

PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Speech Therapy of Parkinson's Disease Patients by Interpreting Texts

Trial Acronym

STOP-IT

URL of the trial

[---]*

Brief Summary in Lay Language

Speech disturbances and reduced intelligibility are a common problem of advanced Parkinson's disease patients. Therefore, patients often avoid communicating which results in a severe impairment of quality of life. This randomized controlled trial is designed to develop new concepts in speech therapy to improve intelligibility and communication-based quality of life in Parkinson's disease patients with hypophonic dysarthria.

Brief Summary in Scientific Language

Parkinson's disease (PD) is a progressive neurological disorder which impairs all aspects of speech and voice resulting in hypophonic dysarthria in more than 80% of patients. The loss of intelligibility considerably impacts on activities of daily life and thereby also on the desire to communicate. In this randomized controlled study new concepts of speech therapy based on text interpretation will be analysed in patients with advanced PD and dysarthria. They received either two weeks of a daily treatment with focus on phonation, respiration, articulation and prosody or two weeks of a daily treatment following fundamentals of oral interpretation and performance. Patients in the control group were put on a waiting list for at least three months. Changes in intelligibility as primary outcome parameter will be evaluated by blinded listeners on the level of words, sentences, texts and spontaneous speech directly following the training as well as after a period of 3 months. As secondary outcome parameters changes in self-perception and assessment by others as well as alterations in communication-based quality of life will be investigated. Additionally, acoustic parameters will be evaluated.

Organizational Data

- DRKS-ID: **DRKS00006333**
- Date of Registration in DRKS: **2014/07/22**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***

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- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **3863-08/13 , Ethikkommission der Friedrich-Schiller-Universität Jena an der Medizinischen Fakultät**

Secondary IDs

Health condition or Problem studied

- ICD10: **G20 - Parkinson disease**

Interventions/Observational Groups

- Arm 1: **Speech and voice treatment focussing respiration, articulation and phonation, 8 training sessions (45 min) over a period of 2 weeks**
- Arm 2: **Speech and voice treatment focussing fundamentals of oral interpretation and performance, 8 training sessions (45 min) over a period of 2 weeks**
- Arm 3: **Control (no treatment, admission to a waiting list)**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]*
- Allocation: **Randomized controlled trial**
- Blinding: [---]*
- Who is blinded: **assessor, data analyst**
- Control: **Active control, No treatment**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Changes in intelligibility on the level of words, sentences and texts as well as in spontaneous speech one day after the last training session and 3 months later (assessment by blinded listeners)

Secondary Outcome

Changes in self perception and perception by others according to the voice handicap index (VHI), communication-related quality of life (PDQ-39), changes in acoustic parameters one day after the last training session as well as 3 months later

Countries of recruitment

- **DE Germany**

Locations of Recruitment

- University Medical Center **Klinik für Neurologie, Jena**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2013/09/30**
- Target Sample Size: **30**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **40 Years**
- Maximum Age: **85 Years**

Additional Inclusion Criteria

Parkinson's disease (Brain Bank criteria, Hoehn & Yahr stage 2 - 4) with hypophonic dysarthria

Exclusion criteria

Presence of dementia or atypical Parkinson's disease, ongoing speech therapy



during the trial, text blindness

Addresses

■ Primary Sponsor

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Sources of Monetary or Material Support

■ **Institutional budget, no external funding (budget of sponsor/PI)**

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Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): [---]*

Trial Publications, Results and other documents

- Abstract **Redecker B, Neuhauser S, Simpson AP, Redecker C. Speech and voice treatment with literary texts in advanced Parkinson's disease patients: assessment of intelligibility and acoustic changes. Poster, 18th International Congress of Parkinson's Disease and Movement Disorders 2014, Stockholm.**
- Abstract **Redecker B, Neuhauser S, Simpson AP, Redecker C. Assessing intelligibility and acoustic changes in individuals with advanced Parkinson's disease: a pre-/ post-treatment study. Poster, 15th International Clinical Phonetics and Linguistics Association Conference 2014, Stockholm.**

* This entry means the parameter is not applicable or has not been set.

*** This entry means that data is not displayed due to insufficient data privacy clearing.