ISRCTN85547604 https://doi.org/10.1186/ISRCTN85547604

Effects of the Ronnie Gardiner Method - A randomized controlled trial on Parkinson's disease

Submission date
04/04/2017

Recruitment status
No longer recruiting

Registration date
05/04/2017

Overall study status
Completed

Last Edited
03/03/2020

Condition category
Nervous System Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Parkinson’s disease (PD) is a common movement disorder, affecting approximately 120,000 people in the UK. It is a lifelong condition, which involves the gradual loss of nerve cells (neurons) in a part of the brain called the substantia nigra. These neurons are normally responsible for producing dopamine, a chemical messenger (neurotransmitter) which carries signals around the brain that help to coordinate movement. In people suffering from PD, these neurons gradually die over time, causing the level of dopamine in the brain to gradually fall. As the levels of dopamine become lower, the brain is unable to coordinate movement as effectively, causing abnormal movements such as stiffness, tremor (uncontrollable shaking) and slowness of movement (bradykinesia). As these symptoms worsen, patients often avoid movement and physical activity, for fear of falling, which can greatly impact on quality of life. The aim of this study is to evaluate the new rhythm and music based therapy program Ronnie Gardiner Method, created by Swedish musician Ronnie Gardiner, with the main focus on dual-task performance (doing two things at once).

Who can participate?
People with Parkinson's disease, diagnosed by a movement disorder specialist, in the community of Linköping, Sweden.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group attend the study centre to take part in the Ronnie Gardiner Method exercise program. This consists of planned, structured, repetitive, and purposive tasks performed to the beat of rhythmical music twice a week for 12 weeks in one hour sessions (total 24 sessions). Those in the second group do not attend any extra activities, and continue with their ordinary exercises and activities. Participants in both groups are followed up after three months.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Rörelse & Hälsa (Sweden)

When is the study starting and how long is it expected to run for?
March 2016 to December 2018

Who is funding the study?
The County Council of Östergötland (Sweden)
The Neuro Association (Sweden)
The Parkinson Disease Research Foundation (Sweden)
The Ståhls Foundation (Sweden)
The Tornspiran Foundation (Sweden)

Who is the main contact?
Dr Petra Pohl

Contact information

Type(s)
Scientific

Contact name
Dr Petra Pohl

ORCID ID
http://orcid.org/0000-0002-3447-6547

Contact details
Rehabgruppen NSC
Dept of Rehabilitation and Dept of Medical and Health Sciences
Linköping University
Linköping
Sweden
58185
+46 725 629882
petra.pohl@liu.se

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT02999997

Secondary identifying numbers
RGM/PD

Study information

Scientific Title
Evaluation of the Ronnie Gardiner Method regarding dual-task performance in Parkinson's disease

Study objectives
1. Participating in the rhythm and music based therapy program Ronnie Gardiner Method will improve the ability to perform simultaneous motor and cognitive tasks in people with Parkinson's disease
2. The program will improve cognitive function (memory, executive function, speed)
3. The program will have a positive effect on psychological wellbeing and reduce fear of falling
4. The program will improve postural stability
5. The program will enhance increased daily physical activity and reduce sedentary behaviour

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethical Review Board in Linköping, 16/06/2016, ref: 2016/179-31

Study design
Single-blind randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet (in Swedish only)

Health condition(s) or problem(s) studied
Parkinson's disease

Interventions
Participants are randomised to one of two groups.

Intervention group: The intervention is based on the rhythm and music based therapy program Ronnie Gardiner Method (RGM), containing planned, structured, repetitive, and purposive tasks. The program includes complex multicomponent movements and cognitive challenges performed to rhythmic music. The leader projects for this method unique symbols in the shape of red or blue hands and feet. In all, there are 19 symbols, each symbol with a specific movement and unique name. When the symbols appear, the participants must make a certain movement

and simultaneously speak the correct name in a loud voice (i.e., dual-tasking). Mostly the exercises are performed standing up, leading to weight-bearing positions, eg. shifting weight from right to left leg while stretching arms, challenging the postural stability. The single exercises last for appr. 3 minutes, i.e., as long as the music lasts. One 1 hour session contains up to 10 different songs, allowing for time to repeat the movements (motor learning). The participants are encouraged to practice some movements at home to their favorite music in between the sessions. The exercises are continuously progressing with higher tempo and more challenging exercises.
The intervention is performed twice weekly for 12 weeks in groups of 15 participants due to size of the intervention facility. The intervention is led by two certified RGM leaders who are also highly skilled registered physiotherapists. The sessions lasts for one hour each, a total of 24 sessions. After each session the leaders register attendance, any adverse events, and intensity achieved, in a structured report.

Control group: Participants will not attend to any extra activity, but are allowed to continue their everyday life, including therapies or exercises.

Both groups will be re-assessed within two weeks after the intervention period of 12 weeks, and again after another three months for a long term follow up. The assessments involve the same cognitive and physical tests and questionnaires as the pre-assessment, as well as wearing the actigraph armband for seven days.

Intervention Type
Behavioural

Primary outcome measure
Motor-cognitive dual-task performance measured with Timed-Up-and-Go test while subtracting 7 from 100, 90, or 80 at baseline, after 12 weeks, and at 3 months post-intervention.

Secondary outcome measures
1. Balance is assessed using the Berg Balance Scale and Mini-BESTest, at baseline, after 12 weeks, and at 3 months post-intervention
2. Mobility is assessed using the Chair-stand test and Four-Step-Square-Test (FSST) at baseline, post-intervention (after 12 weeks), and at 3 months post-intervention
3. Cognitive function is assessed using the Montreal Cognitive Assessment, MoCA (C) (multiple cognitive domains); Symbol Digit Modalities test (attention); Rey Complex Figure (visuospatial skills); Victoria Stroop test and Trails A and B test (executive function); Grooved Pegboard (motor speed); and memory (instant and recalled) at baseline, post-intervention (after 12 weeks), and at 3 months post-intervention
4. Sedentary behaviour and physical activity levels are assessed using GENEActive actigraphy, worn for 7 days at baseline, post-intervention (after 12 weeks), and at 3 months post-intervention
5. Attendance, adverse events and intensity achieved are assessed using a structured report completed by the leaders after each session in the intervention group
6. Psychological wellbeing is assessed using the Parkinson's Disease Questionnaire, 39 items (PDQ-39) at baseline, post-intervention (after 12 weeks), and at 3 months post-intervention
7. Fear of falling is assessed using Falls Efficacy Scale International, Swedish version (FES-I) at baseline, post-intervention (after 12 weeks), and at 3 months post-intervention
8. Participants experiences of participating in the intervention group is assessed by face-to-face interviews and focus groups with 5 participants in each group within one week post-intervention (after 12 weeks)

Overall study start date
01/03/2016

Completion date
21/03/2018

Eligibility

Key inclusion criteria
1. Diagnosed Parkinson's disease living in the community, stage 1.5 - 3 on H & Y scale
2. Age 18-75
3. Able to walk at least 10 m with or without walking aid
4. No colour blindness
5. Must be able to see and hear with or without aids

Participant type(s)
Patient

Age group
All

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
60

Total final enrolment
54

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/01/2017

Date of final enrolment
17/09/2017

Locations

Countries of recruitment
Sweden

Study participating centre
Rörelse & Hälsa
Neurorehab
Region Östergötland
Linköping
Sweden
58185

Sponsor information

Organisation
The County Council of Östergötland

Sponsor details
Region Östergötland
Linköping
Sweden
58191
+46 10 103 0000
region@regionostergotland.se

Sponsor type
University/education

Website
www.regionostergotland.se

ROR
https://ror.org/0326gsy75

Funder(s)

Funder type
Charity

Funder Name
Henry and Margareta Ståhls Foundation

Funder Name
Tornspiran Foundation

Funder Name
The Neuro Association

Funder Name
Parkinson Disease Research Foundation

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal end of 2018.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from petra.pohl@liu.se

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2020	03/03/2020	Yes	No