Falls and injuries during a behavioural change program to increase physical activity in sedentary patients with Parkinson's disease: A randomized controlled trial.

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"ONDERGETEKENDE

     M.S. Gerrits

Bevestigt hierbij dat de onderhavige verhandeling mag worden geraadpleegd en vrij mag worden gefotokopieerd. Bij het citeren moet steeds de titel en de auteur van de verhandeling worden vermeld."

04-07-2012

Abstract

Background: Almost 70% of patients with Parkinson's disease (PD) fall at least once a year, most falls are related to physical activity. Recently, a specific behavioural change program was developed, the ParkFit program. Unpublished data showed that patients changed their sedentary lifestyle and increased their levels of physical activity. However, it was not clear whether this program influences the number of falls and injuries. This study aims to investigate whether participating in the ParkFit program is associated with an increased number of fall incidents and injuries in patients with PD.

Methods: This randomized controlled trial included sedentary patients with PD and compared two arms; the ParkFit group and the control group. The number of falls was monthly measured by 'The Falls Telephone'. Injuries were investigated and classified according to the 'Injury Severity Scale'. Linear mixed models were used to compare both groups.

Results: In total, 586 patients were randomized to the ParkFit group (N=299) and the control group (N=287). The total number of falls did not differ between the groups (-2%, p= 0.89) with 95%-CI of -28% to +34%. There were no differences in the number of injuries between the groups.

Conclusion: The ParkFit program does not ensure more fall incidents or more suffering from injuries.

 206 words

Samenvatting

Inleiding: Ongeveer 70% van de mensen met de ziekte van Parkinson valt minstens één keer per jaar. Bijna alle valincidenten zijn gerelateerd aan fysieke activiteit. Recent is er een specifiek gedragsveranderingsprogramma ontwikkeld voor patiënten met de ziekte van Parkinson, het ParkFit programma. Nog niet gepubliceerde gegevens laten zien dat patiënten hun inactieve leefstijl hebben veranderd naar een actieve leefstijl. Het is echter niet bekend of de actieve leefstijl gepaard gaat met meer valincidenten en blessures. Het doel is om te onderzoeken of deelname aan het ParkFit programma invloed heeft op een verhoogd aantal valincidenten en blessures bij patiënten met de ziekte van Parkinson.

Methode: In deze gerandomiseerde, gecontroleerde studie zijn inactieve patiënten met de ziekte van Parkinson geïncludeerd. Twee groepen zijn met elkaar vergeleken; de ParkFit groep en de controle groep. Het aantal valincidenten werd maandelijks gemeten met 'de Valtelefoon'. Blessures werden uitgevraagd en gecategoriseerd volgens de 'Injury Severity Scale'. De data werd vergeleken middels linear mixed models.

Resultaten: In totaal zijn 586 patiënten gerandomiseerd over de ParkFit groep (N=299) en de controle groep (N=287). Het aantal valincidenten was niet significant verschillend tussen de groepen (-2%, p=0.89) met een 95%-bhi van -28% tot +34%. Er zijn geen verschillen gevonden tussen de groepen in het aantal blessures.

Conclusie: Het ParkFit programma zorgt er niet voor dat mensen vaker vallen of meer blessures oplopen.

222 woorden

Introduction

Parkinson's disease (PD) is a chronic progressive neurological disease. PD comes with motor symptoms like tremor, rigidity, bradykinesia and postural instability as well as non-motor symptoms like depression, sleep disturbances, constipation and cognitive impairment [1]. PD is due to a lack of the neurotransmitter dopamine. Dopamine regulates the substantia nigra and the striatum, which are responsible for movement, balance and walking [2], [3]. The lack of dopamine can be supplemented with the medication Levodopa, which is the most important treatment in PD [2]-[4]. Interestingly, studies have shown that physical exercise leads to an increased level of dopamine, which suggest that an exercise program for patients with PD might be beneficial [2], [3].

Physical activity is known to prevent people from chronic diseases such as cardiovascular events, diabetes mellitus and dementia [5]-[6]. Physical activity has also positive and preventive effects on specific PD symptoms such as depression and sleep disturbances [5]-[6]. Although physical activity is important for health, increasing and maintaining sufficient levels of physical activity is known to be difficult. It may be even more difficult for patients with PD, since PD is accompanied with several motor symptoms [2]-[4].

Despite the extensive benefits of physical activity, becoming more physically active could also have negative effects. Increased levels of physical activity are associated with an increased number of falls in the elderly [7]. Almost 70% of patients with PD fall at least once a year [8], most falls occur at home [9]. Main causes of falling in PD are postural instability, difficulty with transfers, freezing of gait, dual tasking and orthostatic syncope, main causes mentioned here are related to physical activity [10]. Furthermore, an increased risk of physical activity is suffering from injuries like ruptures or overload.

Several programs were developed to stimulate patients with chronic diseases like chronic obstructive pulmonary disease (COPD) and diabetes mellitus (DM) towards a more active lifestyle [11][12]. Patients were coached and guided by professionals to become more physically active, based on behavioural change techniques [13]-[14]. Recently, such a specific behavioural change program for patients with PD was developed, the ParkFit program [15]. Unpublished data showed that patients changed their sedentary lifestyle and increased levels of physical activity [van Nimwegen, Speelman, 2012]. However, it was not clear whether this behavioural change program influences the number of falls and injuries. This study aims to investigate whether participating in the ParkFit program is associated with an increased number of fall incidents and injuries in patients with PD.

Methods

Design

The current study was a randomized controlled trial over two years to gain insight in the number of fall incidents and the number of injuries in patients with PD. The study was performed within the ParkFit study [15], a randomized controlled trial aiming to increase the level of physical activity in sedentary patients with PD. The trial compared two arms; the ParkFit group and the control group.

Participants

Patients were eligible when they met the following criteria: a) diagnosed with idiopathic PD according to the UK Brain Bank Criteria [16], b) age between 40 and 75 years, c) a sedentary lifestyle (defined as < 3 times a week vigorous-intensity physical activity for < 60 minutes; or < 3 times a week moderate-intensity physical activity for < 150 minutes) [17] and d) Hoehn and Yahr score ≤ 3 [18]. Patients were excluded based on the following criteria: a) an unclear diagnosis, b) Mini-Mental State Examination score < 24 [19], c) not able to complete Dutch questionnaires, d) severe co-morbidity interfering with daily functioning, e) daily institutionalized care and f) deep brain surgery. Confirmation of participation was obtained by informed consent before the baseline assessment.

Measurements

Clinical characteristics

Age and gender were assessed at baseline (Figure 1). Disease severity was measured according to the Unified Parkinson's Disease Rating Scale (UPDRS) [20].

The level of physical activity was measured with the LASA Physical Activity Questionnaire (LAPAQ) [21], a 7-days recall based on an interview-based questionnaire. The LAPAQ asked about the daily amount (i.e. frequency and duration) of physical activity performed in the last week. The questionnaire contains walking, cycling, gardening, household activities and sport activities. Total hours spend to these activities were calculated.

Primary outcome

The number of falls was measured by 'The Falls Telephone' [22]. This is a computerized system which calls patients every month during the whole study period of two years. Patients were asked to dial the number of falls during the last month. A fall was defined as 'an unexpected event in which the participant comes to rest on the ground, floor, or lower level' [23].The total number of falls for each patient and a fall-rate per year were calculated for each group.

Secondary outcome

Injuries were investigated by a researcher at 12 and 24 months according to 'the Protocol for injuries' (Figure 2 + appendix 1). Patients were asked if they had suffered from an injury in the last year. The injuries were categorized in nine specified categories: 1) Bleeding, 2) Fracture, 3) Contusion, 4) Luxation, 5) Overload, 6) Rupture, 7) Gall, 8) Strain, 9) Other/otherwise.

In addition, all patients were asked to contact the researcher when they suffered from an injury or had a serious advert event. According to the 'Injury Severity Score' (ISS) , injuries were categorized in five dimensions: 1) minor; 2) moderate; 3) severe, not life threatening; 4) severe, life threatening; 5) critical, survival uncertain [24]. *Minor* injuries contains bruises, wounds, galls, luxations, pain, overload and strain. Patients with *Moderate* injuries suffer from injuries like fractures, ruptures and inflammations. The next dimension is *Severe, not life-threatening* which contains hip fractures, internal bleeding, eye surgery, orthopedics, hospitalization for medication, dementia and internal medicine. Then, *Severe, life-threatening* includes cancer and cardiovascular diseases, and finally *critical, survival uncertain* contains cardiovascular accidents and death.
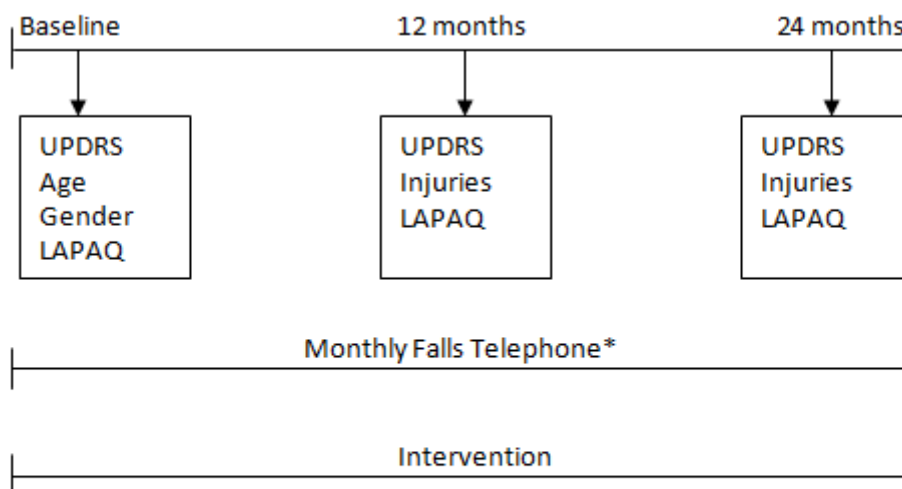

Figure 1: Ascertainment methods for the various measurements in a timeline.
H&Y: Hoehn and Yahr. UPDRS: Unified Parkinson's Disease Rating Scale.
LAPAQ: LASA Physical Activity Questionnaire. * Primary outcome measure.

Intervention

Patients in both groups were referred to a physical therapist. These therapists participate in the Dutch ParkinsonNet [25], [26] and are experienced in the treatment of PD. Additionally, all therapists received a specific training about the treatment in both study arms [15].

Patients in both groups received individualized physical therapy based on the Dutch evidence-based guideline of physical therapy for PD [27]. There were specific tools for each group.

ParkFit group

Patients received a brochure covering specific strategies to promote behavioural change [13]-[28]. Their physical therapist served as personal activity coach who guided the patient towards a more active lifestyle [29], during specific coaching sessions (16 sessions in year 1 and 12 sessions in year 2). Activity goals were created in order to obtain long term goals, based on behavioural change theories [14]. Patients received a personal ambulatory monitor with automated visual feedback showing the amount of actually delivered daily physical activity [30], [31]. Next to the behavioural change program, patients received standard physical therapy (maximum of 19 sessions in year 1 and 23 in year 2) (Figure 2).

Control group

The control group received standard physical therapy [27], with a maximum of 35 sessions each year (Figure 2). In addition, patients received a brochure with information about the benefits of physical therapy in PD.
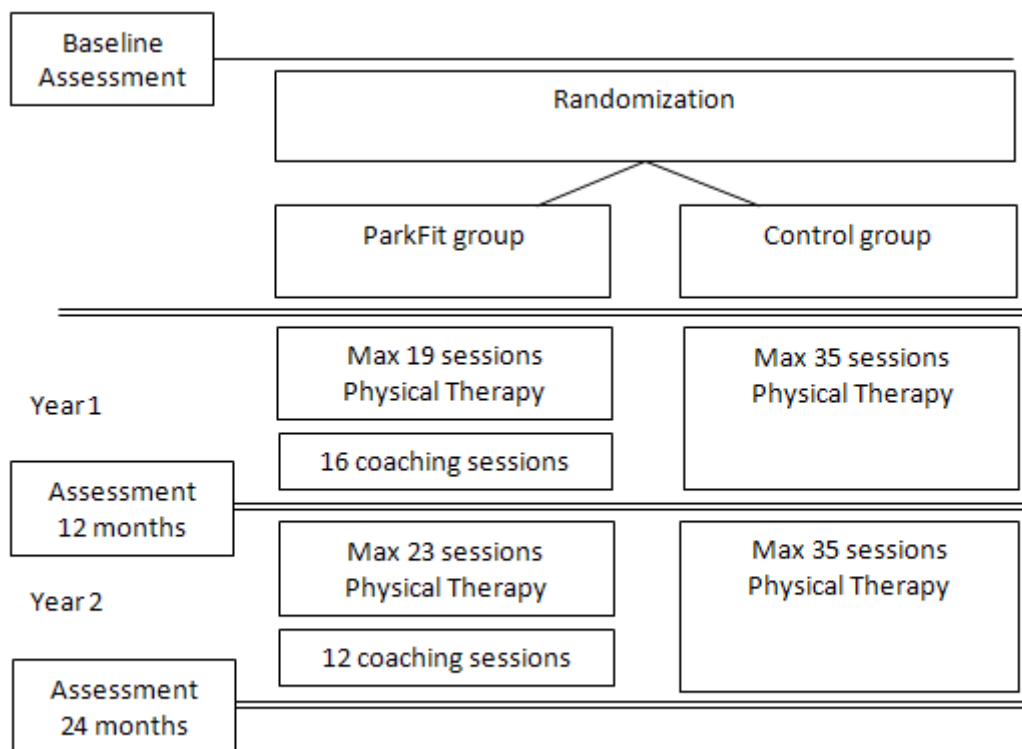

Figure 2: Overview of both study arms

Randomization and blinding

According to the sample size calculation of the ParkFit study, the aim was to include 700 sedentary patients with PD [15]. This calculation was based on the primary endpoint for the ParkFit study, the LAPAQ [21].

Randomization was performed by a computerized system using a minimum algorithm based on: region, Hoehn and Yahr stage, age, gender and the current level of physical activity [15].

Since the researcher who investigated the injuries was unaware of the group allocation, blinding during assessments was ensured.

Statistics

Clinical characteristics were presented by descriptive statistics.

Falls

The total number of falls for each patient and the fall-rate for each patients (mean number of falls over 24 months*24) were calculated.

To compare both groups, linear mixed models with logarithmic link function and negative binomial distribution was used [32][33]. The analysis adjusted for the factors 'the patient has fallen once or twice versus patients has never fallen' and 'patient has fallen more than twice versus patient has never fallen'. The ninety five percent confidence interval (95% CI) was calculated.

Injuries

In order to compare the number and severity of injuries, frequencies and percentages of injuries for each dimension of the ISS were calculated for the ParkFit group and the control group.

Additional analysis

We performed an additional analysis to investigate whether patients with the highest level of physical activity, fell more frequent compared with patients with the lowest level of physical activity. Since the LAPAQ score was not normal distributed, we used the median for the total score and for the indoor activities. Patients were divided in quartiles based on the median LAPAQ score (median of 12 + 24 months). Total numbers of falls was calculated for the lowest and highest quartiles.

The same method was used to investigate whether patients who spent the most time on indoor activities, fell more frequent compared to patients who spent the less time on indoor activities. Statistical analyses were conducted with SAS/STAT Statistics [34] and with SPSS 18.0 for Windows [35].

Results

Descriptive statistics

In total, 586 patients were randomized to the ParkFit group (N=299) and the control group (N=287).

There were no differences between both groups based on the inclusion criteria (Table 1).

Table 1: clinical characteristics

	ParkFit group (N=299)	Control group (N=287)
Age in years mean ± SD	65.1 ± 7.9	65.8 ± 7.2
Gender men *(%)*	194 *(64.9)*	188 *(65.5)*
H&Y		
1	7	4
1,5	7	10
2	221	223
2,5	48	36
3	16	14
Disease duration in years mean ± SD	4.9 ± 4.5	5.5 ± 4.6
UPDRS mean	33.1	32.3
LAPAQ hours/wk	12.8	13.7

N, number of patients; SD, standard deviation; H&Y, Hoehn & Yahr; wk, week; UPDRS, Unified
Parkinson's Disease Rating Scale; LAPAQ, LASA Physical Activity Questionnaire.
H&Y was given in number of patients.

Falls

The number of falls for each patients during follow-up was not significantly different between the

groups (-2%, p= 0.89, 95% CI: -28% to +34%) (Table 2). We also preformed the analyses without the

outliers, there were no differences in the results; p=0.41 (outliers maximized to 24) and p=0.47

(outliers maximized to 12). In addition, the mean fall-rate for each patient per year for each group

showed no differences (Table 3).

Table 2: Number of patients who fell 0, 1, 2 or 3 or more times during follow-up

	ParkFit group	Control group
0	115 *(38.4)*	96 *(33.4)*
1	49 *(16.3)*	48 *(16.7)*
2	34 *(11.3)*	37 *(12.8)*
3 or more	101 *(33.7)*	106 *(36.9)*

Data reflects the number of patients with percentages (%).

Table 3: Mean fall rate per year

	ParkFit group	Control group
0	115 *(38.4)*	96 *(33.4)*
>0, <=1	75 *(25.0)*	79 *(27.5)*
>1, <=2	33 *(11.0)*	38 *(13.2)*
>2	76 *(25.4)*	74 *(25.7)*

Data reflects the number of patients with percentages (%).

Injuries

In the ParkFit group were 221 injuries reported in total, by 139 patients. In the control group were 242 injuries reported in total, by 142 patients. Table 4 shows the numbers of injuries for the different dimensions for both groups. There are no differences between the groups.

In the ParkFit group, 160 patients reported no injuries. In the control group, 145 patients reported no injuries.

After 12 months, 50 patients from the ParkFit group and 43 patients from the control group were not able to come to the assessment day. At 24 months, 52 patients from the ParkFit group and 67 patients from the control group were not able to come to the assessment day. Therefore, for these patients the injuries were not investigated according to the protocol.

Table 4: Injury Severity Scale

	ParkFit group	Control group
Minor	91 *(47.4)*	101 *(52.6)*
Moderate	40 *(52.6)*	36 *(47.4)*
Severe, not life-threatening	63 *(46.0)*	74 *(54.0)*
Severe, life-threatening	22 *(47.8)*	24 *(52.2)*
Critical, survival uncertain	0 *(0)*	4 *(100)*
Died	5 *(62.5)*	3 *(37.5)*
Total	221 *(47.7)*	242 *(52.3)*

Data reflects the number of injuries with percentages (%).

Additional analyses

We analyzed in the total group whether patients with a high LAPAQ score fall more frequent compared to patients with a low score on the LAPAQ. The total number of falls during the follow-up was not different for patients in the highest quartile of the LAPAQ compared to patients in the lowest quartile of the LAPAQ (Table 5).

There were no differences in falls in the quartiles based on indoor activities. The same analysis was performed for outdoor activities which showed comparable results.

Table 5: Number of falls during follow-up based on the scores from the LAPAQ

Number of falls during follow-up	Lowest quartile 0 to 8.3 hours/wk	Highest quartile 18.5 to 71 hours/wk
0	44 (*29.9*)	50 (*34.5*)
1	21 (*14.3*)	29 (*20.0*)
2	24 (*16.3*)	15 (*10.3*)
3 or more	53 (*39.5*)	50 (*35.2*)
Total	142	144

Lapaq, LASA Physical Activity Questionnaire; wk, week; N, number of patients.
 Data reflects the number of patients with percentages (%).

Discussion

Patients who become more physically active according to the ParkFit program did not fall more often compared with patients in the control group. Furthermore, patients in the ParkFit group did not suffer from more injuries.

The difference in mean fall frequency is small. Apparently, there is no difference between both groups which means the ParkFit program is safe for patients with PD. However, the confidence interval is very wide. In exceptional cases, it could be that patients in the ParkFit group fall 28% less compared to patients in the control group. It could also be that patients in the ParkFit group fall 34% more. Since this large confidence interval, it is difficult to conclude that patients in the ParkFit group fell less or more. The methods of this study were very strong; we included a large study population and had a follow-up duration of two years. As we can conclude, the results are established in the most appropriated way and it is questionable whether different approach will change the results.

During two years, patients were called by the Falls Telephone every month. The Falls Telephone is less specific (87%) but very sensitive (100%).The system scored high on the participant satisfaction and is easy to use for the researcher. The reliability and agreement of the Falls Telephone are good, but these properties are defined for a weekly call [22]. The reliability and agreement have not been defined for monthly calls.
Due to this monthly interval, patients might underestimate or overestimate their number of falls [23]. A monthly interval from The Falls Telephone might be too long.
The definition of a fall was given once, in an information letter at the start of the study. Patients could forget this definition over the two years. This also may cause underestimating and overestimating the number of falls. Mentioning the definition at every call from the Falls Telephone could be a solution for the future.

In this study, we found no more falls related to more physical activity in sedentary patients with PD. Another hypothesis is that patients who become more physically active will have more muscle strength, will have a better balance, and will have a better condition [36]. Studies in patients with PD concluded that brief exercise programs improve several properties like muscle strength and balance [2]-[4]. Patients who become more physically active might show more adequate balance reactions, resulting in less frequent falls [37].Patients who are or stay inactive, might be less able to catch up a fall. This means that patients who become more physically active, will fall less frequently and patients who are inactive will fall more frequently, but this hypothesis was not supported by this study.

Some patients were not able to come to the assessment day at 12 and 24 months, we do not know if the data from the injuries are complete. All patients were asked to contact the researcher when they had suffered from an injury. We do not know if everyone had reported their injury. Patients who suffered from an injury were not able to come to the assessment day because of their injury. However, since the number of missings was comparable for both groups, we do not think the number of missings influences the conclusion.

Literature shows a difference between the number of falls for inside and outside activities. It appears that most falls occur at home [9], [38]. This study do not confirm those findings as there were no differences between the number of falls in indoor and outdoor activities. The inclusion criteria could be an explanation, only patients up to H&Y 3 were included. The most affected and maybe housebound patients were excluded from this study. Patients who are the most affected, fall more indoors [9], [39]. Freezing of gait is related to the number of falls and this symptom is more in common in more affected patients [40]. This could be an explanation for the fact that, in this study, there is no difference between indoor and outdoor falls data.

Patients in the ParkFit group were coached by a professional therapist, who participates in the Dutch ParkinsonNet [25],[26], to become more physically active. These therapists received specific education about PD and the physical therapy treatment in PD. They are experts in treating patients with PD. Therefore, whether these results can be extrapolated to other sedentary patients with PD who become more physically active without the accompaniment of an experienced therapist needs to be further investigated.

Conclusion

Under accompaniment of an experienced therapist, this program is safe for sedentary patients with PD who wants to become more physically active. Patients in the ParkFit group do not fall more often or suffer from more injuries compared to controls.

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Appendix

1 Protocol for injuries (in Dutch)

SAE- meldformulier **BLESSURE** - meetdag jaar 2

Datum melding: [- -]   Initialen melder:

Patiëntnummer:

Geboortedatum: [- -]

1. Symptomen en/of diagnose:

☐ valgerelateerd

2. In welke *categorie* valt de blessure:

☐ Bovenste extremiteit
☐ Onderste extremiteit
☐ Romp
☐ Hoofd/gezicht

3. Onder welk *type* valt de blessure:

☐ Bloeding   ☐ Schaafwond
☐ Fractuur   ☐ Verrekking
☐ Kneuzing   ☐ Onbekend
☐ Luxatie   ☐ Anders namelijk:
☐ Overbelasting
☐ Ruptuur   ....

4. *Oorzaak* symptomen en/of diagnose:

5. *Begindatum* symptomen: [- -]

6. Is de proefpersoon hersteld?

☐ Ja, Datum: - -   ☐ Ja, hersteld met restverschijnselen

☐ Nee, is herstellende   ☐ Onbekend