

## Trial Description

### Title

**BIG therapy in Parkinson's disease: dose response relations**

### Trial Acronym

**BIGdr study**

### URL of the trial

[---]\*

### Brief Summary in Lay Language

**„BIG-Therapy in Parkinson's disease: Dose-Response Realtion“**

**BIG is a new physiotherapeutic approach for the treatment of Parkinson's disease (PD). Yet, classical BIG training is time-consuming. The main focus of BIG is intensive training of large amplitude movements.**

**Participants will be randomly allocated to one of two groups:**

- 1. BIG classic: 16 hours of training within 4 weeks**
  - 2. BIG short version: 10 hours of training within 2 weeks.**
- Participants should be diagnosed with Parkinson's disease in mild to moderate stages.**

**The present study aims to assess the effects of a shorter training (10 hours) compared to the classical BIG training.**

### Brief Summary in Scientific Language

**„BIG-Therapy in Parkinson's disease: Dose-Response Realtion“**

**1.1. BIG is a new physiotherapeutic approach for the treatment of Parkinson's disease (PD). The main focus of BIG is intensive training of large amplitude movements. Classical BIG training is time-consuming (16 hours). The present study aims to assess the effects of a shorter training (10 hours)**

#### **1.2.1. Primary endpoint**

**UPDRS-Motor-Score (Part III) in ON-state (Rater blinded video-rating).**

#### **1.2.2. secondary endpoints**

**Quality of life (PDQ-39),  
ADL (UPDRS Part II),  
cognitive function (TAP)  
Motivation (Paremo-20)  
Gait analysis (Hasomed)  
6-min-walk-Test,  
stand-walk-sit-Test,**

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## **Box & Block-Test.**

### **1.3. Schedule**

**Start screening: March 2011**

**Start baseline 1 April 2011**

**Start therapy Mai 2011**

**last patient in 10/2011**

**last follow-up 01/2012**

### **1.4. Facilities**

**·Fachkrankenhaus für Bewegungsstörungen Beelitz Heilstätten, Paracelsusring 6a,  
14547 Beelitz-Heilstätten**

**·KG Praxis H.Unger, Johannisberger Str. 1, 14197 Berlin**

## **2. Subjects and Methods**

### **2.1. Subjects**

#### **2.1.1. Inclusion Criteria·**

**Idiopathic ParkinsonStage Hoehn & Yahr I-III**

**·UPDRS-Motor-Score (III) 12 or more comprising at least 6 points on bradykinesia-  
items**

#### **2.1.2. Ausschlusskriterien**

**·Dementia(MMSE < 20)**

**·Severe Depression**

**·Severe Dyskinesia when ON**

**·Motor impairment due zto other diseases**

**Reduced abilizty to practice due to cardiac or other diseases**

#### **2.1.3. Recruitment**

**Fachkrankenhaus für Bewegungsstörungen / Parkinson Beelitz-Heilstätten**

#### **2.1.4. Randomisation**

**50/50 randomisation according to random numbers (lots)**

#### **2.1.5. Rater-blinding**

**Blinded video rating of UPDRS**

### **2.2. Definition of intervention**



**concomitantly with assessment of primary variable**

## 2.4. Statistics

### 2.4.1. Descriptive statistics

**All parameters will be entered into a database.**

### 2.4.2. Comparative statistics

**ANOVA for repeated measures. Post hoc testing with parametric tests in case of significance ( < .05).**

## Organizational Data

- DRKS-ID: **DRKS00000730**
- Date of Registration in DRKS: **2011/04/19**
- Date of Registration in Partner Registry or other Primary Registry: [---]\*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **S 6(a)/2011 , Ethik-Kommission der Landesärztekammer Brandenburg**

## Secondary IDs

## Health condition or Problem studied

- ICD10: **G20 - Parkinson's disease**

## Interventions/Observational Groups

- Arm 1: **BIG therapy classic (16 hrs / 4weeks)**
- Arm 2: **BIG therapy short version (10hrs/2 weeks)**

## Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]\*
- Allocation: **Randomized controlled trial**
- Blinding: **Single blind**



Study Type: **Interventional**

Study Type Non-Interventional: [---]\*

Allocation: **Randomized controlled trial**

Blinding: **Single blind**

- Who is blinded: [---]\*
- Control: **Active control**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): [---]\*

### Primary Outcome

**UPDRS-Motor-Score (Sum score of all items of UPDRS Part III) in ON-state (Rater blinded video-rating) at baseline, 4 weeks, 8 weeks and 16 weeks. UODRS part III is the international standard for the assessment of motor performance in PD.**

### Secondary Outcome

**Quality of life (PDQ-39), ADL (UPDRS Part II), cognitive function (TAP) Motivation (Paremo-20) Gait analysis (Hasomed) and timed-tests (6-min-walk-Test, stand-walk-sit-Test, Box & Block-Test) will be assessed at baseline and at 16 weeks follow-up. Walking velocity will be measured by manual stopwatch on a 20m indoor parcours. The stand-walk-sit test comprises raising from a chair- walking 5m-turn-walking back 5m-sit down.**

### Countries of recruitment

- **DE Germany**

### Locations of Recruitment



## Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2011/04/20**
- Target Sample Size: **40**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

## Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **30 Years**
- Maximum Age: **85 Years**

## Additional Inclusion Criteria

### **Idiopathic Parkinson Stage Hoehn & Yahr I-III**

**-UPDRS-Motor-Score (III) 12 or more comprising at least 6 points on bradykinesia-items.**

**Ambulatory without walking-aids.**

**Willingness to participate in a randomized study.**

## Exclusion criteria

- **Dementia(MMSE < 20)**
- **Severe Depression**
- **Severe Dyskinesia when ON**
- **Motor impairment due zto other diseases**
- **Reduced abilizty to practice due to cardiac or other diseases**

## Addresses

### ■ Primary Sponsor

**Neurologisches Fachkrankenhaus für Bewegungsstörungen / Parkinson**  
**Mr. PD Dr. med. Georg Ebersbach**  
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**14547 Beelitz-Heilstätten**  
**Germany**

Telephone: **033204 22781**

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### ■ **Secondary Sponsor**

**Deutsche Parkinson Vereinigung e.V.**

**Mr.**

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**41464 Neuss**

**Germany**

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### ■ **Contact for Scientific Queries**

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### ■ **Contact for Public Queries**

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Fax: [---]\*

E-mail: **ebersbach at parkinson-beelitz.de**

URL: [---]\*

## **Sources of Monetary or Material Support**

### ■ **Private sponsorship (foundations, study societies, etc.)**

**Deutsche Parkinson Vereinigung e.V.**

**Moselstrasse 31**

DRKS-ID: **DRKS00000730**

Date of Registration in DRKS: **2011/04/19**

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**41464 Neuss**

**Germany**

Telephone: [---]\*

Fax: [---]\*

E-mail: [---]\*

URL: [---]\*

## Status

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

## Trial Publications, Results and other documents

\* 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.