

The effects of music therapy on expressive and communicative skills in relation to change in behavioral problems for patients with Huntington's Disease

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Research questions: 1. Does music therapy improve the expressive and communicative skills of patients with HD due to (specific) music therapy treatment? 2. Does music therapy change problem behavior of patients with HD?

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|------------------------------|---|
| Ethical review | Approved WMO |
| Status | Recruiting |
| Health condition type | Chromosomal abnormalities, gene alterations and gene variants |
| Study type | Interventional |

Summary

ID

NL-OMON41754

Source

ToetsingOnline

Brief title

Music Therapy with Huntington's Disease

Condition

- Chromosomal abnormalities, gene alterations and gene variants
- Movement disorders (incl parkinsonism)

Synonym

Huntington's disease

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: ntb

Intervention

Keyword: behavioral problems, communication, expressivity, music therapy

Outcome measures

Primary outcome

Outcome measures

Behaviour Observation Scale Huntington (BOSH) contains 32 items in 3 subscales:

1) activities of daily living (ADL), 2) social-cognitive functioning, and 3)

mental rigidity and aggression. Expressive- and communicative skills are also measured.

The Problem Behaviours Assessment-short version is a 5-point rating scale, using the scores 0 (absent) to 4 (severe). Besides that, there is a subscale for severity and one for frequency. The PBA-s is a 10-item semi-structured interview and assesses behavioural problems in the 4 weeks prior to the interview.

Secondary outcome

n.a.

Study description

Background summary

Rationale

Huntington's Disease (HD) is a progressive, neurodegenerative, autosomal dominant disease characterized by motor - and psychiatric disturbances, and cognitive decline. In the attempt to meet the individual needs, the challenge is to develop effective therapeutic strategies. Since there is no cure for the disease, all treatment is aimed at improving quality of life [1].

Cognitive and behavioral changes are the most debilitating aspects of the disease and place the greatest burden on the patient as well as their families and caregivers [2]. This often warrants admission to a nursing home.

The cognitive disorders in HD affect a broad variety of skills, including learning and memory, perceptual skills, executive efficiency and language [2]. Communication, the transfer of information from one person to another, requires a complex integration of thought, muscle control, and breathing. HD can impair all three of these functions. Even in later stages of the disease, language comprehension may be preserved when the ability to speak is significantly diminished. In other words, even if a person with HD might not be able to express him-/herself any longer, it is likely that he/she can still understand what is being said. The difficulty in people with HD is the inability to organize language. In practice this loss of communication results in behavior problems [2].

Study objective

Research questions:

1. Does music therapy improve the expressive and communicative skills of patients with HD due to (specific) music therapy treatment?
2. Does music therapy change problem behavior of patients with HD?

Study design

A single-blind randomized controlled intervention trial (RCT) is proposed to test the propositions and hypotheses. Sixty (60) Patients (see sample size calculation below) will be randomised using centre-stratified block-permuted randomization. Two random groups will be created. The experimental group will be offered a music therapy program, and the control group will participate in regular recreational day activities. Besides that, both groups will receive regular treatment (standard care, treatment as usual. Participants from both the experimental and the control group are not allowed to receive music therapy outside the study.

Intervention

Intervention

While participating in the study, all participants (in both the music therapy group and the control group) continue to receive treatment as usual.

Patients will participate in group interventions with a minimum of three and a maximum of five participants. A total of 16 sessions once a week will be offered to both groups.

Each music therapy intervention will last for 45 minutes. The intervention will be provided at the same time of the same day of the week by a formally trained music therapist with at least 3 years working experience. The music therapy intervention will be standardized without limiting the music therapists in their interactions. However, the music intervention will be (partly) protocolized. Each session starts with the same welcome song/musical piece and ends with the same farewell song/musical piece. In doing so, the participants are fully aware of the start and the end of each session. In between these two songs/musical pieces the music therapist adjusts the level of each intervention to each individual's capacities. After the welcome song the music therapy sessions may be varied in that the music experiences can range from listening to music to playing or singing songs to free improvisation [9]. The music therapist has the liberty to determine what works best at that very moment for that specific patient. The participants will listen to music selected, sung or played by the therapist. Active participation in music activities by singing, dancing or playing a music instrument will be stimulated as much as possible. The music will be selected by the music therapist to incite expressive and communication skills and to reduce agitation, based on musical parameters, such as rhythm, melody, harmony, dynamics, timbre. After each song/musical intervention the therapist will stimulate the participants to reflect verbally on the music.

The basic principle of the intervention is to encourage and engage clients in expressive musical interaction. The role of the therapist is to use musical parameters and interventions combined with reflective discussion. The degree of verbal reflection may vary. The therapeutic process is based on the mutual construction of meaning of emerging thoughts, images, emotional content and expressive qualities that often originate from the musical experience [10].

In the control group, recreational day activities will be offered under the exact same circumstances as the music therapy sessions; once weekly with a total of 16 sessions, lasting 45 minutes. The activities vary from reading the newspaper, cooking activities, arts-and-crafts-activities/handcraft-activities, puzzle games. Music activities such as singing along or watching a music-video is not allowed during these activities. These activities will be provided by trained recreational therapists.

Both music therapy and general activities will be provided in separate rooms, away from the ward. All participants are allowed to leave the intervention at all times.

Study burden and risks

n.a.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Age older than 18 years
- Clinically and genetically confirmed Huntington's Disease (CAG * 36 repeats)
- Total Functional Capacity (TFC) of <7
- Have not received music therapy in the past 3 months

Exclusion criteria

- Patients who suffer from other neurological disorders
- Patients with poor comprehension of the Dutch language.

Study design

Design

| | |
|---------------------|-------------------------------|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Single blinded (masking used) |
| Control: | Active |
| Primary purpose: | Treatment |

Recruitment

| | |
|---------------------------|------------|
| NL | |
| Recruitment status: | Recruiting |
| Start date (anticipated): | 25-06-2014 |
| Enrollment: | 60 |
| Type: | Actual |

Ethics review

| | |
|--------------------|-------------------------------------|
| Approved WMO | |
| Date: | 22-05-2014 |
| Application type: | First submission |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden) |
| | metc-ldd@lumc.nl |

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| Approved WMO | |
| Date: | 25-11-2015 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden) |
| | metc-ldd@lumc.nl |

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

| Register | ID |
|----------|----------------|
| CCMO | NL48029.058.14 |