

# Job Opportunities in Balance', the impact of a GRoup Intervention for working people with Parkinson's disease (JOBGRIP)

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<b>Ethische beoordeling</b>	Positief advies
<b>Status</b>	Werving gestopt
<b>Type aandoening</b>	-
<b>Onderzoekstype</b>	Interventie onderzoek

## Samenvatting

### ID

NL-OMON20658

### Bron

NTR

### Verkorte titel

The JOBGRIP pilot study

### Aandoening

Parkinson's disease

### Ondersteuning

**Primaire sponsor:** Radboud university medical center

**Overige ondersteuning:** Parkinson Vereniging (Dutch Parkinson Association)

### Onderzoeksproduct en/of interventie

# Uitkomstmaten

## Primaire uitkomstmaten

Experienced functioning on prioritized occupational performance based and (work-related) issues at six months, measured with the COPM (performance and satisfaction scales) at 6 months

## Toelichting onderzoek

### Achtergrond van het onderzoek

Rationale:

When people who are still working develop Parkinson's disease (PD), this often leads to changes in work ability, job satisfaction and work-life balance. However, little is known how to effectively support people with PD (PwPD) to deal with these work-related changes and how to balance remaining job opportunities.

The main objective of this pilot study is to explore the impact of the JOBGRIP intervention for PwPD who are in paid work, over a period of 6 months.

Specific objectives are:

1. To evaluate the potential effectiveness of the JOBGRIP intervention for PwPD on experienced functioning on prioritized work-related problems, self-efficacy at work, sick leave, productivity at work (presenteeism), vitality at work, work limitations and satisfaction in participation in social roles.
2. To evaluate the satisfaction of the participants with the JOBGRIP intervention.
3. To gain insight in the working mechanism of action of the JOBGRIP intervention and influencing factors.
4. To evaluate the feasibility of research procedures to inform a future large scale effectiveness study.

Methods/design:

A multicenter, two-armed, exploratory randomised controlled trial will be conducted with a mixed method design and outcome evaluation at 3 and 6 months. Participants will be randomly allocated in a 1:1 ratio to the intervention group, or the control group. Forty persons with PD, who are in paid work for at least 12 hours a week and who experience or expect work-related issues due to the disease within the next year, will be included.

Participants in the experimental group will receive a group training consisting of 6 group meetings of 2 hours over a period of 10-12 weeks. Additionally, they are offered the opportunity to have one individual (tele)consult with the trainer to address specific individual needs. Two months after the last session there will be a follow up group session. The control group will receive no specific work-related intervention (usual care). The primary outcome assessed will be experienced functioning on prioritized occupational performance based and (work-related) issues at six months, measured with the COPM (performance and satisfaction scales). Secondary outcomes measured will be sick leave, productivity (SES and SPS-6),

satisfaction with participation in social roles (USER-P satisfaction), vitality at work (VBBA2.0) and experienced work limitations (WLQ) at six months. Additionally all outcomes at 3 months will serve as a secondary endpoint.

To inform feasibility of study procedures, satisfaction with the intervention and potential working mechanism, both qualitative (interviews) and quantitative data will be collected and triangulated.

Amendment statement (dd 10th April 2020)

Due to COVID 19 outbreak we were forced to stop the face-to-face JOBGRIP intervention. We had collected baseline and T1 (3 months) outcome data of 23 participants before COVID 19 outbreak. To keep the results as meaningful as possible and to make the most of already collected data, we will analyze the data as originally planned but, as expected in current scenario, with fewer patients and without additional follow-measurement at 6 months for the face-to-face JOBGRIP intervention. However, the COVID- 19 outbreak has also given us the opportunity to consider and explore the impact of an online JOBGRIP intervention. For the protocol this means we have divided the study in two parts. Part A is the study of participants recruited prior to the outbreak of the COVID-19; part B starts during the COVID-19 pandemic. Due to the likely impact of COVID-19 on the societal- and work context and the change in delivering mode of the intervention, data for part A and B will be analysed separately.

## **Doel van het onderzoek**

Our hypothesis is that in the long term the training can support people in retaining their jobs for longer in a satisfactory manner. In the short and medium term we expect that experienced functioning on prioritized work-related problems and perceived self-efficacy with regard to work will improve. Through information, self-reflection, group discussion and by using individual action plans the training intends to coach the participants in adjusting the demands of work/work context and expectations as much as possible to their needs and abilities. This can then lead to maintaining or improving productivity and can have a positive impact on perceived satisfaction with participation in different (social) roles. Since the training aims to trigger behavior change and exploration of adjustment possibilities at work, we expect that the greatest effect will be in the longer term and not immediately after the training.

## **Onderzoeksopzet**

3 (6 months taken out due to COVID)

## **Onderzoeksproduct en/of interventie**

The JOBGRIP intervention is a group training of 6 sessions over a period of 10 weeks in order to increase knowledge, skills and sense of self effectiveness and to activate participants to formulate and tackle their own work-related goals. The content (topics) of the training is modular and described in a manual. It contains fixed modules for each group and a selection of modules that can be chosen by the group depending on their needs. During the intervention period, participants are given the opportunity to plan a one-off individual

consultation with the trainer. Two months after the end of the last session there is a one-off follow up session. The group size per training session is 5-7 persons. The intervention is offered at two locations, namely the rehabilitation departments of the Radboudumc and Rijndam Rehabilitation, location Erasmus MC.

## Contactpersonen

### Publiek

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### Wetenschappelijk

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- a diagnosis of Parkinson's disease, confirmed by a report of a neurologist or rehabilitation physician;
- has paid work for at least 12 hours a week;
- is able to identify 3-5 personal priorities for issues related to working with Parkinson's disease;
- sufficiently masters the Dutch language to participate in the group training and fill in questionnaires;
- able to complete online questionnaires;
- willing to attend the group training at the Radboudumc or Rijndam Revalidatie (location Erasmus MC)
- willing to provide written informed consent.

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- people who have followed the training before;
- presence of a comorbidity that has a greater influence on participation in work than PD (as perceived by the PwPD);

## Onderzoeksopzet

### Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Enkelblind
Controle:	N.v.t. / onbekend

### Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	18-09-2019
Aantal proefpersonen:	40
Type:	Werkelijke startdatum

## Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Ja

### Toelichting

After scientific publication of JOBGRIP results, the anonymous data will be published with restricted access in the DANS repository for other researchers, if deemed suitable.(according to the FAIR principle)

## Ethische beoordeling

Positief advies

Datum: 11-09-2019

Soort:

Eerste indiening

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48516

Bron: ToetsingOnline

Titel:

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

### In overige registers

Register	ID
NTR-new	NL8015
CCMO	NL70797.091.19
OMON	NL-OMON48516

## Resultaten

### Samenvatting resultaten

We intend to present the results in a relevant peer-reviewed journal with open access. Additionally, we will present and report the study in layman's terms for magazine of the 'Parkinson Vereniging' (as subsidy provider).