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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20658

Source
NTR

Brief title
The JOBGRIP pilot study

Health condition

Parkinson's disease

Sponsors and support

Primary sponsor: Radboud university medical center
Source(s) of monetary or material Support: Parkinson Vereniging (Dutch Parkinson Association)

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Secondary outcomes are absence, 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 6 months

Study description

Background summary

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 grouptraining 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 groupsession. 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 outomes 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 enpoint.

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.

Study objective

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.

Study design

3 (6 months taken out due to COVID)

Intervention

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 decribed 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.

Contacts

Public
Radboudumc
Ingrid Sturkenboom

0031-243655231
Scientific
Radboudumc
Ingrid Sturkenboom

0031-243655231

Eligibility criteria

Inclusion criteria

- 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.

Exclusion criteria

- 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);

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-09-2019
Enrollment:	40
Type:	Actual

IPD sharing statement

Plan to share IPD: Yes

Plan description
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)

Ethics review

Positive opinion

Date:	11-09-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48516
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results

Summary results
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).