

Online Journal Club-Article Review Template

Background/Overview					
Article Citation	van Nimwegen M, Speelman AD, Overeem S, van de Warrenburg BP, Smulders K, Dontje ML, et al. Promotion of physical activity and fitness in sedentary patients with Parkinson's disease: randomised controlled trial. Bmj. 2013;346:f576				
Study Objective/Purpose (hypothesis)	To evaluate whether a multifaceted behavioral change program increases physical activity (PA) in patients with Parkinson's disease (PD) compared with standard physical therapy (PT) as delivered in the Netherlands.				
Brief Background (why issue is important; summary of previous literature)	Regular PA is beneficial in improving health and quality of life (QoL) in many populations. Physical therapy interventions have been shown to be effective in those with PD in addressing impairments and improving function. PA has been shown to improve symptoms of PD and improve QOL, and in animal models has shown that it could potentially have neuroprotective effects in those with PD. However, this population is less physically active than the general population. Identifying interventions that increase PA and result in health-related behavioral change would be beneficial in improving the health and well-being of those with PD.				
Methods					
Study Design	2-year multicenter randomized control/comparison trial. Randomization was stratified based on region, H&Y stage, age, sex, and current physical activity level. Assessors were blinded, and participants were informed that they would be in 1 of 2 beneficial intervention groups to avoid expectation bias. Treating therapists not blinded.				
Target Population (dx, inclusion/exclusion criteria, etc)	Inclusion- persons with PD; age 40-75; H&Y \leq 3; sedentary; able to answer questionnaires Exclusion- <24/26 on Mini-Mental State Examination; co-morbidity that interfered with daily functioning; daily institutionalized care; previous deep brain surgery				
Interventions (if applicable): (specificity of interventions, ability to replicate, frequency, duration)	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: center;">ParkFit (intervention)</th> <th style="text-align: center;">ParkSafe (comparison)</th> </tr> </thead> <tbody> <tr> <td style="vertical-align: top;"> <ul style="list-style-type: none"> • Physical therapy <ul style="list-style-type: none"> ○ Yr 1 max of 19 ○ Yr 2 max of 23 • Personal activity coach - aimed at promoting active lifestyle <ul style="list-style-type: none"> ○ Yr 1 16 visits ○ Yr 2 12 visits • Brochure re: benefits and goals of PT and information on behavior change • Goal setting • Health contract • Ambulatory Activity Monitor with visual feedback on progress and activity </td> <td style="vertical-align: top;"> <ul style="list-style-type: none"> • Maximum of 35-30 min PT treatment sessions per year for 2 years • Brochure re: benefits and goals of PT and safety with daily activities </td> </tr> </tbody> </table>	ParkFit (intervention)	ParkSafe (comparison)	<ul style="list-style-type: none"> • Physical therapy <ul style="list-style-type: none"> ○ Yr 1 max of 19 ○ Yr 2 max of 23 • Personal activity coach - aimed at promoting active lifestyle <ul style="list-style-type: none"> ○ Yr 1 16 visits ○ Yr 2 12 visits • Brochure re: benefits and goals of PT and information on behavior change • Goal setting • Health contract • Ambulatory Activity Monitor with visual feedback on progress and activity 	<ul style="list-style-type: none"> • Maximum of 35-30 min PT treatment sessions per year for 2 years • Brochure re: benefits and goals of PT and safety with daily activities
ParkFit (intervention)	ParkSafe (comparison)				
<ul style="list-style-type: none"> • Physical therapy <ul style="list-style-type: none"> ○ Yr 1 max of 19 ○ Yr 2 max of 23 • Personal activity coach - aimed at promoting active lifestyle <ul style="list-style-type: none"> ○ Yr 1 16 visits ○ Yr 2 12 visits • Brochure re: benefits and goals of PT and information on behavior change • Goal setting • Health contract • Ambulatory Activity Monitor with visual feedback on progress and activity 	<ul style="list-style-type: none"> • Maximum of 35-30 min PT treatment sessions per year for 2 years • Brochure re: benefits and goals of PT and safety with daily activities 				

Outcome Measures (relevant to purpose of the study; reliable, valid, clinical utility)	<p>Primary: LASA physical activity questionnaire (LAPAQ) – 7 day recall of frequency/duration doing specific listed activities. Variable is hours/week. Assessed at baseline, 6, 12, 18, 24 months with mean value of all non-baseline timeframes used in analysis.</p> <p>Secondary: 6MWT (baseline, 12,24 mos), PDQ-39 (baseline, 6, 12, 18, 24 months), physical activity monitor (14-day mean at 6, 12, 18, 24 mos), activity diary (7-day diary at 6, 12, 18, 24 mos)</p> <p>All outcomes were analyzed by calculating the change between mean baseline value with mean at 6-24 mos.</p>
Statistical Analysis (statistics used, appropriate application)	<p>Modified intent to treat analysis (excluded those with no follow up measurements)</p> <p>Data analyzed with linear mixed model with random nested factors of “patient” and “exercise group.”</p> <p>Region, H&Y, age, sex, and current physical activity level of the patient were used as co-variables.</p> <p>Power analysis completed and determined n=700 was needed for 80% power.</p>
Results	
Enrollment/Subject Characteristics (sample size, gender, age, functional level)	<p>Sample size: n=586, ParkFit (n=299) ParkSafe (n=287)</p> <p>Baseline mean (SD) characteristics include: age=65 (7), M>F, BMI: 27.4 (4.5) PD duration=5 years (4.5), MMSE=28.1 (1.7), H+Y1-3, greatest in HY2, UPDRS motor=33.1 (11.3), daily levodopa equivalent(mg)=458-499 (414), LAPAQ 12.8-13.8(8.3-23.9)</p> <p>Groups similar at baseline for all variables except ParkFit group had lower LAPAQ (less physically active)</p>
Summary of Primary and Secondary Outcomes (include aggregate and sub-group findings if reported); note results that were statistically significant; How many reached a level of clinical significance (exceed MCID if known); retention of changes?	<p>Primary outcome (LAPAQ in hrs/week): no significant differences between groups for mean change in LAPAQ, p=0.19</p> <p>Secondary outcomes: Significant increase in activity according to activity diary with a mean change of 1.3 hrs/week in ParkFit vs. 0.5 hrs/week in ParkSafe; significant increase in activity according to activity monitor with a mean change of +38.7 kcal/day in ParkFit compared to -14.2 kcal/day in ParkSafe; non-significant trend for increase in 6MWT in ParkFit (8.4 m) compared to ParkSafe(-1.6 m); mean change in QOL did not differ between groups (ParkFit=0.1 Control=1.7).</p> <p>Lost to follow up: 540 (92.2%) of 586 completed 24 month follow up; % was comparable in both groups ParkFit (8.7%) and ParkSafe (6.7%); those lost to follow up were similar to those who completed assessments except for older age.</p> <p>Compliance: 75 (12.8%) of 586 did not complete the 2 year intervention (ParkFit=44, ParkSafe=31); main reasons: refusal to change to ParkinsonNet PT, too great a burden, or dissatisfaction with intervention; mean # PT visits annually did not differ between groups ParkFit (13.6) control (13.0).</p> <p>Safety/falls: 8 patients died during f/u unrelated to exercise (CV issues, CA, or medical complications ParkFit=5, control=3); hip fractures in control=8, in Parkfit=2; frequency/severity of all other adverse events were similar in both groups (ParkFit=221 control=242); patients with >= 1 fall was comparable ParkFit= 184(62%) control=191(67%)</p>

Authors' Discussion and Conclusions	
Brief Summary of Authors' Main Discussion Points; Authors' Conclusion	<ul style="list-style-type: none"> • This is a negative trial, because no significant difference was found in primary outcome measure. A multifaceted behavioral change programme did not change volume of PA in older, sedentary patients with PD. However, secondary outcome measures of PA suggest greater participation in different aspects of PA and showed improved in fitness among ParkFit patients. • LAPAQ was chosen because it was validated for use in large populations in two other studies. • Activity diary demonstrated increase in physical activity, but the LAPAQ which is also a subjective, self-reported measure, did not. One possible explanation could be that the LAPAQ uses the sum of all physical activity (strenuous PA and household activities); the diary only included strenuous PA. • Further research: looking at the validity/reliability of different measures of physical activity and different aspects of physical activity; reproducing a similar study using an activity monitor/diary as primary outcome; studies investigating which components of the protocol are most effective
Reviewer's Discussion and Conclusion	
Study Strengths	Long term intervention (24 months); Large sample size (n=586); Multi-center RCT ; Double blinded: subjects got "one of two potentially beneficial interventions"; Modified intention to treat analysis (excluded only those with no follow-up measurements at all); High retention rate; High compliance rate; Use of ParkinsonNet physical therapists to administer treatment; ParkFit was a theoretically-sound intervention with good face validity; Used multiple outcome measures of physical activity
Study Limitations and Potential for Bias	Unequal LAPAQ at baseline (ParkFit were less active); Primary endpoint (LAPAQ) is a subjective self-report and sums all physical activity (household and strenuous PA); Did not meet "n" calculated during power analysis; Does not generalize to those with apathy, severe cognitive impairment, or depression; Population was less sedentary compared to those that declined participation; Difference between "usual care" in Netherlands and U.S.; Risk of contamination due to same therapists administering both treatments
Applicability:	<ul style="list-style-type: none"> • Given the importance of physical activity for all patient populations, the behavioral change intervention could be integrated into our work with all patients. • The study design and implementation suggests that this intervention is more appropriate for an outpatient setting, but elements of education regarding health-related behavior change could easily and practically be used across all settings. • Elements of intervention could easily be reproduced, but delivery model of health care in U.S. is a barrier to full implementation.
How will study results impact PT management of this patient population?	<ul style="list-style-type: none"> • Provides a rationale and data for changing the model of care in the U.S. to allow for more routine PT referral for those with PD, or in creating such opportunity in those states with direct access. <ul style="list-style-type: none"> ○ Provide education and information re: behavior change ○ Add elements of coaching and barrier reduction into our treatment plans ○ Assist with developing truly meaningful, specific, and patient –centered goals ○ Develop comprehensive plans of care and use the contract model of this intervention to foster commitment ○ Provide more immediate and accessible feedback of activity levels, e.g. fitbit, mobile health technologies, and fitness apps

