Clinical Rehabilitation 2010; **24:** 523–532

Do metronomes improve the quality of life in people with Parkinson's disease? A pragmatic, single-blind, randomized cross-over trial

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Received 6th August 2009; returned for revisions 24th November 2009; revised manuscript accepted 28th November 2009.

Objective: To evaluate the effect of acoustic cueing using metronomes on the quality of life of people with moderate to severe Parkinson's disease.
Study design: Pragmatic, single-blind, randomized cross-over trial.
Participants: Forty-two people aged 50–85 years, in Hoehn and Yahr stage II–IV and on stable medication. Eight were lost to follow-up.
Intervention: Participants were randomized using concealed allocation to either an early group ($n = 21$) to receive an electronic metronome without therapy but limited support (5–10 minutes instruction and on-demand telephone assistance) for four weeks, or a late group ($n = 21$) to receive the same intervention at 10 weeks. In both groups the beat frequency was initially set to be comfortable for walking.
Outcomes measures: Primary and secondary outcomes were measured at baseline, 4, 10 and 14 weeks using the Parkinson's Disease Questionnaire 39 (PDQ-39), the Short Form 36 version 2 (SF-36 version 2) and a falls diary.
Results: There were positive effects in six domains of the SF-36 version 2 and eight domains of the PDQ-39, although only one mean difference was clinically important: the role limitation (emotional) domain of SF-36 version 2 (a mean difference of 3.77, 95% confidence interval (CI), –2.68 to 10.22), a secondary outcome. None of these changes were statistically significant. There were no statistically significant differences in falls rates over the study period. Ten participants (24%) wanted to continue with their metronomes at the end of the study.
Conclusion: To demonstrate metronomes are beneficial on the role limitation domain of the SF-36 version 2 in people with moderate to severe Parkinson's disease a sample size of 600 would be required.

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10.1177/0269215509360646

Introduction

Parkinson's disease is a degenerative, neurological condition which affects around one in 55 people over the age of 65 years.[1] A common feature of the condition is difficulty walking, rising from a chair or getting in and out of bed.[1,2] As the disease progresses, walking rhythm deteriorates, leading to 'freezing' and 'festination', increasing the risk of falls.[3,4] This lack of mobility can be debilitating,[2] impacting on patient's physical and social functioning,[5,6] their independence[3] and, consequently, on their quality of life.[7]

Although drugs therapies can improve mobility, their effectiveness diminishes with prolonged use and disease progression.[2,7] In addition, they often have significant side-effects.[8] Non-pharmaceutical adjunct therapies to improve gait and balance deficits include physiotherapy and sensory cueing. Physiotherapy has been used for many years, although the evidence of its efficacy when used alone is not strong.[9] In contrast, there is good evidence that sensory cueing in persons with moderate to severe Parkinson's disease improves walking speed.[9] A recent systematic review[10] identified two good-quality randomized controlled trials (RCTs) that used a portable metronome/personal music player to deliver a regular beat significantly improved walking speed, stride length, and cadence.[2,11] One study[11] also showed improvements in mobility and activities of daily living (ADL) measured using the Unified Parkinson's Disease Rating Scale (UPDRS). In these studies, auditory cueing was usually provided as part of a physiotherapy programme: one home-based for three weeks[2] and the other clinic-based for six weeks.[10] More recently, the RESCUE trial showed smaller but significant improvements in gait, 'freezing' and confidence to carry out functional activities, but not in ADL or quality of life.[7] However, this study offered auditory, visual or somatosensory cueing with additional therapy, and did not analyse cueing strategies separately.

Although there is good evidence to suggest that acoustic cueing accompanied by physiotherapy or training improves walking in a clinical setting, uncertainty remains as to whether this benefit improves patient's mobility, ADL and quality of life at home. Furthermore, no trials have evaluated the effect of home-based acoustic cueing therapy alone on quality of life.

We sought to determine whether acoustic cueing, provided by an affordable, portable electronic metronome, would not only improve mobility in people with moderate to severe Parkinson's disease, but also lead to an increase in ADL, physical and social functioning and social support, and, as a consequence, influence positively other quality-of-life domains.

Methods

We recruited 42 patients using the Northern Devon Healthcare NHS Trust's Parkinson's disease database, which contains details on the vast majority of people diagnosed with Parkinson's disease in the area since 1999. Potential recruits were selected by the neurologist and the Parkinson's disease nurse specialists, contacted by telephone and sent formal letters inviting them to participate. All those interested were assessed against the following eligibility criteria: aged 18–85 years; diagnosed with moderate to severe idiopathic Parkinson's disease (defined by the UK Brain Bank Criteria) or other 'parkinsonian' syndrome; moderate to severe Parkinson's disease (e.g. Hoehn and Yahr staging II–IV)[12]; no change in medication within three months; and no previous experience of using a metronome.

Patients were excluded if they had: difficulty understanding verbal or written English; cognitive impairment or dementia (assessed by a Mini Mental State Examination score <24)[13]; deafness such that they were unable to hear the metronome reliably; and comorbidities that interfered significantly with mobility, including cardiopulmonary disease, orthopaedic disease and visual impairment.

As nine respondents gave short notice of not being able to attend the first clinic, potentially undermining the power of the study, we organized a second entry phase 10 weeks later. These participants were subject to the same criteria and procedures.

We conducted a pragmatic, single-blind, randomized trial with cross-over design and 'wash-out' period. This design had the advantage of

providing all participants access to a potentially beneficial intervention and increasing statistical power.

On obtaining informed consent, participants were randomly allocated to groups by using sealed envelopes. The early group received the metronome for four weeks (sufficient time to familiarize themselves with the device, try it in multiple settings and to have an effect[2]) in addition to their usual medication, while the late group continued with their usual medication over the same period. This was followed by a six-week period without a metronome. At 10 weeks, the late group then received the metronome for four weeks, while the early group continued on their regular medication.

Investigators gave a 5–10 minute, one-to-one training session on how to use the metronome (Qwik Time QT7 Quartz), which included adjusting the time signature, frequency, speaker volume and fitting the ear-piece. As the objective of the study was to improve mobility and quality of life (not walking speed per se), we took a pragmatic approach where participants were told to use their metronomes for daily activities around their homes and for walking outside as they felt helpful, and to adjust the frequency of the beep (set at 2/4 time) to allow them to step in time with the beat at their preferred walking cadence. Additional on-demand telephone support was available throughout the study from the Parkinson's disease nurses.

Outcome measures (test 1) were assessed immediately before randomization to avoid observer bias, at 4 (test 2), 10 (test 3) and 14 weeks (test 4), using the disease-specific Parkinson's Disease Questionnaire 39 (PDQ-39) and generic quality-of-life measure, the Short Form-36 version 2 (SF-36 version 2), both of which are well-validated and reliable.[14–17] These are scored on a scale between 0 and 100, with higher scores indicating better health for the SF-36 version 2 and worse health for the PDQ-39. Participants completed their questionnaires when attending the clinic to receive or return their metronomes or by post during control or wash-out periods. The Parkinson's disease nurses telephoned participants who failed to return questionnaires promptly.

Participants were also given a diary and requested to enter daily any falls which resulted in their ending up on the floor, in order to capture any adverse effect of cueing. At the end of the study, participants were asked to complete a change in medication form, and asked if they would be interested in continuing with metronome.

All data were double-entered into two separate databases by administrators unfamiliar with the study or participants to avoid observer bias. The databases were then compared to identify and resolve discrepancies, minimizing transcription errors.

Primary outcomes were mean change in the SF-36 version 2 domain scores for physical functioning, role limitation (physical) and social functioning, and mean change in the PDQ-39 domain scores for mobility, ADL, social support and total PDQ-39 score.

Secondary outcomes were: mean change in the SF-36 version 2 domains for general health, vitality, role limitation (emotional), mental health and bodily pain; mean change in the PDQ-39 domains for emotional well-being, stigma, cognitions, communications and bodily discomfort; percentage change in gait speed (cm/s), measured in the clinic by timing participants over a marked 10-metre walk using a stopwatch, immediately before and after receiving the metronome and; mean number of fall days per week (the total number of days per group any one person had one or more falls divided by four for the intervention and control periods and six for the washout period).

We based our power analysis on the PDQ-39 mobility scores from the RESCUE study.[7] For a paired *t*-test, we estimated between 31 and 42 participants were required to show a significant clinical change at 80% power and 5% statistical significance. To allow for 15% loss to follow-up we aimed to recruit 48 participants.

Data variables were explored using the Shapiro–Wilks Normality Test. Where normal, the mean and standard deviations were calculated for demographic characteristics, baseline values and outcomes, and inter- and intra-group differences were assessed using the *t*-test or paired *t*-test respectively. For outcomes with asymmetric distributions, differences between groups were assessed using the χ^2, Fisher's exact or Mann–Whitney *U*-test, as indicated.

To evaluate the magnitude of effect of the metronomes we compared the mean difference in domain scores at test 2 and 4, using test 1 as the baseline in both groups. We calculated the effect size for the PDQ-39 only by dividing the effect magnitude by the standard deviation of both groups at test 1.

Thirteen participants had missing values: seven in the early group and six in the late group. For the SF-36 version 2, scores were not calculated for domains where there were missing data. For the PDQ-39, at each time point we imputed missing values using a technique called Expectation Maximization,[18] unless all values for that time point were absent.

Summary data and statistical tests were performed in SPSS version 15, except for the cross-over analysis which was undertaken in StatsDirect version 2.6.6. Bonferroni corrections were not applied, and statistical tests were considered significant at $P \leq 0.05$.

The study was approved by the Devon and Torbay Local Research Ethics Committee.

Results

All outcome variables were normally distributed, except for bodily pain, bodily discomfort and fall days per week.

Figure 1 shows the trial flow diagram. Fifty-five people were identified as potentially eligible to participate, 45 of whom attended the clinic. Three of these were excluded for having a Mini Mental State Examination score <24 ($n=2$) or age >85 years ($n=1$). One person had a comorbidity that was considered insufficient to interfere with their mobility. Forty-two consenting participants were randomized, all could ambulate independently. Eight subsequently discontinued treatment (19%, 8/42), one before completing test 1 and six after test 1 (but before the timed walk), and one at test 3. Reasons for withdrawal included: death ($n=1$); arthritic knees ($n=1$); pemphigus blisters ($n=1$); contact with other Parkinson's disease sufferers ($n=1$); and fear of the metronome ($n=1$). All but five participants remained on stable medication. These and those lost to follow-up did not occur disproportionately in early or late groups ($P=0.4099$ and $P>0.9999$ respectively).

Table 1 shows that there were no statistically significant differences in baseline characteristics between participants in the early and late groups.

Table 2 shows that baseline SF-36 version 2 and PDQ-39 domain scores between the early and late groups were not significantly different, except for the PDQ-39 emotional domain ($P=0.03$). As variability in domain scores across groups did not appear to follow any particular pattern, we assumed this result was due to chance, and that the characteristics of the two groups were statistically identical.

There were no statistically significant differences in mean outcomes for the SF-36 version 2 or PDQ-39 between phase 1 and 2 (not shown). Comparison of the mean differences for outcomes at test 1 and test 3 in the early group, in order to establish if there were any effects remaining after the 'washout' period, showed seven domains of the SF-36 version 2 increased in value but only two were statistically significant (physical functioning ($P=0.029$) and general health ($P=0.004$)). Five domains of the PDQ-39 fell over the same period but none were statistically significant (not shown). Again, as there was no consistent pattern to the changes in mean difference in both outcome measures we assumed that those seen on the SF-36 version 2 were due to chance, and that after six weeks of ceasing to use the metronome there were no remaining effects.

Table 3 shows the mean difference for early and late groups and the combined effect magnitude of using metronomes. None of the tests for treatment period interaction or period effect were statistically significant, implying that any change in mean difference of domain scores could be attributed to the metronome. However, at the time of measuring the last outcome (test 4) 11 participants had missing data on SF-36 version 2, weakening the power of the study.

In relation to primary outcomes on the SF-36 version 2 the mean difference scores increased in two out of three domains (physical functioning and social functioning), and on the PDQ-39 the mean difference decreased on all four domains (mobility, ADL, social support and total PDQ-39 score), although none of these

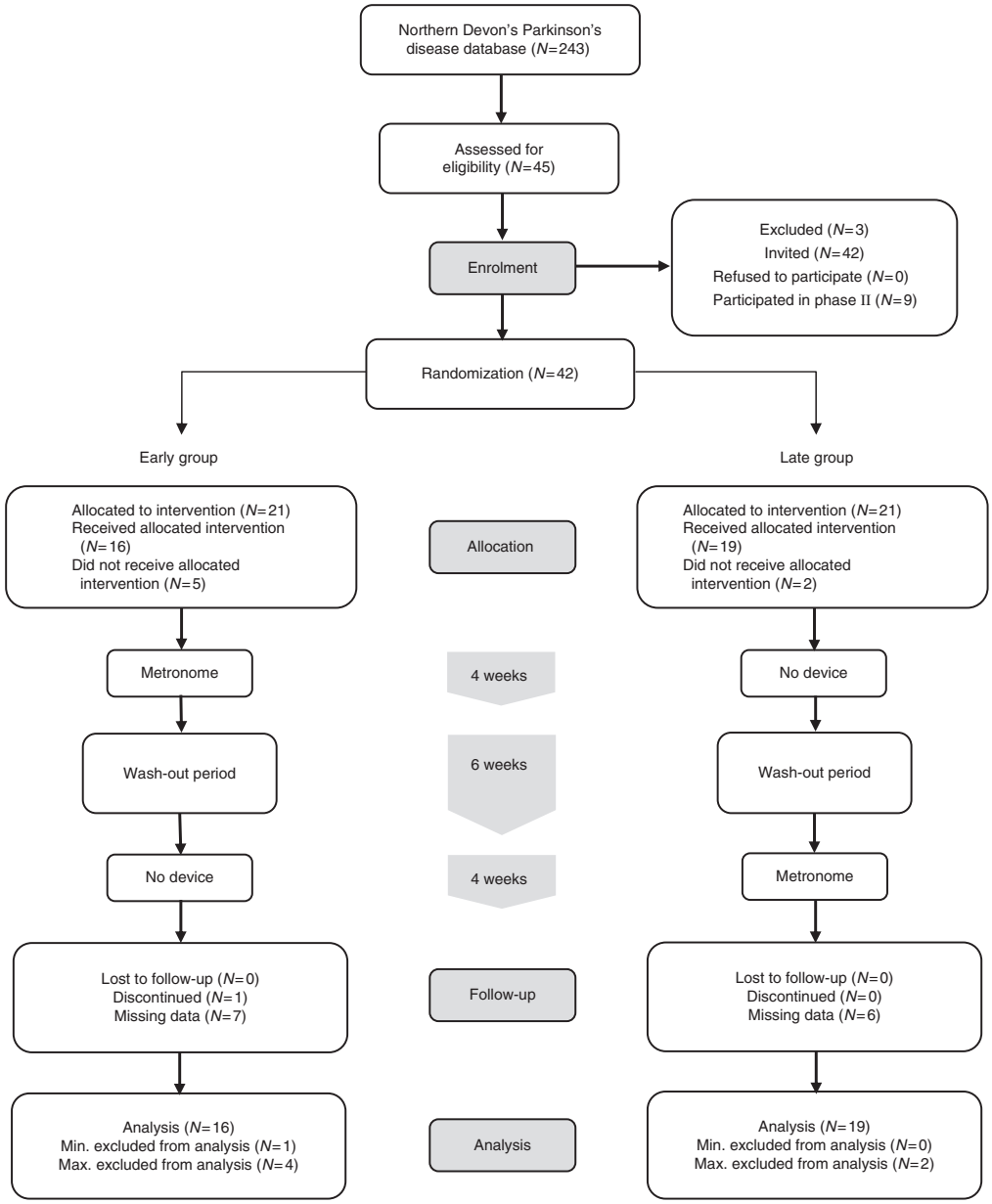

Figure 1 Trial flow diagram.

improvements in quality of life were clinically important (i.e. 3–5 points)[19,20] or statistically significant.

In relation to secondary outcomes, mean differences improved slightly on all domains, except for the mental health (SF-36 version 2) and emotional (PDQ-39) domains. None of the changes were statistically significantly. One improvement in mean difference reached a subjectively meaningful level for patients – role limitation (emotional) domain

Table 1 Comparison between early and late allocation groups

Characteristics	Early ($n=21$)	Late ($n=20$)	*P*-value
Male/female (no. of patients)	13/8	15/5	0.572[†]
Mean age (years) (SD)	71.5 (11.3), ($n=21$)	70.4 (8.7), ($n=21$)	0.714[‡]
H&Y score (II/III/IV) (no. of patients)	14/2/0	13/6/0	0.244[‡‡]
MMSE score (SD)	28.4 (1.6), ($n=16$)	28.3 (1.4), ($n=19$)	0.515[††]
Co-morbidities (no. of patients)	1/20	0/20	>0.9999[‡‡]
Timed walk without metronome (s) (SD)	11.6 (3.9), ($n=16$)	12.1 (6.1), ($n=19$)	0.921[‡]
Timed walk without metronome (s) (range)	6.7–22.1	7.9–34.1	–
Gait speed without metronome (m/s) (SD)	0.9 (5.3), ($n=16$)	0.9 (4.3), ($n=19$)	0.939[‡]
Timed walked with metronome (s) (SD)	11.2 (3.5), ($n=16$)	12.0 (4.9), ($n=19$)	0.856[‡]
Change in medication during study (no. of patients)	3/18	2/18	>0.9999[‡‡]

H&Y, Hoehn and Yahr score; MMSE, Mini Mental State Examination Score.
[†]χ^2 test; [‡]*t*-test; [‡‡]Fisher's exact test; [††]Mann–Whitney *U*-test.

Table 2 Baseline (test 1) quality-of-life outcomes in early and late groups

Outcome measures	Domain	Early group	Late group	*P*-value
		Mean (SD)	Mean (SD)	
SF-36 version 2				
Primary	Physical functioning	50.0 (22.0), ($n=21$)	49.3 (22.4), ($n=21$)	0.917
	Role limitation – physical	48.8 (21.6), ($n=21$)	55.9 (24.4), ($n=20$)	0.327
	Social functioning	65.4 (28.9), ($n=21$)	71.4 (23.4), ($n=21$)	0.390
Secondary	General health	52.2 (17.0), ($n=20$)	60.3 (15.8), ($n=21$)	0.122
	Vitality	47.1 (14.7), ($n=19$)	51.0 (13.2), ($n=21$)	0.389
	Role limitation – emotional	67.1 (23.3), ($n=20$)	64.7 (22.2), ($n=21$)	0.737
	Mental health	64.8 (11.0), ($n=20$)	66.1 (12.8), ($n=21$)	0.730
	Bodily pain	53.3 (21.2), ($n=20$)	64.2 (22.7), ($n=21$)	0.149[††]
PDQ-39				
Primary	Mobility	38.6 (22.7), ($n=20$)	38.4 (20.0), ($n=20$)	0.970
	Activity of daily living	30.8 (22.9), ($n=20$)	33.8 (20.3), ($n=20$)	0.672
	Social support	7.5 (12.0), ($n=20$)	11.3 (16.1), ($n=20$)	0.408
	Total PDQ-39 score	26.1 (10.8), ($n=20$)	26.5 (10.7), ($n=20$)	0.907
Secondary	Emotional	27.1 (15.7), ($n=20$)	16.9 (12.7), ($n=20$)	**0.030**[‡]
	Stigma	16.3 (15.6), ($n=20$)	21.9 (20.9), ($n=20$)	0.342
	Cognitions	27.2 (15.1), ($n=20$)	30.6 (19.4), ($n=20$)	0.536
	Communication	25.8 (19.8), ($n=20$)	19.2 (15.6), ($n=20$)	0.244
	Bodily discomfort	35.8 (20.3), ($n=20$)	40.4 (22.3), ($n=20$)	0.529[††]
Timed walk				
	Without–with metronome (s)	0.37 (1.9), ($n=16$)	0.08 (2.6), ($n=19$)	0.551[††]
	Change in gait speed (cm/s)	3.3 (21.0), ($n=16$)	–1.7 (17.4), ($n=19$)	0.441[††]

Statistically significant results are shown in bold.
[‡]$P<0.05$; [††]Mann–Whitney *U*-test.

(SF-36 version 2) – although on a similar domain on the PDQ-39 (emotional) it increased by 0.83 (95% CI –3.58 to 5.24) representing a reduced quality of life. There was a small, non-significant increase in gait speed (2 cm/s, $P=0.585$) using the metronome and there was no statistically significant difference in the median number of fall days per week between groups in each of the three time periods.

At the end of the study, 10 participants (seven from the late group) wanted to continue using the metronomes. Although the difference in proportions between groups was not statistically significant ($P=0.253$), it was still possible that the higher number in the late group was a result of social desirability bias, being offered a metronome shortly after the trial finished.

Table 3 The effect of metronomes on patients' quality of life ($N = 40$)

Outcome measures	Domain	Early group	Late group	Effect magnitude*		Effect size**	Test for treatment effect	Test for period effect	Test for treatment–period interaction
		Mean difference	Mean difference	Mean difference	(95% CI)		*P*-value	*P*-value	*P*-value
SF-36 version 2									
Primary	Physical functioning	0.71	–0.95	0.83	(–1.55–3.22)	–	0.485	0.920	0.658
	Role limitation – physical	0.60	2.38	–0.89	(–4.44–2.66)	–	0.614	0.402	>0.9999
	Social functioning	1.79	0.00	0.89	(–5.76–7.55)	–	0.788	0.788	0.250
Secondary	General health	–0.48	–2.29	0.90	(–3.27–5.08)	–	0.664	0.508	0.958
	Vitality	1.67	–1.19	1.43	(–1.45–4.31)	–	0.322	0.868	>0.9999
	Role limitation – emotional	3.97	–3.57	**3.77**	(–2.68–10.22)	–	0.245	0.951	0.428
	Mental health	1.33	3.81	–1.24	(–4.52–2.05)	–	0.451	0.122	>0.9999
	Bodily pain	0.48	–0.57	0.52	(–5.38–6.43)	–	0.859	0.987	>0.9999
PDQ-39									
Primary	Mobility	–2.49	0.71	–1.60	(–5.61–2.42)	–0.08	0.426	0.656	0.645
	Activities of daily living	–2.92	0.63	–1.77	(–6.00–2.46)	–0.08	0.402	0.587	0.360
	Social support	–0.51	4.74	–2.63	(–7.18–1.93)	–0.19	0.250	0.353	0.272
	Total PDQ-39 score	–1.26	1.66	–1.46	(–4.59–1.67)	–0.14	0.350	0.897	0.251
Secondary	Emotional	1.46	–0.21	0.83	(–3.58–5.24)	0.06	0.704	0.776	0.492
	Stigma	0.63	3.13	–1.25	(–7.53–5.03)	–0.07	0.689	0.549	0.399
	Cognitions	–1.25	3.07	–2.16	(–6.22–1.90)	–0.13	0.289	0.653	0.147
	Communication	–2.50	0.83	–1.67	(–5.77–2.44)	–0.09	0.416	0.684	0.738
	Bodily discomfort	–2.50	0.42	–1.46	(–6.06–3.15)	–0.07	0.525	0.649	0.391

Clinically (but not statistically) important results are shown in bold.
*Positive scores for effect magnitude indicate an improvement in quality of life on the SF-36 version 2 domains and a decline in symptoms on the PDQ-39. Negative scores indicate the opposite for the SF-36 version 2 and PDQ-39.
**Effect size = effect magnitude/SD_{test1}.

The Parkinson's disease nurses reported telephone support was minimal, with four participants wanting to be reminded of the instructions. Attitudes were generally positive towards the device; one person used it for all his daily activities. Two people stopped using the metronome due to lack of benefit.

Discussion

Providing moderate to severe Parkinson's disease patients with a metronome for four weeks in a community-based clinic, with just 5–10 minutes' instruction, resulted in small improvement in quality of life in all but three domains of the SF-36 and PDQ-39. However, none of these improvements were statistically significant, and only the role emotional domain on the SF-36 version 2 attained clinical importance – a secondary outcome. The use of metronomes did not result in an increased rate of fall days per week, a potential harm. Despite our modest findings, a quarter of the participants wanted to continue using the metronome after the study finished.

This is the first pragmatic, home-based experimental study of acoustic cueing therapy which has evaluated the effect of metronomes, without additional physiotherapy or exercise training, on patient quality of life.

However, the study had a number of limitations. The cross-over design could have resulted in early group participants becoming disappointed when asked to give up their metronomes, possibly reducing their scores at test 2 (and test 3 and 4) and weakening the overall effect. The offer of a metronome to all participants on finishing the study should have minimized this bias. The power of the study is also more sensitive to loss to follow-up than non-crossover designs. In this study, six fewer participants were recruited than anticipated and eight were lost to follow-up. The analysis was therefore based on data from 35 people, undermining the study's power to detect a treatment effect. However, none of the loss to follow-up was related to metronome use, suggesting that cueing was acceptable and well-tolerated. Participants whose medication changed during the study were not excluded from the analysis, as this would have reduced the study's power further. This may have biased our results in favour of metronomes, if changes in medication occurred during the four-week intervention period. However, a provisional analysis which excluded these individuals resulted in less conservative effects than reported here (results not shown).

Given the number outcomes and multiple time points in our study, we would have expected some type 1 errors. However, we found very few statistically significant results. A possible reason for this was that our analysis included participants who only partially completed the study. Thus, the degrees of freedom by which the statistical significance was judged was greater than if these cases had been excluded, resulting in more conservative *P*-values. On the other hand, we did not apply Bonferroni corrections when interpreting our *P*-values. Nevertheless, given that the majority of outcomes were positive, though smaller than anticipated, the reduced power of our study may have accounted for the lack of statistically significant results. An alternative explanation for the lack of significant effect may be that participants did not use their metronomes. However, the Parkinson's disease nurses only reported two participants not using their metronomes for lack of benefit.

Despite a large number of observational studies, only three reasonable quality experimental[2,7,11] (and three pre-experimental)[3,21,22] studies have specifically evaluated auditory rhythmical cueing.[10] These suggest that walking can be positively influenced by acoustic cueing. However, until the RESCUE study, it was unclear whether the effects seen in the clinic could be generalized to improved ADL and reduced frequency of falls in the community, or how long the effects of cueing persist.[10] Although the RESCUE study showed small but significant improvements in posture and gait speed (5 cm/s, $P = 0.005$), and reduced freezing rates, the influence on ADL (1.71, $P = 0.07$) and PDQ-39 total score (–1.36, $P = 0.23$) were clinically small and not statistically significant.

Our findings echo those in the RESCUE study, although the improvement in gait speed at baseline was smaller (2 cm/s) and non-significant (as expected given this was not the aim of the intervention). This may have been due to the

Hawthorne effect, as the Parkinson's disease nurses noted many participants were more mobile than usual.

The study by Ellis *et al*. study showed greater, statistically significant effect sizes (ES) on ADL (ES = 0.45, $P = 0.014$) and total score (ES = 0.56, $P = 0.007$), albeit on the disease-specific UPDRS, plus mobility on the Sickness Impact Profile (ES = 0.55, $P = 0.015$). This may have been due to the different regimen (also twice as long) to that in the RESCUE study. However, the evidence of the impact of training/physiotherapy on improving gait is not strong.[9]

The study by Thaut *et al*. showed that training on its own resulted in a non-significant increase in gait speed, but combined with acoustic cueing the effect tripled and was statistically significant. This suggests that significant increases in gait speed (and possibly mobility and quality of life) may only be attained when cueing is accompanied by home-based physiotherapy or exercise training, and the synergistic effect is probably dependent on its intensity and length. How long such an effect persists without a metronome or accompanying training is not clear. In the RESCUE study, effects were still evident three weeks after the three-week training programme (and still using the metronome), but not at six weeks post metronome – as in this study.

The evidence suggests, therefore, that the pragmatic, minimalist approach taken in this study may not yield benefits unless accompanied by a more substantive training regimen. However, nearly a quarter of our participants wanted to continue using a metronome after the study finished, with one patient reporting he could not get by without it. This implied the small benefits of cueing detected may have been restricted to a subgroup of patients. We did not explore this in our analysis as the results would have been underpowered and prone to type 1 errors.

Our results suggest that the use of metronomes without therapy for four weeks in people with moderate to severe Parkinson's disease does not dramatically improve mobility and ADL, social and physical functioning. However, if used in conjunction with intensive training and support they may improve the quality of life in this client group. Since no studies have evaluated the cost-effectiveness of such an approach, it would be premature to recommend the widespread adoption of this therapy. However, given that metronomes are safe and cost little (£ 20), an individual trial-and-error approach to use may be worth while.

Given the short time frame of this (and other cueing) studies and the degenerative nature of Parkinson's disease, future research should focus on identifying subgroups of patients which stand to benefit the most from using a metronome and the level and length of support or training that is required to maximize any effect. This will facilitate an assessment of acoustic cueing's value for money.

Our data indicate that to demonstrate a clinically significant effect of metronomes on the role limitation (physical) domain of the SF-36 version 2 in our patient group (assuming a change in score of 5 points, 80% power and 5% significance) would require a sample size of 600.

Clinical message

- The use of metronomes without therapy for four weeks in patients with moderate to severe Parkinson's disease does not dramatically improve mobility, ADL, social and physical functioning or other domains of quality of life.

Acknowledgements

We thank the Northcott Devon Medical Foundation which funded this research. We are also grateful to: Dr Glen Harper and Dr Julia Saunders for their help at the clinics; our patient representatives, Andrew Palmer and David Burchfield, for their contribution to the protocol; Jo Perry, Janet Stanley and Russell Holloway for administration and computer support; and the patients with Parkinson's disease who participated in this study.

Conflict of interests

None declared.

Study registration details

NHS Research Ethics Committee reference number: 07/H0202/99; study name: North Devon

Acoustic Cueing Therapy Study; submission date: 16 July 2007.

References

1 de Rijk MC, Launer LJ, Berger K *et al*. Prevalence of Parkinson's disease in Europe: A collaborative study of population-based cohorts. Neurologic Diseases in the Elderly Research Group. *Neurology* 2000; **5411**(suppl 5): S21–S23.

2 Thaut MH, McIntosh GC, Rice RR, Miller RA, Rathbun J, Brault JM. Rhythmic auditory stimulation in gait training for Parkinson's disease patients. *Mov Disord* 1996; **1**: 193–200.

3 Howe TE, Lövgreen B, Cody FW, Ashton VJ, Oldham JA. Auditory cues can modify the gait of persons with early-stage Parkinson's disease: a method for enhancing parkinsonian walking performance? *Clin Rehabil* 2003; **17**: 363–67.

4 Cubo E, Leurgans S, Goetz CG. Short-term and practice effects of metronome pacing in Parkinson's disease patients with gait freezing while in the 'on' state: randomized single blind evaluation. *Parkinsonism Relat Disord* 2004; **10**: 507–10.

5 Schrag A, Jahanshahi M, Quinn N. How does Parkinson's disease affect quality of life? A comparison with quality of life in the general population. *Mov Disord* 2000; **15**: 1112–18.

6 Reuther M, Spottke EA, Klotsche J *et al*. Assessing health-related quality of life in patients with Parkinson's disease in a prospective longitudinal study. *Parkinsonism Relat Disord* 2007; **13**: 108–14.

7 Nieuwboer A, Kwakkel G, Rochester L *et al*. Cueing training in the home improves gait-related mobility in Parkinson's disease: the RESCUE trial. *J Neurol Neurosurg Psychiatry* 2007; **78**: 134–40.

8 Kumar P, Clarke M. Neurological disease. *Clin Med* 2007; 1173–272.

9 Rubinstein TC, Giladi N, Hausdorff JM. The power of cueing to circumvent dopamine deficits: a review of physical therapy treatment of gait disturbances in Parkinson's disease. *Mov Disord* 2002; **17**: 1148–60.

10 Lim I, van Wegen E, de Goede C *et al*. Effects of external rhythmical cueing on gait in patients with Parkinson's disease: a systematic review. *Clin Rehabil* 2005; **19**: 695–713.

11 Ellis T, de Goede CJ, Feldman RG, Wolters EC, Kwakkel G, Wagenaar RC. Efficacy of a physical therapy program in patients with Parkinson's disease: a randomized controlled trial. *Arch Phys Med Rehabil* 2005; **86**: 626–32.

12 Hoehn M, Yahr M. Parkinsonism: onset, progression and mortality. *Neurology* 1967; **17**: 427–42.

13 Folstein MF, Folstein SE, McHugh PR. 'Mini-mental state.' A practical method for grading the cognitive state of patients for the clinician. *J Psychiatr Res* 1975; **123**: 189–98.

14 Peto V, Jenkinson C, Fitzpatrick R. PDQ-39: a review of the development, validation and application of a Parkinson's disease quality of life questionnaire and its associated measures. *J Neurol* 1998; **245**(suppl 1): S10–S14.

15 Jenkinson C, Fitzpatrick R, Peto V, Greenhall R, Hyman N. The Parkinson's Disease Questionnaire PDQ-39: development and validation of a Parkinson's disease summary index score. *Age Ageing* 1997; **265**: 353–57.

16 Marinus J, Ramaker C, van Hilten JJ, Stiggelbout AM. Health related quality of life in Parkinson's disease: a systematic review of disease specific instruments. *J Neurol Neurosurg Psychiatry* 2002; **722**: 241–48.

17 Ware Jr JE, Gandek B. Overview of the SF-36 Health Survey and the International Quality of Life Assessment IQOLA Project. *J Clin Epidemiol* 1998; **5111**: 903–12.

18 Jenkinson C, Heffernan C, Doll H, Fitzpatrick R. The Parkinson's Disease Questionnaire PDQ-39: evidence for a method of imputing missing data. *Age Ageing* 2006; **355**: 497–502.

19 Walters SJ, Brazier JE. What is the relationship between the minimally important difference and health state utility values? The case of the SF-6D. *Health Qual Life Outcomes* 2003; **1**: 4.

20 Peto V, Jenkinson C, Fitzpatrick R. Determining minimally important differences for the PDQ-39 Parkinson's disease questionnaire. *Age Ageing* 2001; **304**: 299–302.

21 Freedland RL, Festa C, Sealy M *et al*. The effects of pulsed auditory stimulation on various gait measurements in persons with Parkinson's disease. *NeuroRehabilitation* 2002; **171**: 81–87.

22 McIntosh GC, Brown SH, Rice RR, Thaut MH. Rhythmic auditory-motor facilitation of gait patterns in patients with Parkinson's disease. *J Neurol Neurosurg Psychiatry* 1997; **621**: 22–26.