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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
14/03/2022		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
15/03/2022	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
13/06/2024	Other			

## 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? Veronika Mittly mittly.veronika@dpckorhaz.hu

# **Contact information**

## Type(s)

Scientific

## Contact name

Dr Veronika Mittly

## **ORCID ID**

https://orcid.org/0000-0003-1670-2501

## Contact details

Jahn Ferenc Street 62-66
Budapest
Hungary
1196
+36 (0)202102530
mittly.veronika@dpckorhaz.hu

# Additional identifiers

## Clinical Trials Information System (CTIS)

Nil known

## ClinicalTrials.gov (NCT)

Nil known

## Protocol serial number

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

## Study type(s)

Quality of life

## 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 comorbidities. 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(s)

- 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

## Key secondary outcome(s))

- 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

## 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

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 years

#### Sex

All

#### 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 Jahn Ferenc Street 62-66 Budapest Hungary 1196

# Sponsor information

## Organisation

Semmelweis University

## **ROR**

https://ror.org/01g9ty582

# Funder(s)

## Funder type

Other

## **Funder Name**

Investigator initiated and funded

# **Results and Publications**

# 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, comorbidities 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes