Improvement of Freezing of Gait in Patients with Parkinson's Disease by Music Exercise Therapy: A Study Protocol for a Randomized Controlled Trial

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Study protocol

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Abstract

Background: Freezing of gait, a common pathological gait in Parkinson's disease, is progressive with the progression of the disease. It is an important risk factor for patients to fall easily, lose their independent living ability and decline their quality of life. The treatment of Parkinson's disease with freezing of gait is very difficult, and the effect of medicine and operation is not ideal. Music exercise therapy is a kind of treatment technology that can change the behavior, emotion and physiological activity of patients by listening to music at the same time of exercise therapy. In recent years, music exercise therapy has been widely used in motor disorders and neurological diseases, and has achieved remarkable results. The small sample study in the early stage of this research group initially found that music exercise therapy can improve the freezing of gait of Parkinson's patients and improve the quality of life of patients. The overall purpose of this experiment is to expand the sample size to further evaluate the clinical effect of music exercise therapy on freezing of gait of Parkinson's patients.

Methods/design: This randomized controlled trial will evaluate the clinical efficacy of music exercise therapy in improving the freezing of gait of Parkinson's patients. The patients will receive music exercise therapy, exercise therapy without music and routine rehabilitation therapy at random. We will recruit 81 inpatients of Parkinson's who meet the trial criteria to observe the changes of gait and limb motor function after 4 weeks of intervention. The first evaluation index is to use three-dimensional gait analysis system to evaluate the change of patients' gait. The second evaluation index includes limb function, activity of daily living and fall risk assessment.

Discussion: Our aim is to evaluate the efficacy of music exercise therapy in the treatment of Parkinson's patients with freezing of gait. This result will provide more evidence for the clinical application of this therapy in the future.

Trial registration: The trial has been registered at the Chinese Clinical Trial Registry (<http://www.chictr.org.cn>) on September 20, 2019. Registration number: ChiCTR1900026063

Background

Parkinson's disease (PD) is a common neurodegenerative disease in the elderly, which was first described by James Parkinson in 1817. The incidence rate of PD is about 1%~2% among people over 60 years old. It is the second most serious neurodegenerative disease that seriously affects human health [1]. In addition, most patients also have movement or non movement symptoms, mainly manifested in intermittent gait restriction or obstruction during walking, especially in turning, walking and obstacle avoidance, which seriously endangers people's living ability [2, 3]. The progress of population aging and the increasing incidence rate of PD suggest that it is very important for PD to prevent, treat and delay the progress of the disease[4].

Freezing of gait (FOG), a kind of pathological gait with disability, which is common in patients with Parkinson's disease in the middle and late stage. It is characterized by short-term retardation or very short

pace. It usually occurs when the step is started or the direction changes[5]. Patients often describe their feet as "stuck" while trying to lift them forward, as if they were stuck to the ground. This process usually lasts for a few seconds [6]. The content includes three aspects: starting freezing, turning freezing and walking freezing, which can occur or aggravate when patients face space obstacles, under pressure, low attention or dual tasks. Previous study has shown that FOG is the primary cause of walking difficulties in Parkinson's patients, which can lead to falls, decreased motor function and quality of life [7]. Modern management of Parkinson's disease aims to control symptoms, reduce disability and improve quality of life [8]. Unfortunately, the mechanism of FOG is not clear enough, so there is no direct and effective treatment for FOG symptoms, and the available drugs and surgical treatment are not ideal[9]. Drug therapy has little effect on the improvement of FOG, and the advanced cases have very low response to drugs[10]. Therefore, drug therapy can only be used as an adjunctive therapy to prevent FOG.

In the field where traditional medicine has been declared a failure, sometimes music exercise therapy can achieve curative effect. The goal of music therapy is to cause behavioral changes in patients, which are caused by the remodeling of brain nerves[11]. Rhythm, as an inherent characteristic of music, can associate various behaviors with an external beat, which may lead to the synchronization of neural network behaviors [12]. Therefore, music therapists can match music with various behaviors (such as movement, phonation, respiration, heart rate) to cause synchronous stimulation of neurons in the brain area involved in regulating these behaviors, strengthen the connection of neurons, so as to make patients have faster and more lasting changes[13].

Because music involves various brain regions related to emotion, motivation, cognition and motor function, music intervention is used to improve socialization and cognition, emotion and neuromotor function[14]. In recent decades, there were more and more evidence of using music intervention in clinical environment [15]. The application forms of music therapy mainly include passive music therapy, active music therapy, improvisational music therapy and combined music therapy. Combined music therapy is a kind of special therapy that combines music with other therapies after integrating the characteristics of music. For example, music exercise therapy combines two kinds of therapies: exercise therapy and music therapy. Music exercise therapy is a supplement to traditional exercise therapy. It not only enriches the means of exercise therapy, but also expands the scope of application. In addition, it also increases patients' interest and compliance in rehabilitation treatment, and improves the efficacy of exercise therapy. Moreover, it has the advantages of simple operation and low price, so there is a very broad development prospect and application value. Music exercise therapy plays an active role in the treatment of various diseases, which can improve the patients' limb motor dysfunction and improve their ability of living activities [16, 17]. Previous studies have shown that cooperative dance and music training can improve the walking function of Parkinson's patients and improve their transfer ability [18-20]. However, the current research mostly adopts a single active or passive application form of music therapy. Moreover, most of the current evaluation of the clinical effect of music therapy focuses on subjective indicators such as the improvement of clinical symptoms and the change of score of the evaluation scale. The lack of objective indicators leads to the low persuasion of the research results. The previous study of our group found that music exercise therapy can improve the rehabilitation effect of stroke,

spinal cord injury, Parkinson's disease and other nervous system patients, indicating that music exercise therapy can not only improve the depression of patients, improve the rehabilitation participation of patients, but also increase the limb function of patients, so as to improve the ability of daily life. This study will expand the sample size on the basis of previous research, and introduce objective observation indicators such as three-dimensional gait analysis to further study the clinical effect of music movement therapy on improving FOG.

Trial objectives

The objectives of this trial are as follows:

1. To verify the therapeutic effect of music exercise therapy on FOG of Parkinson's patients, and to improve their motor function and quality of life.
2. To provide more evidence for the clinical application of the treatment in the future.

Methods/design

Trial design

This is a prospective randomized controlled trial supported by Shanghai Municipal Health Commission. The trial will be carried out by Shanghai Second rehabilitation hospital. Patients who meet the pre-defined criteria will be randomly divided into three groups: music exercise therapy group undergoing music exercise therapy with routine rehabilitation treatment, exercise therapy group undergoing exercise therapy without music with routine rehabilitation treatment, and control group undergoing routine rehabilitation treatment. The patients will be followed up for three months to observe the FOG and limb function after treatment. Figure 1 shows the study flow chart. An example template for the content of admission plans, interventions and evaluation recommendations is shown in Figure 2.

Ethics

The ethical committee of Shanghai Second rehabilitation hospital approved the ethical approval of this study on September 20, 2018 (reference number 2018-01). The research scheme, patient information table and informed consent form were approved by the ethics committee. Informed consent will be obtained for all included cases. Their real names will not appear in the relevant reports of this trial to protect their privacy.

Study setting

The research objects will be enrolled from Shanghai Second rehabilitation hospital. All patients will be treated at the hospitals where participants are recruited.

Sample size

Pass software method (Pass15): This study is a randomized controlled trial to evaluate the efficacy of three methods in the treatment of Parkinson's FOG. The main observation index is gait parameters. Since there is no three-dimensional gait analysis result to evaluate the effect of music exercise therapy on Parkinson's FOG before this study, Since there is no three-dimensional gait analysis result to evaluate the effect of music kinesitherapy on Parkinson's FOG before this study, the results of the unified Parkinson's disease assessment scale (UPDRS III) in the preliminary trial of this study group are temporarily used for calculation. According to the pre trial, the mean value of UPDRS (III) score reduction of three groups after treatment is predicted to be 20.7, 7.9 and 2.6 respectively, and the standard deviation of each group is 16.6, 6.3 and 2.2 respectively. Two side test is required, α is 0.05, and the assurance (test efficiency) is 90%. The sample size was calculated by pass 15 software: $n = 66$ cases. At least 81 cases need to be included in the study finally considering 20% drop out rate.

Inclusion criteria

- (1) In accordance with the clinical diagnosis of Parkinson's disease related standards [21];
- (2) Brain CT and other related imaging confirmed that there was no brain organic disease;
- (3) Standing for at least 30 minutes with or without auxiliary equipment and walking independently for 3 meters or more;
- (4) Age: 40 - 70 years old;
- (5) The clinical manifestations were frozen gait, and the patients were in Hoehn and Yahr stage 2 or 3;
- (6) Response to levodopa or other dopaminergic therapy;
- (7) Stable condition, clear consciousness, no aphasia, mental retardation, can understand the content of the scale and cooperate with the examination and treatment;
- (8) Patients have signed informed consent forms

Exclusion criteria

- (1) Secondary Parkinson's disease;
- (2) Those with deafness, aphasia or severe cognitive impairment who are difficult to communicate normally;
- (3) Patients with vascular dementia and frontotemporal dementia;
- (4) Intolerant of treatment;
- (5) Those who are unable to cooperate with the study program for rehabilitation;

- (6) Those who participate in other clinical trials within 3 months or receive other related treatment midway through the study that may affect the efficacy judgment of this study;
- (7) Have a history of neurological deficits other than Parkinson's disease

Elimination criteria

- (1) Patients who have been mistakenly admitted or misdiagnosed;
- (2) After the case is included, no intervention is given.

Recruitment

Recruitment of patients began on 1 June 2020 and will be completed on December 31, 2021, or after the required number is obtained, whichever is earlier. We will prepare the informed consent form, necessary audio, pictures and other relevant materials in advance to help the subjects clearly understand the purpose of the trial before recruitment. We will also explain to the subjects the benefits and potential risks of participating in this study and the relevant safety measures taken during the trial. In addition, we will recruit subjects by posting posters offline or using the Internet online.

Randomization

After signing the informed consent, participants will be randomly divided into three groups: music exercise therapy group, exercise therapy group and control group. Randomization will be accomplished by a trained researcher using randomization software to generate a sequence of random numbers. In the process of randomization, we will keep the allocation hidden. All patients will be randomly divided into groups according to the ratio of 1:1:1. The slips of paper that revealing the treatment allocation slip will be placed in a sequentially numbered sealed opaque envelope. After obtaining informed consent, the envelopes were opened in turn. Patients, evaluators, and data analysts will be not aware of the randomization.

Intervention

The interventions in the three groups are as follows:

Music exercise therapy group

In addition to routine rehabilitation treatment, music exercise therapy (patients perform scheduled exercise therapy training according to the rhythm of music) will be given 5 times a week for 4 weeks, with 1 hour each time.

Music selection: music therapists screen music tracks and rhythms according to the actual situation and music preferences of patients with Parkinson's disease, and then create a personalized music playlist for each subject (because the lyrics in the music will distract the attention of patients with Parkinson's

disease, so when selecting music, music with lyrics should be avoided). Each playlist will be loaded into a personal music player, and subjects can choose earplugs or headphones for maximum comfort. The mode setting of the music player will be "sequential play", not "random play". Music will be played by a designated music therapist. Subjects will be also told that they can request changes to their playlists at any stage of the intervention.

Exercise therapy: while listening to music with earphones, the patients conduct flat start walking training→turn around training→stop training at the end→narrow space walking training and stair step training according to the music beat. When the music playlist completes a cycle, the patients complete a cycle of exercise simultaneously.

Points for attention→the precondition of exercise therapy is to ensure the safety of patients, so there are requirements for the venue, patients' clothing, accompanying personnel, etc. The site shall be spacious, bright and free of obstacles, and the ground shall be flat, antiskid and dry. Clothes and shoes should make patients feel soft and comfortable during training, which is convenient for cooling and avoiding unnecessary body injury. In addition, patients should be accompanied and guarded by their families during training. The appropriate warm-up, including relatively slow and gentle exercise, should be conducted before the training to increase the activity of all parts of the body, posture coordination and breathing to prevent muscle strain.

Exercise therapy group

In addition to routine rehabilitation treatment, the patients will be given the exercise therapy without music. In the condition of wearing earphones without music, the patients will conduct flat start walking training→turn around training→stop training at the end→narrow space walking training and stair step training for 5 times a week for 4 weeks, with 1 hour each time.

Control group

Routine rehabilitation treatment mainly includes: (1) routine drug treatment; (2) joint mobilization technology; (3) posture correction training; (4) balance training; (5) limb passive and active activity training; (6) walking training; (7) physical factor treatment; (8) operation ability training; (9) daily life ability training for 5 times a week for 4 weeks, with 1 hour each time.

Outcome measures

Therapeutic evaluation will be carried out by the same team member who will be blinded to treatment allocation. The primary evaluation index of this study is the change of gait in patients with Parkinson's disease. The secondary evaluation indexes include the evaluation of limb function, activity of daily life and fall risk. Three dimensional gait analysis system will be used to evaluate the gait information and surface electromyography of muscles related to lower limbs at baseline, four weeks after intervention and 1, 2 and 3-months follow-up.

The Unified Parkinson's Disease Rating Scale (UPDRS) will be used to assess the mental cognition, motor function and daily living ability at baseline, four weeks after intervention and 1, 2 and 3-month follow-up[22]. Fall efficacy scale (FES) will be used to assess the risk of falls at baseline, four weeks after intervention, and at 1, 2, and 3-month follow-up. All results of the measurements will be recorded in the data center[23].

Harms

In our study, any adverse medical events of the participants will be collected after the subjects sign the informed consent and participate in the study. The event will be not considered to be related to music exercise therapy if the adverse events occur after the participant signed the informed consent, but before the intervention. All adverse events occurring after entry into the study and before discharge will be recorded and reported to the local Institutional Review Board.

Data management

Data collection

All information shall be recorded in the case report form (CRF) truthfully and accurately.

The evaluation of three-dimensional gait analysis and UPDRS will be conducted by a specially trained evaluator who is not clear about the trial group. The CRF will be recorded by the researchers. Specially-assigned person will be arranged to manage the relevant data during the trial. All data will be identified using participants' numbers, which will not directly display participants' personal information, so as to keep their personal information strictly confidential

Data will not be shared unless explicitly approved by the researchers. The CRF and trial summary shall be submitted in time at the end of the trial to facilitate the completeness and accuracy of CRF examination.

Case report form

As an important part of original materials, CRF must meet the following criteria:

- (1) The handwriting shall be neat and complete with pen or black signing pen;
- (2) If the participants have been involved in the intervention and evaluation for more than 2 weeks, their data will be included in the statistical analysis even if the participants fall off later.
- (3) If it is necessary to modify the errors occurred in the record, it shall be marked under the original record with horizontal line, and then signed after the modification and marked with the date of correction. Note that the original record should be recognizable after modification.

Database management and quality control

The research team will take effective measures to ensure the quality of research. The method of double entry will be adopted in order to ensure the quality of data. Then the statistician will compare the two databases through the program. If the input results are not consistent, the statistician will check to find out the error. After final confirmation, the database will be saved and kept by a special person. Any future changes to the database must be agreed in writing by the clinical study director, statistician, and data manager.

Data analysis

Statistical analysis

Health statisticians will use SPSS or SAS for statistical analysis of study data. Pearson's χ^2 test or Fisher's exact test will be used for categorical variable analysis, and Student's t-test or an appropriate non-parametric method will be used for continuous variables. Set the statistical significance level to be 5%. All will be tested by double-sided statistics. The measured data will be expressed as mean $\pm$ standard deviation. It will be necessary to test the normality and homogeneity of variance before analysis. If the normal distribution is satisfied, t-test will be used, LSD method or SNK method will be used for multiple comparison. If not, rank sum test will be used.

Discussion

FOG, the most common gait abnormality in Parkinson's disease, occurs in the middle and late stages of the disease, which can lead to falls and injuries. At present, the effect of drug treatment is not good, but rehabilitation treatment has a certain effect. Early recognition and intervention of FOG can reduce disability rate and improve prognosis. The small sample study in the early stage of our research team initially found that music exercise therapy can improve the FOG of Parkinson's patients and improve their quality of life, but its long-term effect needs further clinical research. Therefore, we propose a prospective randomized clinical trial to further evaluate the clinical efficacy of music exercise therapy in the treatment of FOG in Parkinson's patients.

In order to eliminate the interference of headphone wearing behavior on the test results, this study will set up a group of exercise therapy without music. However, bias exists in all clinical trials. In our trial, the blindness of music therapists and patients to the intervention will be the most challenging aspect for designing a randomized controlled trial involving music intervention. In addition, blindness to evaluators should also be considered to reduce potential bias. Therefore, in addition to the scale evaluation used in previous studies, we will also use three-dimensional gait analysis as part of the result evaluation. In recent years, three-dimensional gait analysis system has been widely used in gait evaluation, especially in the evaluation of neurological diseases. The application of time and space, ankle kinematic parameters and electrophysiological measurements in the process of walking will provide quantitative information about gait, and it is expected to reduce the interference of subjective factors in the scale evaluation. We believe that the experimental results will be helpful for the improvement of FOG and motor function in patients with Parkinson's disease.

Trial status

The total registration period will last for 2 years, with a follow-up of 3 months. Patient recruitment began on January 1, 2020, and the trial is currently underway. Protocol version number and date: V1.0 May 16, 2020. Recruitment of patients is expected to be completed in December 2021.

Declarations

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Authors' contributions

ZZQ and ZY, the academic guidance of this study, designs this study. LKP and ZZL are the main implementer of the study and is responsible for drafting the manuscript. ZRZ assists in participation in the design of this study and drafting of manuscripts.

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Availability of data and materials

Data sharing is not applicable to this article as no datasets were generated or analysed during the current study.

Ethics approval and consent to participate

The ethical committee of Shanghai second rehabilitation hospital has approved the ethical approval of this study (reference number 2018-01). Informed consent will be provided for all included cases prior to participation. Any relevant changes to the protocol will be communicated to the study participants, and any adverse events will be reported to the ethical committee of Shanghai second rehabilitation hospital.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

References

1. Cabreira V, Massano J. [Parkinson's Disease: Clinical Review and Update]. *Acta medica portuguesa*. 2019 Oct 1;32(10):661-70. PubMed PMID: 31625879. Epub 2019/10/19. Doença de Parkinson: Revisao Clinica e Atualizacao. por.
2. Armstrong MJ, Okun MS. Diagnosis and Treatment of Parkinson Disease: A Review. *Jama*. 2020 Feb 11;323(6):548-60. PubMed PMID: 32044947. Epub 2020/02/12. eng.
3. Goldman JG, Guerra CM. Treatment of Nonmotor Symptoms Associated with Parkinson Disease. *Neurologic clinics*. 2020 May;38(2):269-92. PubMed PMID: 32279710. Epub 2020/04/14. eng.
4. Draoui A, El Hiba O, Aimrane A, El Khiat A, Gamrani H. Parkinson's disease: From bench to bedside. *Revue neurologique*. 2020 Jan 9. PubMed PMID: 31928746. Epub 2020/01/14. eng.
5. Nutt JG, Bloem BR, Giladi N, Hallett M, Horak FB, Nieuwboer A. Freezing of gait: moving forward on a mysterious clinical phenomenon. *The Lancet Neurology*. 2011 Aug;10(8):734-44. PubMed PMID: 21777828. Epub 2011/07/23. eng.
6. Lenka A, Naduthota RM, Jha M, Panda R, Prajapati A, Jhunjhunwala K, et al. Freezing of gait in Parkinson's disease is associated with altered functional brain connectivity. *Parkinsonism & related disorders*. 2016 Mar;24:100-6. PubMed PMID: 26776567. Epub 2016/01/19. eng.
7. Kader M, Ullen S, Iwarsson S, Odin P, Nilsson MH. Factors Contributing to Perceived Walking Difficulties in People with Parkinson's Disease. *Journal of Parkinson's disease*. 2017;7(2):397-407. PubMed PMID: 28505982. Epub 2017/05/17. eng.
8. Amadori K, Steiner T. [Parkinson's syndromes in geriatric patients : Epidemiological, clinical and therapeutic characteristics]. *Der Nervenarzt*. 2019 Dec;90(12):1279-91. PubMed PMID: 31776592. Epub 2019/11/30. Parkinson-Syndrome bei geriatrischen Patienten : Epidemiologische, klinische und therapeutische Besonderheiten. ger.
9. de Baat C, van Stiphout MAE, van Dijk KD, Berendse HW, Verhoeff MC, Lobbezoo F. [Possible treatment options for Parkinson's disease]. *Nederlands tijdschrift voor tandheelkunde*. 2019 Mar;126(3):127-32. PubMed PMID: 30838979. Epub 2019/03/07. Behandelingsmogelijkheden voor de ziekte van Parkinson. dut.
10. Kim SD, Allen NE, Canning CG, Fung VSC. Parkinson disease. *Handbook of clinical neurology*. 2018;159:173-93. PubMed PMID: 30482313. Epub 2018/11/30. eng.
11. Boso M, Politi P, Barale F, Enzo E. Neurophysiology and neurobiology of the musical experience. *Functional neurology*. 2006 Oct-Dec;21(4):187-91. PubMed PMID: 17367577. Epub 2007/03/21. eng.
12. Kim SJ, Yoo GE, Shin YK, Cho SR. Gait training for adults with cerebral palsy following harmonic modification in rhythmic auditory stimulation. *Annals of the New York Academy of Sciences*. 2020 Apr 30. PubMed PMID: 32356332. Epub 2020/05/02. eng.
13. Nikmaram N, Scholz DS, Grossbach M, Schmidt SB, Spogis J, Belardinelli P, et al. Musical Sonification of Arm Movements in Stroke Rehabilitation Yields Limited Benefits. *Frontiers in*

- neuroscience. 2019;13:1378. PubMed PMID: 31920526. Pubmed Central PMCID: PMC6933006. Epub 2020/01/11. eng.
14. Gómez Gallego M, Gómez García J. Music therapy and Alzheimer's disease: Cognitive, psychological, and behavioural effects. *Neurologia (Barcelona, Spain)*. 2017 Jun;32(5):300-8. PubMed PMID: 26896913. Epub 2016/02/22. Musicoterapia en la enfermedad de Alzheimer: efectos cognitivos, psicológicos y conductuales. eng spa.
 15. Jauset-Berrocal JA, Soria-Urios G. [Cognitive neurorehabilitation: the foundations and applications of neurologic music therapy]. *Revista de neurologia*. 2018 Oct 16;67(8):303-10. PubMed PMID: 30289154. Epub 2018/10/06. Neurorrehabilitacion cognitiva: fundamentos y aplicaciones de la musicoterapia neurologica. spa.
 16. Grau-Sanchez J, Munte TF, Altenmuller E, Duarte E, Rodriguez-Fornells A. Potential benefits of music playing in stroke upper limb motor rehabilitation. *Neuroscience and biobehavioral reviews*. 2020 May;112:585-99. PubMed PMID: 32092314. Epub 2020/02/25. eng.
 17. Wittwer JE, Winbolt M, Morris ME. Home-Based Gait Training Using Rhythmic Auditory Cues in Alzheimer's Disease: Feasibility and Outcomes. *Frontiers in medicine*. 2019;6:335. PubMed PMID: 32083083. Pubmed Central PMCID: PMC7005067. Epub 2020/02/23. eng.
 18. de Dreu MJ, van der Wilk AS, Poppe E, Kwakkel G, van Wegen EE. Rehabilitation, exercise therapy and music in patients with Parkinson's disease: a meta-analysis of the effects of music-based movement therapy on walking ability, balance and quality of life. *Parkinsonism & related disorders*. 2012 Jan;18 Suppl 1:S114-9. PubMed PMID: 22166406. Epub 2011/12/23. eng.
 19. Pacchetti C, Mancini F, Aglieri R, Fundaro C, Martignoni E, Nappi G. Active music therapy in Parkinson's disease: an integrative method for motor and emotional rehabilitation. *Psychosomatic medicine*. 2000 May-Jun;62(3):386-93. PubMed PMID: 10845352. Epub 2000/06/14. eng.
 20. Thaut MH, McIntosh GC, Rice RR, Miller RA, Rathbun J, Brault JM. Rhythmic auditory stimulation in gait training for Parkinson's disease patients. *Movement disorders : official journal of the Movement Disorder Society*. 1996 Mar;11(2):193-200. PubMed PMID: 8684391. Epub 1996/03/01. eng.
 21. Postuma RB, Berg D, Stern M, Poewe W, Olanow CW, Oertel W, et al. MDS clinical diagnostic criteria for Parkinson's disease. *Movement disorders : official journal of the Movement Disorder Society*. 2015 Oct;30(12):1591-601. PubMed PMID: 26474316. Epub 2015/10/17. eng.
 22. Goetz CG, Tilley BC, Shaftman SR, Stebbins GT, Fahn S, Martinez-Martin P, et al. Movement Disorder Society-sponsored revision of the Unified Parkinson's Disease Rating Scale (MDS-UPDRS): scale presentation and clinimetric testing results. *Movement disorders : official journal of the Movement Disorder Society*. 2008 Nov 15;23(15):2129-70. PubMed PMID: 19025984. Epub 2008/11/26. eng.
 23. Dewan N, MacDermid JC. Fall Efficacy Scale-International (FES-I). *Journal of physiotherapy*. 2014 Mar;60(1):60. PubMed PMID: 24856947. Epub 2014/05/27. eng.

Figures

Figure 1

Flow chart of the study

	STUDY PERIOD							
	Enrolment	Allocation		Post-allocation				Close-out
TIMEPOINT**	-t 1	Music	Exercise therapy	1m	2m	4m	etc.	3 months after treatment
ENROLMENT								
Eligibility screen	X							
Informed consent	X							
Allocation		X	X					
INTERVENTIONS								
Music exercise therapy group		X	X					
Exercise therapy group			X					
Control group								
ASSESSMENTS								
Three dimensional gait analysis				X	X	X	etc	X
fall risk				X	X	X	etc	X
Limb function scale				X	X	X	etc	X
Activity of daily living				X	X	X	etc	X

Figure 2

Example template of recommended content

Supplementary Files

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- [EQUATORNetworkReportingChecklist.doc](#)