

Where is the study run from?
South-Pest Central Hospital National Institute of Haematology and Infectology, Center for Rehabilitation (Hungary)

When is the study starting and how long is it expected to run for?
September 2018 to May 2021

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
183/2019

Study information

Scientific Title
Dog-assisted rehabilitation: the role of animal-assisted therapy in clinical recovery and improving quality of life: a randomized controlled trial

Study objectives

The aim of this research is to demonstrate the potential place and relevance of dog-assisted therapy as an adjuvant treatment in rehabilitation medicine and to confirm that therapy with dogs reduces patients' anxiety and pain, improves their quality of life, and advances their complex rehabilitation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/10/2019, Hungarian Medical Research Council (Széchenyi István Square 7-8, Budapest, 1051, Hungary; +36 (0)1 795 1197; tukeb@emmi.gov.hu), ref: 183/2019

Study design
Prospective randomized 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 participant information sheet

Health condition(s) or problem(s) studied
Quality of life of patients with neurological and musculoskeletal disorders

Interventions
Group dog therapy sessions are introduced once a week at South-Pest Central Hospital National Institute of Haematology and Infectology, Center for Rehabilitation, in Budapest, Hungary, with a trained therapy dog and a therapy dog handler. Groups have a maximum of five participants at a time, with two groups per week for 3 weeks for each group. The dog is a 5-year-old wire-haired Hungarian Vizsla.

Patients who wished to participate in the study are randomized by a random number generator to an intervention or active control group. Patients in both the intervention group and the control group receive the same overall amount of therapy sessions, with an average of 2-3 hours of therapy per day. The concept is to replace one physical therapy session in the intervention group with a dog therapy session, where patients receive the same training exercise but are assisted by a therapy dog. During the intervention group therapy, reflecting the group composition, the research group work with the therapy dog handler to set up tasks aimed at improving motor coordination and endurance, improving fine motor skills of the hands, mobilizing joints, improving balance, developing memory, reducing attention deficit, creating

peer support, reducing symptoms of anxiety and depression, and building and utilizing group cohesiveness.

A questionnaire pack is completed with the subjects at baseline and after the 3-week program. The researchers use a self-compiled questionnaire on sociodemographic data such as age, residence, marital status, highest level of education, lifestyle factors such as activity, coping strategies and disease-specific information such as diagnosis, time since diagnosis, and co-morbidities. In addition, the Beck Depression Inventory (BDI-9) is used to measure depression, the Spielberger State Anxiety Inventory (STAI) to define the rate of anxiety, the WHO Well-Being Index (WBI) to find out about quality of life, the Illness Intrusiveness Rating Scale (IIRS) to rate general condition and the impact of the therapy received on different aspects of life, as well as the Visual Analogue Scale (VAS) to measure pain.

Intervention Type
Behavioural

Primary outcome measure
1. Anxiety measured using the Spielberger State Anxiety Inventory (STAI) at baseline and after the last, third therapy session
2. Quality of life measured using the WHO Well-Being Index (WBI) at baseline and after the last, third therapy session
3. General condition and the impact of the therapy on different aspects of life measured using the Illness Intrusiveness Rating Scale (IIRS) at baseline and after the last, third therapy session

Secondary outcome measures
1. Depression measured using the Beck Depression Inventory (BDI-9) at baseline and after the last, third therapy session.
2. Pain measured using the Visual Analogue Scale (VAS) at baseline and after the last, third therapy session

Overall study start date
01/09/2018

Completion date
31/05/2021

Eligibility

Key inclusion criteria
Patients aged 18 years and over with neurological and musculoskeletal disorders (e.g. stroke, multiple sclerosis, arthrosis, amputation, bone fractures)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
250

Total final enrolment
118

Key exclusion criteria
1. Dog hair allergy
2. Immunosuppressed status
3. Early postoperative status
4. Age less than 18 years
4. Dementia
5. Refusal to participate in research
6. Decompensated physical and psychological status determined by the treating physician

Date of first enrolment
01/10/2019

Date of final enrolment
15/03/2020

Locations

Countries of recruitment
Hungary

Study participating centre
South-Pest Central Hospital
National Institute of Haematology and Infectology, Center for Rehabilitation
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Sponsor information

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Sponsor type
University/education

Website
http://semmelweis.hu/english/the-university/

ROR
https://ror.org/01g9ty582

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
15/07/2022

Individual participant data (IPD) sharing plan
Veronika Mittly (mittly.veronika@dpckorhaz.hu) should be contacted for access to the dataset. Data will be shared for scientific purposes, e.g. meta-analysis, and raw data will be sent by email upon request. Data will be released at the request of members of any research team. The dataset contains sensitive data, patients are anonymised so that they cannot be identified. The database includes patient code, age, sex, level of education, marital status, diagnosis, co-morbidities and their answers to questionnaires at baseline and after the last, third therapy session. Informed, written consent of participants for data sharing is available.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		12/06/2024	13/06/2024	Yes	No